



FDA-Regulated Medical Device Studies

Tools for Investigators

The Office of Responsible Research Practices has created tools to assist Ohio State investigators in completing application materials when research reviewed by an Ohio State IRB involves articles regulated by the FDA as medical devices. The tools are designed to be used sequentially.

Note: These tools do not account for emergency use, expanded access, or other “compassionate use” scenarios.

Step 1: Determine whether your study involves a medical device as [defined](#) by the FDA.

“Device” means an instrument, apparatus, implement, machine, contrivance, implant, software, in vitro reagent, or other similar or related article including a component part or accessory that is:

- *Recognized by the FDA as [an approved device](#); or*
- *Intended for use in the **diagnosis, cure, mitigation, treatment, or prevention** of disease; or*
- *Intended to **affect the structure or any function of the body** in man or other animals; and*

*which does not achieve its primary intended purposes **through chemical action** within or on the body and which is not dependent upon **being metabolized** for the achievement of its primary intended purposes.*

Step 2: Use the [Common Medical Device Research Scenarios Decision Tree](#) to determine which of the **five medical device scenarios** applies to your research.

Step 3: Use the [Buck-IRB Cheat Sheet](#) for device research to see a list of Buck-IRB pages that must reflect the administration and/or evaluation of medical devices, as well as which documents must be revised and/or provided for IRB review.

Step 4: Refer to the [Buck-IRB Device Research Screenshots](#) for details about how to complete the Buck-IRB application form to reflect the medical device research scenario(s) involved in your study.

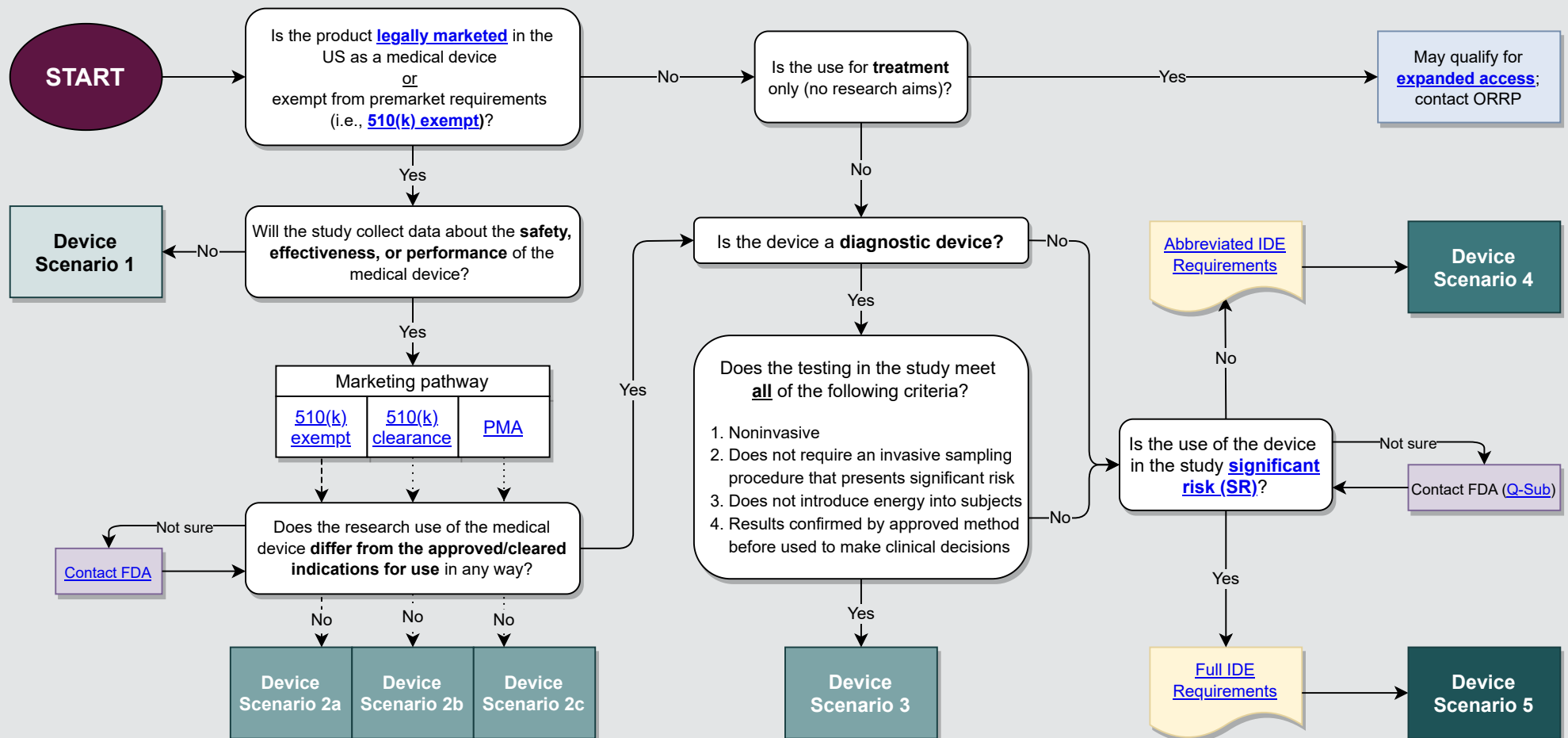
Remember:

- Multiple medical device research scenarios may be applicable to a single study.
- If multiple medical devices are studied/administered, use the decision tree and tools *for each device separately*.
- Questions? [Contact ORRP](#) for further guidance.

These tools are provided for educational purposes only and should not be considered official regulatory documents.

DECISION TREE: COMMON MEDICAL DEVICE RESEARCH SCENARIOS

If your study involves administering a medical device¹ or has aims related to medical device products, use the decision tree to determine which of the **five most common medical device research scenarios** applies to your research and whether or not an IDE may be required. Please note, the decision tree does not account for every possible scenario or IDE exemption.



¹ "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory, which is: (1) recognized by the FDA as an approved device; (2) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or other conditions; or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

This decision tree is provided for educational purposes only and should not be considered an official regulatory document.

Buck-IRB Cheat Sheet: FDA-Regulated Medical Device Research

This cheat sheet reflects the five most common medical device research scenarios. It does not account for every possible scenario or IDE exemption.

Scenario #	Description & example	FDA regulatory oversight	Buck-IRB Application Pages	Required documentation and documents that should reflect device information
Device Scenario 1	<p>Not a device study</p> <p>Approved/cleared medical device(s):</p> <ul style="list-style-type: none"> used as tools for data collection study does not collect data evaluating the device <p><i>Examples:</i> <i>Research CT scan to measure cancer response to chemo drug</i></p> <p><i>Non-invasive medical devices used to measure vitals, visual acuity, etc.</i></p>	<p>Clinical investigation: No*</p> <p>IDE: No</p>	<p><u>Required</u></p> <ul style="list-style-type: none"> Research Methods & Activities <p><u>As applicable</u>⁺</p> <ul style="list-style-type: none"> Funding & Financial Conflicts (if support provided by external device manufacturer) Confidentiality of Data (if external device manufacturer will receive study data, or if device is digital health) Risks, Harms & Discomforts 	<p><u>Required</u></p> <ul style="list-style-type: none"> Protocol Consent form (should include risks of device-related research procedures) <p><u>As applicable</u></p> <ul style="list-style-type: none"> Information about devices used as tools if they are not commonly used in medical practice or if the information may help the IRB conduct its overall review of the study
Device Scenario 2a, 2b, 2c	<p>IDE exempt, on-label device study</p> <p>Study is evaluating safety, effectiveness, or performance of medical device(s) and:</p> <ul style="list-style-type: none"> The device(s): <ul style="list-style-type: none"> Is exempt from 510(k) premarket requirements (2a) Has 510(k) clearance (2b) Has a PMA (2c) Use in the study is consistent with approved/cleared indications for use ("on label") <p><i>Examples:</i> <i>Comparative effectiveness study of two ultrasound machines cleared for identifying abnormal heart function (2b)</i></p> <p><i>Clinical validation of un-marketed stand-on patient scale (2a)</i></p>	<p>Clinical Investigation: Yes</p> <p>IDE: No</p>	<p><u>Required</u></p> <ul style="list-style-type: none"> Research Methods & Activities Devices: <i>FDA Approved Devices</i> Alternatives to Study Participation Risks, Harms, and Discomforts <p><u>As applicable</u>⁺</p> <ul style="list-style-type: none"> Funding & Financial Conflicts (if support provided by device manufacturer) Confidentiality of Data (if external device manufacturer will receive study data, or if device is digital health) Monitoring (if greater than minimal risk) 	<p><u>Required</u></p> <ul style="list-style-type: none"> FDA IDE exempt determination letter (if available; rare in this scenario) FDA documentation of marketing eligibility showing indications for use <ul style="list-style-type: none"> 2a: Regulation number/description (print-to-PDF) 2b: 510(k) summary (letter) 2c: PMA approval order/safety summary & FDA-approved labeling Manufacturer's instructions for use, user manuals, etc. for each device Protocol Consent form <p><u>As applicable</u></p> <ul style="list-style-type: none"> Recruitment materials Subject materials/instructions, etc.

Buck-IRB Cheat Sheet: FDA-Regulated Medical Device Research

Scenario #	Description & example	FDA regulatory oversight	Buck-IRB Application Pages	Required documentation and documents that should reflect device information
<u>Device Scenario 3</u>	<p>IDE exempt diagnostic device study</p> <p>Study is evaluating safety, effectiveness, and/or performance of a diagnostic device and testing:</p> <ul style="list-style-type: none"> • is noninvasive • doesn't require an invasive sampling procedure • doesn't introduce energy into a subject • will not be used for clinical decision-making without confirmation by an approved method <p><i>Examples:</i> <i>Validation of in vitro diagnostic device using discarded clinical samples</i></p> <p><i>Development of machine learning (ML) algorithm for prediction of surgical outcomes</i></p>	<p>Clinical investigation: Yes</p> <p>IDE: No</p>	<p><u>Required</u></p> <ul style="list-style-type: none"> • Research Methods & Activities • Devices: <i>Investigational Devices/ Investigational Use of Approved Devices</i> • Alternatives to Study Participation • Risks, Harms, and Discomforts <p><u>As applicable*</u></p> <ul style="list-style-type: none"> • Funding & Financial Conflicts (if support provided by device manufacturer) • Confidentiality of Data (if external device manufacturer will receive study data, or if device is digital health) • Monitoring (if greater than minimal risk) 	<p><u>Required</u></p> <ul style="list-style-type: none"> • FDA IDE exempt determination letter (if available) or explanation of how study meets IDE exemption criteria • Device information: <ul style="list-style-type: none"> ○ Manufacturer's instructions for use, user manuals, labeling, etc. (if diagnostic is already marketed or in later stage of development) ○ Robust description of device function, safety measures, quality controls, risks, etc. (if diagnostic is still in early development) • Protocol • Consent form <p><u>As applicable</u></p> <ul style="list-style-type: none"> • Recruitment materials • Subject materials/instructions, etc.
<u>Device Scenario 4</u>	<p>Nonsignificant Risk (NSR) device study</p> <p>Study is evaluating safety, effectiveness, or performance of a medical device and:</p> <ul style="list-style-type: none"> • Use is investigational (unapproved device or "off-label" use of legally marketed device) • Use in the study does NOT present potential for serious risk to the health, safety, or welfare of participants <p><i>Examples (assuming devices do not require additional procedures that are SR):</i> <i>Evaluation of MRI machines within FDA-specific parameters</i></p>	<p>Clinical investigation: Yes</p> <p>IDE: Abbreviated requirements (no submission to FDA)</p>	<p><u>Required</u></p> <ul style="list-style-type: none"> • Research Methods & Activities • Devices: <i>Investigational Devices/ Investigational Use of Approved Devices</i> • Alternatives to Study Participation • Risks, Harms, and Discomforts <p><u>As applicable*</u></p> <ul style="list-style-type: none"> • Funding & Financial Conflicts (if support provided by device manufacturer) • Confidentiality of Data (if external device manufacturer will receive study data, or if device is digital health) 	<p><u>Required</u></p> <ul style="list-style-type: none"> • NSR Documentation: FDA NSR determination letter (if available), or description of how study is NSR • Device information: <ul style="list-style-type: none"> ○ Manufacturer's labeling, operations manual, instructions for use, etc. (if device is already marketed or in later stage of development) ○ Robust description of device function, safety measures, quality controls, risks, etc. (if device is still in early development)

Buck-IRB Cheat Sheet: FDA-Regulated Medical Device Research

Scenario #	Description & example	FDA regulatory oversight	Buck-IRB Application Pages	Required documentation and documents that should reflect device information
Device Scenario 4 cont'd	<p><i>Studies of externally worn, continuous glucose monitors</i></p> <p><i>Comparative effectiveness study of conventional laparoscopes, if participants would undergo surgery anyway and research does not prolong the surgical procedure</i></p>		<ul style="list-style-type: none"> Monitoring (if overall study is greater than minimal risk) 	<ul style="list-style-type: none"> Protocol Consent form <p><u>As applicable</u></p> <ul style="list-style-type: none"> Recruitment materials Subject materials/instructions, etc.
<u>Device Scenario 5</u>	<p>Significant Risk (SR) device study</p> <p>Study is evaluating safety, effectiveness, or performance of a medical device and:</p> <ul style="list-style-type: none"> use is investigational (unapproved device or “off-label” use of legally marketed device) use in the study presents potential for serious risk to the health, safety, or welfare of participants <p><i>Examples:</i></p> <p><i>Testing of modified replacement heart valves</i></p> <p><i>Studies of novel or modified contraceptive devices of any kind</i></p> <p><i>Device studies involving sham surgeries (e.g., in a control group versus an intervention group that receives a device)</i></p>	<p>Clinical investigation: Yes</p> <p>IDE: Full IDE requirements (including IDE submission to FDA)</p>	<p><u>Required</u></p> <ul style="list-style-type: none"> Research Methods & Activities Devices: <i>Investigational Devices/ Investigational Use of Approved Devices</i> Alternatives to Study Participation Risks, Harms, and Discomforts Monitoring <p><u>As applicable[‡]</u></p> <ul style="list-style-type: none"> Funding & Financial Conflicts (if support provided by device manufacturer) Confidentiality of Data (if external device manufacturer will receive study data, or if device is digital health) 	<p><u>Required</u></p> <ul style="list-style-type: none"> IDE Documentation: FDA IDE “study may proceed” letter (for investigator-initiated studies) or IDE# on protocol (if sponsor is external to Ohio State & Ohio State is not lead site) Device information: <ul style="list-style-type: none"> Manufacturer’s labeling, operations manual, instructions for use, etc. (if device is already marketed or in later stage of development) Robust description of device function, safety measures, quality controls, risks, etc. (if device is still in early development) Protocol Consent form <p><u>As applicable</u></p> <ul style="list-style-type: none"> Recruitment materials Subject materials/instructions, etc.

* If a study involves administering a device that is not legally marketed, Device Scenario 1 would not apply, even if no data will be collected about the device. Treatment-only studies of unmarketed devices may qualify for a Humanitarian Use Exemption or an expanded access pathway. [Contact ORRP](#) for more information.

[‡] Buck-IRB page designated “as applicable” are not represented in the Buck-IRB Screenshots that follow.

Device Scenario 1

Approved/cleared medical devices used as tools; not evaluated for safety/effectiveness

Research Methods & Activities

Use the boxes provided below to provide information on all interventions and activities that are to be performed in the research. Based on the selections chosen in the list of activities and components, completion of additional form pages may be necessary to provide required information for IRB review.

Identify and describe all interventions and interactions that are to be performed solely for the research study.

Describe any procedures related to devices used as tools for data collection or other research procedures here. Specific devices typically do not need to be identified if procedures are described well (e.g., “we will collect height, weight, blood pressure,...participants get CT scans at 3 time points...”)

Check all research activities and/or components that apply.

<input type="checkbox"/> Anesthesia (general or local) or sedation
<input type="checkbox"/> Audio, video, digital, or image recordings
<input type="checkbox"/> Biohazards (e.g., rDNA, infectious agents, select agents, toxins)
<input type="checkbox"/> Biological sampling (other than blood)
<input type="checkbox"/> Blood drawing
<input type="checkbox"/> Coordinating center
<input type="checkbox"/> Data repositories (future unspecified use, including research databases)
<input type="checkbox"/> Data, not publicly available
<input type="checkbox"/> Data, publicly available (e.g., census data, unrestricted data sets)
<input type="checkbox"/> Deception
<input type="checkbox"/> Devices
<input type="checkbox"/> Diet, exercise, or sleep modifications
<input type="checkbox"/> Drugs or biologics (including dietary supplements/ingredients)
<input type="checkbox"/> Emergency research

Select any procedures/activities related to use of the device(s) **as tools** in the study. Common activities for this scenario are identified below.

Devices should NOT be checked in this scenario, as the devices themselves are not being evaluated/developed

<input type="checkbox"/>	Focus groups
<input type="checkbox"/>	Food supplements
<input type="checkbox"/>	Gene transfer
<input type="checkbox"/>	Genetic testing
<input type="checkbox"/>	Internet or e-mail data collection
<input checked="" type="checkbox"/>	Magnetic resonance imaging (MRI)
<input type="checkbox"/>	Materials that may be considered sensitive, offensive, threatening, or degrading
<input checked="" type="checkbox"/>	Non-invasive medical procedures (e.g., EKG, Doppler)
<input type="checkbox"/>	Observation of participants (including field notes)
<input type="checkbox"/>	Oral history (does not include dental or medical history)
<input type="checkbox"/>	Placebo
<input type="checkbox"/>	Pregnancy testing
<input type="checkbox"/>	Program Protocol (Umbrella Protocol)
<input checked="" type="checkbox"/>	Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures)
<input type="checkbox"/>	Randomization
<input type="checkbox"/>	Record review (which may include PHI)
<input type="checkbox"/>	Specimen research
<input type="checkbox"/>	Stem cell research
<input type="checkbox"/>	Storage of biological materials (future unspecified use, including repositories)
<input type="checkbox"/>	Surgical procedures (including biopsies)
<input type="checkbox"/>	Surveys, questionnaires, or interviews (group)
<input type="checkbox"/>	Surveys, questionnaires, or interviews (one-on-one)
<input type="checkbox"/>	Other (Specify)

Select if subjects will undergo MRI for research purposes

Select if devices used as "tools" involve non-invasive medical procedures (blood pressure)

Select if subjects will undergo radiation procedures for research purposes

Device Scenario 2a, 2b, & 2c

IDE exempt device study: evaluation of legally marketed device(s) used in accordance with approved indications for use

Research Methods & Activities

Use the boxes provided below to provide information on all interventions and activities that are to be performed in the research. Based on the selections chosen in the list of activities and components, completion of additional form pages may be necessary to provide required information for IRB review.

Identify and describe all interventions and interactions that are to be performed solely for the research study.

Describe the research use of device(s) here, including how administration is dictated by the protocol (e.g., randomization, timing, dose, etc.).

Check all research activities and/or components that apply.

<input type="checkbox"/>	Anesthesia (general or local) or sedation
<input type="checkbox"/>	Audio, video, digital, or image recordings
<input type="checkbox"/>	Biohazards (e.g., rDNA, infectious agents, select agents, toxins)
<input type="checkbox"/>	Biological sampling (other than blood)
<input type="checkbox"/>	Blood drawing
<input type="checkbox"/>	Coordinating center
<input type="checkbox"/>	Data repositories (future unspecified use, including research databases)
<input type="checkbox"/>	Data, not publicly available
<input type="checkbox"/>	Data, publicly available (e.g., census data, unrestricted data sets)
<input type="checkbox"/>	Deception
<input checked="" type="checkbox"/>	Devices
<input type="checkbox"/>	Diet, exercise, or sleep modifications
<input type="checkbox"/>	Drugs or biologics (including dietary supplements/ingredients)
<input type="checkbox"/>	Emergency research
<input type="checkbox"/>	Focus groups
<input type="checkbox"/>	Food supplements

Also select any procedures/activities related to use of the device(s) in the study, such as surgeries, radiation, imaging procedures, non-invasive medical procedures, etc.

<input type="checkbox"/> Gene transfer
<input type="checkbox"/> Genetic testing
<input type="checkbox"/> Internet or e-mail data collection
<input type="checkbox"/> Magnetic resonance imaging (MRI)
<input type="checkbox"/> Materials that may be considered sensitive, offensive, threatening, or degrading
<input type="checkbox"/> Non-invasive medical procedures (e.g., EKG, Doppler)
<input type="checkbox"/> Observation of participants (including field notes)
<input type="checkbox"/> Oral history (does not include dental or medical history)
<input type="checkbox"/> Placebo
<input type="checkbox"/> Pregnancy testing
<input type="checkbox"/> Program Protocol (Umbrella Protocol)
<input type="checkbox"/> Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures)
<input type="checkbox"/> Randomization
<input type="checkbox"/> Record review (which may include PHI)
<input type="checkbox"/> Specimen research
<input type="checkbox"/> Stem cell research
<input type="checkbox"/> Storage of biological materials (future unspecified use, including repositories)
<input type="checkbox"/> Surgical procedures (including biopsies)
<input type="checkbox"/> Surveys, questionnaires, or interviews (group)
<input type="checkbox"/> Surveys, questionnaires, or interviews (one-on-one)
<input type="checkbox"/> Other (Specify)

Devices

Select from the options below to request inclusion of medical devices (e.g., instruments, implants, in vitro reagents, etc.) in the proposed research or to request approval for a Humanitarian Use device. *Include only those devices that are to be used as part of the research protocol (except for Humanitarian Use devices), i.e., not those used for routine care or evaluation.* Enter as many devices as required for the research.

The College of Medicine Office of Research (COM/OR) provides assistance to investigators obtaining IDEs for human subjects research. A COM/OR representative will meet with investigators to review the FDA requirements of sponsor-investigators, including device accountability and recordkeeping procedures. For assistance, contact the College of Medicine Office of Research at 614-292-2595.

For more information on the requirements for conducting research involving medical devices, see HRPP policy [Research Involving Medical Devices](#) or [Device Advice](#) on FDA website.

FDA APPROVED DEVICES



ADD DEVICE

You have listed no FDA Approved Devices.

INVESTIGATIONAL DEVICES OR INVESTIGATIONAL USE OF APPROVED DEVICES



ADD DEVICE

You have listed no Investigational Devices.

HUMANITARIAN USE DEVICES

You have listed no Humanitarian Use Devices.

Add each legally marketed medical device that will be evaluated and will be used consistent with approved indications for use.

FDA Approved Devices

Devices cleared for marketing and used according to intended use.

Name of device

Name of device

Regulatory Status

☐ 510(k) (i.e., "substantially equivalent" to a marketed device)

Select for
Scenario 2b

☐ 510(k) exempt

Select for
Scenario 2a

☐ PMA (pre-market approval)

Select for Scenario 2c
Note: Select this box for
devices marketed under De
Novo reclassification orders.

Device Classification

Select appropriate
device class

☐ I (e.g., bandages, examination gloves, hand-held surgical instruments)

☐ II (e.g., wheelchairs, infusion pumps, surgical drapes)

☐ III (e.g., replacement heart valves, silicone breast implants, implanted stimulators)

Proposed use

Describe how the device will be administered in the study. A description of device use may include:

- Proposed intended use/indications for use
- Identification of the disease or condition the device is intended to prevent, mitigate, screen, monitor, treat, or diagnose
- Part of the body or type of tissue to which the device will be applied or interacting, where applicable
- Frequency of use
- Physiological use

(Note: if frequency/route of administration, target population, user population, setting of use (hospital vs. home use), etc. differs from the approved indications for use in any way, Scenario 4 or 5 will apply rather than Scenario 2.)

Provide a brief description of the device.

The description may include:

- Physical, chemical, and/or biological processes/principles used by the device to generate device output (if applicable)
- Physical and biological characteristics of the device output (if applicable)
- An explanation of the user interface and/or how the device interacts with other devices or with the user (medical professional and/or patient)

Additional details, such as pictures or engineering drawings, can be uploaded in the device labeling section.

Provide the proposed rationale for choice of the device (compared to other devices that could have been used).

Explain why the device is being used in this research.

Summarize the potential adverse effects (including serious warnings and more common adverse effects).

Provide a snapshot of the *most common* adverse effects; these may be summarized by grouping AEs into general categories (e.g., “mild to moderate short-term GI side effects”), as opposed to listing individual symptoms. Do not copy a comprehensive list of potential risks from the device labeling.

Provide a copy of the device manufacturer’s approved labeling (e.g., package insert, device label, descriptive and informational literature, operations manual, etc.).

UPLOADED FILES

No files have been uploaded.

SELECT FILES

For all Scenario 2 devices:

- Provide labeling, descriptive information, user manuals, etc. so that the IRB can assess use & risks. As applicable, upload pictures or engineering drawings. **Promotional brochures alone are not sufficient.**
- Provide evidence of marketing clearance & indications for use as indicated below. Examples of documents for each scenario are on following pages.

2a: 510(k) exempt devices

- Provide screenshot of reg. # / description (print to PDF)

Search [here](#).

2b: Devices with 510(k)

- Provide 510(k) summary (PDF)

Search [here](#).

2c: Devices with PMA

- Provide PMA order & Summary of Safety and Effectiveness (PDFs)

Search [here](#).

2a: Example screenshot of regulation number/description for "Stand-on patient scale"

Find device in [list of Class I and Class II Exempt Devices](#) or search [Product Classification Database](#)

Device	Scale, Stand-On, Patient
Regulation Description	Stand-on patient scale.
Regulation Medical Specialty	General Hospital
Review Panel	General Hospital
Product Code	FRI
Premarket Review	Gastrorenal, ObGyn, General Hospital, and Urology Devices (OHT3) Drug Delivery and General Hospital Devices, and Human Factors (DHT3C)
Submission Type	510(K) Exempt
Regulation Number	880.2700
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	Yes

Note: This device is also exempted from the GMP regulation, except for general requirements concerning records (820.180) and complaint files (820.198), as long as the device is not labeled or otherwise represented as sterile.

Click this link to go to
regulation #/ description

CFR - Code of Federal Regulations Title 21

[FDA Home](#) [Medical Devices](#) [Databases](#)



The information on this page is current as of April 1 2020.

For the most up-to-date version of CFR Title 21, go to the [Electronic Code of Federal Regulations \(eCFR\)](#).

Print-to-PDF, then
upload this page to
Buck-IRB



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[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2020]
[CITE: 21CFR880.2700]



See Related
Information

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H - MEDICAL DEVICES

PART 880 -- GENERAL HOSPITAL AND PERSONAL USE DEVICES

Subpart C - General Hospital and Personal Use Monitoring Devices

Sec. 880.2700 Stand-on patient scale.

(a) Identification. A stand-on patient scale is a device intended for medical purposes that is used to weigh a patient who is able to stand on the scale platform.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682, Oct. 21, 1980, as amended at 66 FR 38803, July 25, 2001]

2b: Example first page of 510(k) summary

Note: Sometimes the summary is preceded by the FDA letter indicating 510(k) clearance. In the example below, the summary appears first, with the FDA letter appearing on page 2. In either case, the entire PDF document should be uploaded in Buck-IRB. Use [510\(k\) database](#) to find device, then click "Summary" for PDF.

K051419

Section 5: 510(k) Summary

510(k) Summary
21CFR § 807.92

APR 27 2005

Submitter:	<i>Inditherm Medical Houndhill Park Bolton Road Rotherham S63 7LG United Kingdom</i>
Contact:	<i>Nick Bettles, Division Director - Medical</i>
Date Prepared:	<i>1 June, 2005</i>
Trade Name:	<i>Inditherm Patient Warming System Model numbers: MECU1, OTM1, OTM2, GTM1, PTM1, OTB, RB1</i>
Common Name:	<i>Thermal Regulating System</i>
Equivalence to:	<i>Klimamed Thermal Mat and Controller (K011859) Klimamed Thermal Blanket and Controller (K031728)</i>
Description:	<i>The Inditherm Patient Warming System consists of a precision temperature control unit that controls and monitors the temperature of a mattress or blanket composed of a carbon polymer material. A pressure relief pad is integrated into the mattress, underneath the flexible warming surface.</i>
Intended Use:	<i>Designed for use in the operating room, recovery room, anesthetic room, intensive care, medical and surgical floors, patient transport and emergency department; the Inditherm Patient Warming System provides safe and controlled warming to assist patients to maintain normal body temperature. In addition to providing warming and control, the mattress also provides pressure relief to help prevent pressure sores.</i>
Technological Characteristics:	<i>Comparisons between the new and predicate devices shows that technological characteristics (i.e. device design, materials, components, and dimensions) and indications for use for the Inditherm Patient Warming System are equivalent to the currently marketed predicate devices.</i>

2c: Example first page of PMA Summary & Effectiveness Data

Approval Order Statement

APPROVAL FOR THE 7F FREEZOR CARDIAC CRYOABLATION CATHETER CRYOCONSOLE SYSTEM. THE DEVICE IS INDICATED FOR THE CRYOABLATION OF THE CONDUCTING TISSUES OF THE HEART IN THE TREATMENT OF PATIENTS WITH ATRIOVENTRICULAR NODAL REENTRANT TACHYCARDIA (AVNRT).

Approval Order

[Approval Order](#)

Summary

[Summary Of Safety And Effectiveness](#)

Labeling

[Labeling](#)

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

1.0 GENERAL INFORMATION

Device Generic Name: Cardiac Cryoablation Catheter and Console System

Device Trade Name: 7F Freezor® Cardiac Cryoablation Catheter and CCT.2 CryoConsole System

Name & Address of Applicant: CryoCath Technologies Inc.
16771 Chemin Ste Marie
Kirkland, Quebec
Canada, H9H 5H3

U.S. Premarket Approval (PMA) Application Number:

P020045

Representative: Fred Milder, Ph.D.
Applied Physics
204 Clinton Road
Brookline, MA 02445-5814

Date of Panel Recommendation: March 6, 2003

Date of Notice of Approval to Applicant: April 17, 2003

2.0 INDICATIONS FOR USE

The 7F Freezor® Cardiac Cryoablation Catheter and CCT.2 CryoConsole System is indicated for the cryoablation of the conducting tissues of the heart in the treatment of patients with atrioventricular nodal reentrant tachycardia (AVNRT).

3.0 CONTRAINDICATIONS

Do not use this device:

- in patients with active systemic infection;
- in conditions where manipulation of the catheter would be unsafe (e.g., intracardiac mural thrombus); and
- in patients with cryoglobulinemia.

After searching [PMA database](#), use links to download device's PMA order & summary info

Alternatives to Participation

Other than choosing not to participate, are there any alternatives to participating in the research?

List the specific alternatives to participation, including available procedures or treatments that may be advantageous to the subject.

Alternatives to participating in a therapeutic study may include the following:

- **Receiving different device(s) or other treatment**
- **Receiving the device(s) at a frequency and/or route of administration determined by one's physician (as opposed to the protocol)**
- **Enrolling in a different clinical trial**

There may or may not be alternatives to participating in non-therapeutic studies.

Risks, Harms & Discomforts

Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Discuss severity and likelihood of occurrence. As applicable, include potential risks to an embryo or fetus if a woman is or may become pregnant.

General study risks go here. Do not duplicate risks of devices listed elsewhere or copy a comprehensive list of adverse effects from device labeling.

Describe how risks, harms, and/or discomforts will be minimized.

Address mitigation of general study risks rather than individual adverse effects of study devices.

Device Scenario 3

IDE exempt diagnostic device study

Research Methods & Activities

Use the boxes provided below to provide information on all interventions and activities that are to be performed in the research. Based on the selections chosen in the list of activities and components, completion of additional form pages may be necessary to provide required information for IRB review.

Identify and describe all interventions and interactions that are to be performed solely for the research study.

Describe the research use of diagnostic device here, including source(s) of data/specimens, sampling method(s), and type of specimen(s), as applicable.

Check all research activities and/or components that apply.

- ☐ Anesthesia (general or local) or sedation
- ☐ Audio, video, digital, or image recordings
- ☐ Biohazards (e.g., rDNA, infectious agents, select agent)
- ☐ Biological sampling (other than blood)
- ☐ Blood drawing
- ☐ Coordinating center
- ☐ Data repositories (future unspecified use, including res)
- ☐ Data, not publicly available
- ☐ Data, publicly available (e.g., census data, unrestricted data sets)
- ☐ Deception
- ☒ **Devices**
- ☐ Diet, exercise, or sleep modifications
- ☐ Drugs or biologics (including dietary supplements/ingredients)
- ☐ Emergency research
- ☐ Focus groups
- ☐ Food supplements

Also select any additional activities resulting from the use of the device(s) in the study, such as procedures required for obtaining samples and/or data **if they will be performed for the research.**

If the diagnostic device involves **only** secondary use of leftover specimens or data collected for clinical purposes, do not identify activities associated with the clinical collection (e.g., blood drawing, biological sampling, surgical procedures, imaging procedures, etc.).

<input type="checkbox"/> Gene transfer
<input type="checkbox"/> Genetic testing
<input type="checkbox"/> Internet or e-mail data collection
<input type="checkbox"/> Magnetic resonance imaging (MRI)
<input type="checkbox"/> Materials that may be considered sensitive, offensive, threatening, or degrading
<input type="checkbox"/> Non-invasive medical procedures (e.g., EKG, Doppler)
<input type="checkbox"/> Observation of participants (including field notes)
<input type="checkbox"/> Oral history (does not include dental or medical history)
<input type="checkbox"/> Placebo
<input type="checkbox"/> Pregnancy testing
<input type="checkbox"/> Program Protocol (Umbrella Protocol)
<input type="checkbox"/> Radiation (e.g., CT or DEXA scans, X-rays, nuclear
<input type="checkbox"/> Randomization
<input checked="" type="checkbox"/> Record review (which may include PHI)
<input checked="" type="checkbox"/> Specimen research
<input type="checkbox"/> Stem cell research
<input type="checkbox"/> Storage of biological materials (future unspecified use, including repositories)
<input type="checkbox"/> Surgical procedures (including biopsies)
<input type="checkbox"/> Surveys, questionnaires, or interviews (group)
<input type="checkbox"/> Surveys, questionnaires, or interviews (one-on-one)
<input type="checkbox"/> Other (Specify)

*Diagnostic device studies—particularly those using **artificial intelligence or machine learning (AI/ML) for algorithm development**—often involve use of medical records/imaging results.*

*For **in vitro diagnostic (IVD) devices**, select **specimen research**.*

Devices

Select from the options below to request inclusion of medical devices (e.g., instruments, implants, in vitro reagents, etc.) in the proposed research or to request approval for a Humanitarian Use device. *Include only those devices that are to be used as part of the research protocol (except for Humanitarian Use devices), i.e., not those used for routine care or evaluation.* Enter as many devices as required for the research.

The College of Medicine Office of Research (COM/OR) provides assistance to investigators obtaining IDEs for human subjects research. A COM/OR representative will meet with investigators to review the FDA requirements of sponsor-investigators, including device accountability and recordkeeping procedures. For assistance, contact the College of Medicine Office of Research at 614-292-2595.

For more information on the requirements for conducting research involving medical devices, see HRPP policy [Research Involving Medical Devices](#) or [Device Advice](#) on FDA website.

FDA APPROVED DEVICES

[ADD DEVICE](#)

You have listed no FDA Approved Devices.

INVESTIGATIONAL DEVICES OR INVESTIGATIONAL USE OF APPROVED DEVICES

[ADD DEVICE](#)

You have listed no Investigational Devices.

HUMANITARIAN USE DEVICES

You have listed no Humanitarian Use Devices.

Add each diagnostic device that will be evaluated/developed in the study.

Investigational Devices or Investigational Use of Approved Devices

Devices that are investigational, modified, or proposed new intended uses.

Name of device

Name of device

Manufacturer

Manufacturer / developer (e.g., PI name for diagnostics developed at Ohio State)

Device status

- ☐ Investigational
- ☒ Approved, but its use in this research is investigational

Select appropriate option based on marketing status.

Most diagnostic studies at Ohio State are investigator-initiated studies of investigational in vitro diagnostics or algorithms.

Proposed use

Describe how the device will be used/evaluated in the study. A description of device use may include:

- Proposed intended use/indications for use
- Identification of the disease or condition the device is intended to prevent, mitigate, screen, monitor, treat, or diagnose
- Part of the body or type of tissue to which the device will be applied or interacting, where applicable; note if only leftover specimens will be used
- Whether results of diagnostics will be returned to participants and/or physicians for clinical decision-making
- Frequency of use
- Physiological use

This device research should be determined to be (complete one):

- ☐ Significant Risk (SR) - (e.g, sutures, cardiac pacemakers, hydrocephalus shunts, orthopedic implants)
- ☐ Non-significant Risk (NSR) - (e.g., daily-wear contact lenses, lens solutions, dental scalers, foley catheters). Provide supporting documentation from sponsor regarding why the device does not pose a significant risk.
- ☒ IDE Exempt

Category (1-7)

Enter “Category 3,” as this is the IDE exemption category for diagnostic devices.

See [21 CFR 812.2\(c\)](#) for a description of the categories.

Explain how the device is exempt from the requirements of [21 CFR 812.2\(c\)](#) for this research.

To be eligible for IDE exemption under this category, the study must be four criteria. Provide a point-by-point, study-specific explanation of how each criterion is met:

(1) Testing is noninvasive.

Explain how the use of the diagnostic device in the study meets the FDA’s definition of “noninvasive” testing (see definition below).

(2) Testing does not require an invasive sampling procedure that presents significant risk.

Explain how any sampling procedures required to obtain specimens/data for the diagnostic meet the FDA’s definition of “noninvasive” (see definition below).

(3) Testing does not by design or intention introduce energy into a subject.

Confirm that the diagnostic, as used in the study, will not introduce energy (light, sound, radiation, electromagnetic, etc.) of any kind into a participants’ body.

(4) Testing is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

Indicate whether results from the diagnostic device will be returned to participants and/or their clinicians or will be used in any other way for clinical decision-making. If so, describe the medically established diagnostic test/method that will confirm results prior to using them for clinical purposes. (Note: Novel diagnostics may not have any medically established method for confirming diagnosis; in that case, they are ineligible for IDE exemption.)

Notes:

- If any of the criteria are not met, Scenario 4 or 5 will apply to this study, rather than Scenario 3.
- In rare cases, the FDA may have made an IDE exempt determination for the diagnostic study. In such cases, write “see uploaded FDA letter” in this box and upload the determination letter as noted below.

Definition of “noninvasive” ([21 CFR 812.3\(k\)](#))

“Noninvasive,” when applied to a diagnostic device or procedure, means one that does not by design or intention:

- 1) Penetrate or pierce the skin or mucous membranes of the body, the ocular cavity, or the urethra, or
- 2) enter the ear beyond the external auditory canal, the nose beyond the nares, the mouth beyond the pharynx, the anal canal beyond the rectum, or the vagina beyond the cervical os.

For purposes of the diagnostic IDE exemption criteria, blood sampling that involves simple venipuncture is considered noninvasive, and the use of surplus samples of body fluids or tissues that are left over from samples taken for noninvestigational purposes is also considered noninvasive.

Provide a brief description of the device.

Provide a detailed device description. The description may include:

- Physical, chemical, and/or biological processes/principles used by the device to generate device output (if applicable)
- Physical, biological, or technological characteristics of the device output (if applicable)
- An explanation of the user interface and/or how the device interacts with other devices or with the user (medical professional and/or patient)

Additional details, such as pictures or engineering drawings, can be uploaded as noted below.

Provide the proposed rationale for choice of the device (compared to other devices that could have been used).

Explain why the device is being used in this research.

Summarize the potential adverse effects (including serious warnings and more common adverse effects).

Provide a snapshot of the *most common* risks of the diagnostic device as used in the study. Do not copy a comprehensive list of potential risks from the device labeling.

If diagnostic testing results will be used for clinical decision-making in the study, describe risks of false positives and false negatives.

Provide documentation of all applicable FDA approvals/exemptions for the investigational or research use of the devices. Copies of any correspondence to and from the FDA must be provided to the IRB. Final IRB approval cannot be granted until regulatory status is confirmed.

UPLOADED FILES

No files have been uploaded.

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For files greater than 20MB, please see [instructions for large files](#).

SELECT FILES

Provide any other applicable correspondence from the FDA pertaining to the investigation, such as a determination of IDE exemption.

Provide a copy of the device manufacturer's approved labeling (e.g., package insert, device label, descriptive and informational literature, operations manual, etc.).

UPLOADED FILES

No files have been uploaded.

Click **Select Files** to add files to this form.
For files greater than 20MB, please see [instructions for large files](#).

SELECT FILES

Provide labeling, descriptive information, user manuals, etc. so that the IRB can evaluate the intended use and potential risks of the device. If the device is still in development, a robust description of these items must be provided. As applicable, upload pictures or engineering drawings.

Promotional brochures alone are not sufficient.

Page 1 of **in vitro diagnostic device** labeling (example); example **dx software** labeling [here](#).

Note: Device labeling & user manuals will vary; unlike drugs, there is not a universal format.

ms_11820583160_USA V1.5 HBeAg Hepatitis B e antigen		cobas [®]									
REF	Σ	SYSTEM									
11820583 160	100	MODULAR ANALYTICS E170									
English											
For use in the USA only											
Warning <ul style="list-style-type: none"> Federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted by or on the order of a physician. Assay performance characteristics have not been established in pregnant women, or in populations of immunocompromised or immunosuppressed patients. This assay has not been FDA licensed for the screening of blood, plasma and tissue donors. 		R1 Anti-HBeAg-Ab-biotin (gray cap), 1 bottle, 12 mL: Biotinylated monoclonal anti-HBeAg antibody (mouse) > 0.8 mg/L; TRIS buffer 50 mmol/L, pH 7.4; preservative.									
		R2 Anti-HBeAg-Ab-Ru(bpy) (black cap), 1 bottle, 12 mL: Monoclonal anti-HBeAg antibody (mouse) labeled with ruthenium complex 0.3 mg/L; TRIS buffer 50 mmol/L, pH 7.4; preservative.									
		HBEAG Cal1 Negative calibrator 1 (white cap), 2 bottles of 1.0 mL each: Human serum, preservative.									
		HBEAG Cal2 Positive calibrator 2 (black cap), 2 bottles of 1.0 mL each: HBEAG (E. coli, rDNA derived) ≥ 3.5 PEI U/mL ^{b)} in HEPESt ^{c)} buffer, pH 7.4; preservative.									
		b) Paul-Ehrlich-Institute units c) HEPESt = [4-(2-hydroxyethyl)-piperazine]-ethane sulfonic acid									
Intended use The Elecsys HBeAg immunoassay is intended for the in vitro qualitative determination of hepatitis B e antigen (HBeAg) in human serum or plasma (K ₂ -EDTA, lithium or sodium heparin, and sodium citrate) in adult patients with symptoms of hepatitis or at risk for hepatitis B virus (HBV) infection. The assay results, in conjunction with other serological and clinical information, may be used for the laboratory diagnosis of individuals with acute or chronic hepatitis B or recovery from hepatitis B infection. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the MODULAR ANALYTICS E170 analyzer.		Precautions and warnings For in vitro diagnostic use only. Exercise the normal precautions required for handling all laboratory reagents. Disposal of all waste material should be in accordance with local guidelines. Safety data sheet available for professional user on request. All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A. However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed. ^{6,7} Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).									
Summary The hepatitis B e antigen (HBeAg) is a product of the pre-C/C gene that has been found in hepatocytes during proliferation of the hepatitis B virus (HBV). ¹ Following proteolysis, the HBe protein is secreted from infected cells as a 15 kD protein. ¹ The detection of HBeAg is generally associated with the presence of large quantities of virus as it is a surrogate of viral replication. ^{1,2} HBeAg appears in serum during acute HBV infections and usually disappears when alanine aminotransferase (ALT) levels peak, followed by the presence of the corresponding antibody (anti-HBe). ^{1,2} However, the presence of HBeAg for more than 10 weeks is indicative of a transition to persistent infection. ⁴ HBeAg can also be detected during chronic infection when viral replication is high, before loss of HBeAg and seroconversion to anti-HBe as viral titers decline. ^{1,3,4} HBV infections can, however, occur without detectable HBeAg due to infection with HBV variants containing precore stop codon mutants; while the virus can no longer produce HBeAg, disease activity is ongoing. ^{1,4,5} The Elecsys HBeAg assay uses monoclonal anti-HBe antibodies (mouse) for the detection of HBeAg.		Reagent handling The reagents in the kit are ready-for-use and are supplied in bottles compatible with the system. Unless the entire volume is necessary for calibration on the analyzer, transfer aliquots of the ready-for-use calibrators into empty snap-cap bottles (CalSet Vials). Attach the supplied labels to these additional bottles. Store the aliquots at 2-8 °C for later use. Perform only one calibration procedure per aliquot. All information required for correct operation is entered in from the respective reagent barcodes.									
Test principle Sandwich principle. Total duration of assay: 18 minutes.		Storage and stability Store at 2-8 °C. Do not freeze. Store the Elecsys reagent kit upright in order to ensure complete availability of the microparticles during automatic mixing prior to use.									
<ul style="list-style-type: none"> 1st incubation: HBe antigen from 35 µL sample, a biotinylated monoclonal HBeAg-specific antibody, and a monoclonal HBeAg-specific antibody labeled with a ruthenium complex^{a)} form a sandwich complex. 2nd incubation: After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell M. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier. Results are determined automatically by the instrument by comparing the electrochemiluminescence signal obtained from the reaction product of the sample with the signal of the cutoff value previously obtained by calibration. 		<table border="1"> <tr> <th colspan="2">Stability of the reagent rackpack</th> </tr> <tr> <td>unopened at 2-8 °C</td> <td>up to the stated expiration date</td> </tr> <tr> <td>after opening at 2-8 °C</td> <td>8 weeks</td> </tr> <tr> <td>on MODULAR ANALYTICS E170 analyzer</td> <td>8 weeks</td> </tr> </table>		Stability of the reagent rackpack		unopened at 2-8 °C	up to the stated expiration date	after opening at 2-8 °C	8 weeks	on MODULAR ANALYTICS E170 analyzer	8 weeks
Stability of the reagent rackpack											
unopened at 2-8 °C	up to the stated expiration date										
after opening at 2-8 °C	8 weeks										
on MODULAR ANALYTICS E170 analyzer	8 weeks										
		<table border="1"> <tr> <th colspan="2">Stability of the calibrators</th> </tr> <tr> <td>after opening at 2-8 °C</td> <td>8 weeks</td> </tr> </table>		Stability of the calibrators		after opening at 2-8 °C	8 weeks				
Stability of the calibrators											
after opening at 2-8 °C	8 weeks										

Alternatives to Participation

Other than choosing not to participate, are there any alternatives to participating in the research?

Yes

No

List the specific alternatives to participation, including available procedures or treatments that may be advantageous to the subject.

Alternatives to participating in a therapeutic study may include the following:

- **Receiving different approved device(s) or other treatment**
- **Receiving the device(s) at a frequency and/or route of administration determined by one's physician (as opposed to the protocol)**
- **Enrolling in a different clinical trial**

There may or may not be alternatives to participating in non-therapeutic studies.

Risks, Harms & Discomforts

Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Discuss severity and likelihood of occurrence. As applicable, include potential risks to an embryo or fetus if a woman is or may become pregnant.

General study risks go here. Do not duplicate risks of devices listed elsewhere or copy a comprehensive list of side effects from device labeling.

Describe how risks, harms, and/or discomforts will be minimized.

Address mitigation of general study risks rather than individual adverse effects of study device(s).

Device Scenario 4

Nonsignificant Risk (NSR) device study

Research Methods & Activities

Use the boxes provided below to provide information on all interventions and activities that are to be performed in the research. Based on the selections chosen in the list of activities and components, completion of additional form pages may be necessary to provide required information for IRB review.

Identify and describe all interventions and interactions that are to be performed solely for the research study.

Describe the research use of NSR device(s) here, including any additional procedures resulting from the use of the device(s) in the study.

Check all research activities and/or components that apply.

<input type="checkbox"/>	Anesthesia (general or local) or sedation
<input type="checkbox"/>	Audio, video, digital, or image recordings
<input type="checkbox"/>	Biohazards (e.g., rDNA, infectious agents, select agents, toxins)
<input type="checkbox"/>	Biological sampling (other than blood)
<input type="checkbox"/>	Blood drawing
<input type="checkbox"/>	Coordinating center
<input type="checkbox"/>	Data repositories (future unspecified use, including research databases)
<input type="checkbox"/>	Data, not publicly available
<input type="checkbox"/>	Data, publicly available (e.g., census data, unrestricted data sets)
<input type="checkbox"/>	Deception
<input checked="" type="checkbox"/>	Devices
<input type="checkbox"/>	Diet, exercise, or sleep modifications
<input type="checkbox"/>	Drugs or biologics (including dietary supplements/ingredients)
<input type="checkbox"/>	Emergency research
<input type="checkbox"/>	Focus groups
<input type="checkbox"/>	Food supplements

Also select any additional procedures resulting from the use of the device(s) in the study, such as surgeries, radiation or imaging procedures, etc.

<input type="checkbox"/> Gene transfer
<input type="checkbox"/> Genetic testing
<input type="checkbox"/> Internet or e-mail data collection
<input type="checkbox"/> Magnetic resonance imaging (MRI)
<input type="checkbox"/> Materials that may be considered sensitive, offensive, threatening, or degrading
<input type="checkbox"/> Non-invasive medical procedures (e.g., EKG, Doppler)
<input type="checkbox"/> Observation of participants (including field notes)
<input type="checkbox"/> Oral history (does not include dental or medical history)
<input type="checkbox"/> Placebo
<input type="checkbox"/> Pregnancy testing
<input type="checkbox"/> Program Protocol (Umbrella Protocol)
<input type="checkbox"/> Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures)
<input type="checkbox"/> Randomization
<input type="checkbox"/> Record review (which may include PHI)
<input type="checkbox"/> Specimen research
<input type="checkbox"/> Stem cell research
<input type="checkbox"/> Storage of biological materials (future unspecified use, including repositories)
<input type="checkbox"/> Surgical procedures (including biopsies)
<input type="checkbox"/> Surveys, questionnaires, or interviews (group)
<input type="checkbox"/> Surveys, questionnaires, or interviews (one-on-one)
<input type="checkbox"/> Other (Specify)

Devices

Select from the options below to request inclusion of medical devices (e.g., instruments, implants, in vitro reagents, etc.) in the proposed research or to request approval for a Humanitarian Use device. *Include only those devices that are to be used as part of the research protocol (except for Humanitarian Use devices), i.e., not those used for routine care or evaluation.* Enter as many devices as required for the research.

The College of Medicine Office of Research (COM/OR) provides assistance to investigators obtaining IDEs for human subjects research. A COM/OR representative will meet with investigators to review the FDA requirements of sponsor-investigators, including device accountability and recordkeeping procedures. For assistance, contact the College of Medicine Office of Research at 614-292-2595.

For more information on the requirements for conducting research involving medical devices, see HRPP policy [Research Involving Medical Devices](#) or [Device Advice](#) on FDA website.

FDA APPROVED DEVICES



ADD DEVICE

You have listed no FDA Approved Devices.

INVESTIGATIONAL DEVICES OR INVESTIGATIONAL USE OF APPROVED DEVICES



ADD DEVICE

You have listed no Investigational Devices.

HUMANITARIAN USE DEVICES

You have listed no Humanitarian Use Devices.

Add each NSR device that will be evaluated in the study. Remember that device study risk is based on how the device is used, not just the risk of the device alone.

Investigational Devices or Investigational Use of Approved Devices

Devices that are investigational, modified, or proposed new intended uses.

Name of device

Name of device

Manufacturer

Manufacturer / developer (PI name for devices developed at Ohio State)

Device status

Select appropriate option based on marketing status

- ☐ Investigational
- ☐ Approved, but its use in this research is investigational

Proposed use

Describe how the device will be administered in the study. A description of device use may include:

- Proposed intended use/indications for use
- Identification of the disease or condition the device is intended to prevent, mitigate, screen, monitor, treat, or diagnose
- Part of the body or type of tissue to which the device will be applied or interacting, where applicable
- Frequency of use
- Physiological use

If a marketed device is used "off label," describe how the use differs from approved indications (e.g., frequency/route of administration, target population, user population, setting of use (hospital vs. home use), etc.).

This device research should be determined to be (complete one):

- ☐ Significant Risk (SR) - (e.g., sutures, cardiac pacemakers, hydrocephalus shunts, orthopedic implants)
- ☒ Non-significant Risk (NSR) - (e.g., daily-wear contact lenses, lens solutions, dental scalers, foley catheters). Provide supporting documentation from sponsor regarding why the device does not pose a significant risk.
- ☐ IDE Exempt

UPLOADED FILES

No files have been uploaded.

Provide supporting documentation from the sponsor regarding why the device does not pose a significant risk.

Click Select Files to add file
For files greater than 20MB, please see

Upload **one** of the following documents:

- **FDA study risk determination letter confirming the study is NSR.** This must be specific to this research project. It is irrelevant if other studies involving the same device were NSR.
- **Study-specific explanation from the study sponsor for why the study is NSR.** See below for tips!
Reminder: For investigator-initiated studies, the sponsor is the PI.

SELECT FILES

What should be included in the study-specific NSR explanation?

Definition of NSR: An NSR study is one involving a device that:

- *is not an implant;*
- *does not support or sustains human life;*
- *is not substantially important in diagnosing, curing, mitigating, or treating a disease or in preventing impairment of human health;*
- *does not otherwise present potential for serious risk to the health, safety, or welfare of a subject.*

The NSR explanation should address how the study meets this definition.

- ✓ **DO** address each of the four points in the NSR definition.
- ✓ **DO** refer to the FDA guidance document on SR and NSR studies (examples included!)
- ✓ **DO** base the risk determination on the proposed use of the device in the specific study, not just the device alone. Consider the patient population(s), user population, setting, etc. Remember, the same device may be SR in one study and NSR in another, depending on how it is used.
- ✓ **DO** address the nature of harm that may result from the use of the device, including physical and non-physical risks; potential adverse events; impacts of malfunctions/misuse, such as false positives/false negatives for diagnostics; etc.
- ✓ **DO** include potential harms from additional procedures that are part of the study, such as surgical procedures, radiation/imaging, etc.
- ✓ **DO** provide supporting documentation for the risk determination, such as literature/publications of similar studies of the device in the same population/used the same way.
- ✗ **DON'T** copy the NSR definition and merely add a statement saying “The study meets this definition” (or state that the study does not meet the definition of SR). The NSR justification is an explanation, not a statement.
- ✗ **DON'T** merely state that a different study using the same device was NSR. The determination should be based on the proposed use in the current study.
- ✗ **DON'T** compare use of the device to alternative treatments or weigh risks against potential benefits of the device (e.g., “The investigational pacemaker is safer than those currently commercially available; therefore the study is NSR.”). The device risk determination is not a relative assessment.

Provide a brief description of the device.

Provide a detailed device description. The description may include:

- Physical, chemical, and/or biological processes/principles used by the device to generate device output (if applicable)
- Physical and biological characteristics of the device output (if applicable)
- An explanation of the user interface and/or how the device interacts with other devices or with the user (medical professional and/or patient)

Additional details, such as pictures or engineering drawings, can be uploaded as noted below.

Provide the proposed rationale for choice of the device (compared to other devices that could have been used).

Explain why the device is being used in this research.

Summarize the potential adverse effects (including serious warnings and more common adverse effects).

Provide a snapshot of the *most common* adverse effects; these may be summarized by grouping AEs into general categories (e.g., “mild to moderate short-term GI side effects”), as opposed to listing individual symptoms. Do not copy a comprehensive list of potential risks from the device labeling.

Provide documentation of all applicable FDA approvals/exemptions for the investigational or research use of the devices. Copies of any correspondence to and from the FDA must be provided to the IRB. Final IRB approval cannot be granted until regulatory status is confirmed.

UPLOADED FILES

No files have been uploaded.

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For files greater than 20MB, please see [instructions for large files](#).

SELECT FILES

Provide any other applicable correspondence from the FDA pertaining to the NSR investigation.

Provide a copy of the device manufacturer's approved labeling (e.g., package insert, device label, descriptive and informational literature, operations manual, etc.).

UPLOADED FILES

No files have been uploaded.

Click **Select Files** to add files to this form.
For files greater than 20MB, please see [instructions for large files](#).

SELECT FILES

Provide labeling, descriptive information, user manuals, etc. so that the IRB can evaluate the intended use and potential risks of the device. If the device is still in development, a robust description of these items must be provided. As applicable, upload pictures or engineering drawings.

Promotional brochures alone are not sufficient.

Page 1 of device labeling (example)

Note: Device labeling & user manuals will vary; unlike drugs, there is not a universal format.



7F Freezor® Cardiac Cryoablation Catheter Instructions For Use

Device Description

The 7F Freezor® Cardiac Cryoablation Catheter and CCT.2 CryoConsole System consists of a CryoConsole, the Freezor® Catheter, connection components and accessories.

The Freezor® Catheter is a flexible, steerable device specifically designed for tissue cryomapping and cryoablation. Electrodes at the tip surface provide temperature-reading capabilities. Freezor® Catheters are introduced into the vasculature by traditional minimally invasive techniques. The distal end of the Freezor® Catheter reaches temperatures as cold as -75°C when refrigerant is injected from the console to the tip of the catheter.

Indications for Use

The 7F Freezor® Cardiac Cryoablation Catheter and CCT.2 CryoConsole System and related accessories are indicated for the cryoablation of the conducting tissues of the heart in the treatment of patients with atrioventricular nodal reentrant tachycardia (AVNRT).

Contraindications

This device is contraindicated:

- In patients with active systemic infection.
- In conditions where manipulation of the catheter would be unsafe (e.g. intracardiac mural thrombus).
- In patients with cryoglobulinemia

Warnings

- Additional studies are needed to fully characterize the impact of cryomapping with respect to patient outcomes.
- The Freezor® Catheter contains pressurized refrigerant during operation. Release of this gas into the circulatory system due to equipment failure or misuse could result in gas embolism.
- If an unanticipated event occurs, stop the procedure at any time by pushing the RED button on the console control panel.
- Do not pull on the Freezor® Catheter, umbilicals or CryoConsole while the catheter tip is frozen to the endocardial tissue, as this could lead to cardiac or vascular damage.
- Do not connect the Freezor® Catheter to any radio frequency generator or use the Freezor® Catheter to deliver RF ablation energy, because this could cause catheter malfunction and / or patient harm.
- Introducing any catheter into the circulatory system entails the risk of gas embolism, which can occlude vessels and lead to tissue infarction with serious consequences.
- Catheter procedures may mechanically induce arrhythmias.
- The use of fluoroscopy during catheter ablation procedures presents the potential for significant x-ray exposure to both patients and laboratory staff. Extensive exposure can result in acute radiation injury and increased risk for somatic and genetic effects. Only perform catheter ablation after giving adequate attention to the potential radiation exposure associated with the procedure, and taking steps to minimize this exposure. Give careful consideration before using the device in pregnant women.
- Careful catheter manipulation must be performed in order to avoid cardiac damage such as perforation or tamponade.
- Catheter advancement should be performed under fluoroscopic guidance. Do not use excessive force to advance or withdraw the Freezor® Catheter, especially if resistance is encountered. Ensure the appropriate intravascular tip positioning.
- Catheter entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures. The potential for catheter entrapment may be increased when the catheter is

Alternatives to Participation

Other than choosing not to participate, are there any alternatives to participating in the research?

List the specific alternatives to participation, including available procedures or treatments that may be advantageous to the subject.

Alternatives to participating in a therapeutic study may include the following:

- **Receiving different approved device(s) or other treatment**
- **Receiving the device(s) at a frequency and/or route of administration determined by one's physician (as opposed to the protocol)**
- **Enrolling in a different clinical trial**

There may or may not be alternatives to participating in non-therapeutic studies.

Risks, Harms & Discomforts

Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Discuss severity and likelihood of occurrence. As applicable, include potential risks to an embryo or fetus if a woman is or may become pregnant.

General study risks go here. Do not duplicate risks of devices listed elsewhere or copy a comprehensive list of side effects from device labeling.

Describe how risks, harms, and/or discomforts will be minimized.

Address mitigation of general study risks rather than individual adverse effects of study device(s).

Device Scenario 5

Significant Risk (SR) device study

Research Methods & Activities

Use the boxes provided below to provide information on all interventions and activities that are to be performed in the research. Based on the selections chosen in the list of activities and components, completion of additional form pages may be necessary to provide required information for IRB review.

Identify and describe all interventions and interactions that are to be performed solely for the research study.

Describe the research use of SR device(s) here, including any additional procedures resulting from the use of the device in the study.

Check all research activities and/or components that apply.

<input type="checkbox"/>	Anesthesia (general or local) or sedation
<input type="checkbox"/>	Audio, video, digital, or image recordings
<input type="checkbox"/>	Biohazards (e.g., rDNA, infectious agents, select agents, toxins)
<input type="checkbox"/>	Biological sampling (other than blood)
<input type="checkbox"/>	Blood drawing
<input type="checkbox"/>	Coordinating center
<input type="checkbox"/>	Data repositories (future unspecified use, including research databases)
<input type="checkbox"/>	Data, not publicly available
<input type="checkbox"/>	Data, publicly available (e.g., census data, unrestricted data sets)
<input type="checkbox"/>	Deception
<input checked="" type="checkbox"/>	Devices
<input type="checkbox"/>	Diet, exercise, or sleep modifications
<input type="checkbox"/>	Drugs or biologics (including dietary supplements/ingredients)
<input type="checkbox"/>	Emergency research
<input type="checkbox"/>	Focus groups
<input type="checkbox"/>	Food supplements

Also select any additional procedures resulting from the use of the device in the study, such as surgeries, radiation or imaging procedures, etc.

<input type="checkbox"/> Gene transfer
<input type="checkbox"/> Genetic testing
<input type="checkbox"/> Internet or e-mail data collection
<input type="checkbox"/> Magnetic resonance imaging (MRI)
<input type="checkbox"/> Materials that may be considered sensitive, offensive, threatening, or degrading
<input type="checkbox"/> Non-invasive medical procedures (e.g., EKG, Doppler)
<input type="checkbox"/> Observation of participants (including field notes)
<input type="checkbox"/> Oral history (does not include dental or medical history)
<input type="checkbox"/> Placebo
<input type="checkbox"/> Pregnancy testing
<input type="checkbox"/> Program Protocol (Umbrella Protocol)
<input type="checkbox"/> Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures)
<input type="checkbox"/> Randomization
<input type="checkbox"/> Record review (which may include PHI)
<input type="checkbox"/> Specimen research
<input type="checkbox"/> Stem cell research
<input type="checkbox"/> Storage of biological materials (future unspecified use, including repositories)
<input type="checkbox"/> Surgical procedures (including biopsies)
<input type="checkbox"/> Surveys, questionnaires, or interviews (group)
<input type="checkbox"/> Surveys, questionnaires, or interviews (one-on-one)
<input type="checkbox"/> Other (Specify)

Devices

Select from the options below to request inclusion of medical devices (e.g., instruments, implants, in vitro reagents, etc.) in the proposed research or to request approval for a Humanitarian Use device. *Include only those devices that are to be used as part of the research protocol (except for Humanitarian Use devices), i.e., not those used for routine care or evaluation.* Enter as many devices as required for the research.

The College of Medicine Office of Research (COM/OR) provides assistance to investigators obtaining IDEs for human subjects research. A COM/OR representative will meet with investigators to review the FDA requirements of sponsor-investigators, including device accountability and recordkeeping procedures. For assistance, contact the College of Medicine Office of Research at 614-292-2595.

For more information on the requirements for conducting research involving medical devices, see HRPP policy [Research Involving Medical Devices](#) or [Device Advice](#) on FDA website.

FDA APPROVED DEVICES



ADD DEVICE

You have listed no FDA Approved Devices.

INVESTIGATIONAL DEVICES OR INVESTIGATIONAL USE OF APPROVED DEVICES



ADD DEVICE

You have listed no Investigational Devices.

HUMANITARIAN USE DEVICES

You have listed no Humanitarian Use Devices.

Add each SR device that will be evaluated in the study. Remember that SR is based on how the device is used in the study, not just the risk of the device alone.

Investigational Devices or Investigational Use of Approved Devices

Devices that are investigational, modified, or proposed new intended uses.

Name of device

Name of device

Manufacturer

Manufacturer / developer (PI name for devices developed at Ohio State)

Device status

Select appropriate option
based on marketing status

- ☒ Investigational
- ☐ Approved, but its use in this research is investigational

Proposed use

Describe how the device will be administered in the study. A description of device use may include:

- Proposed intended use/indications for use
- Identification of the disease or condition the device is intended to prevent, mitigate, screen, monitor, treat, or diagnose
- Part of the body or type of tissue to which the device will be applied or interacting, where applicable
- Frequency of use
- Physiological use

If a marketed device is used "off label," describe how the use differs from approved indications (e.g., frequency/route of administration, target population, user population, setting of use (hospital vs. home use), etc.).

This device research should be determined to be (complete one):

- ☒ **Significant Risk (SR)** - (e.g, sutures, cardiac pacemakers, hydrocephalus shunts, orthopedic implants)
- ☐ **Non-significant Risk (NSR)** - (e.g., daily-wear contact lenses, lens solutions, dental scalers, foley catheters). Provide supporting documentation from sponsor regarding why the device does not pose a significant risk.
- ☐ **IDE Exempt**

Investigational Device Exemption (IDE) number:

Provide IDE # (will start with a G)

State who holds the IDE (i.e., sponsor, investigator, other)

State who holds the IDE

Provide protocol-specific documentation (e.g., sponsor's protocol cover sheet, FDA or sponsor correspondence, etc.) of the IDE number.

UPLOADED FILES

No files have been uploaded.

Click Select Files to add files to the upload area.
For files greater than 20MB, please see [instructions](#).

SELECT FILES

Acceptable forms of IDE documentation are as follows:

- Preferred documentation: **FDA IDE Study May Proceed letter** (see example on following page).
 - This document is required for clinical investigations initiated by Ohio State investigators.
- Alternative documentation: IDE number is identified on the protocol document. This method is acceptable when the IDE sponsor is external to Ohio State and Ohio State is not the lead site reviewing the research.


Describe the process for investigational device accountability, storage, and recordkeeping to ensure that the device will be used according to the approved protocol, under the direction of approved investigator(s).

Indicate who will handle storage and dispensing of the device, recordkeeping, etc.

For an investigator-held IDE, describe the process of assuring compliance with FDA regulations pertaining to sponsors (e.g., recordkeeping, reporting).

This section should describe how serious adverse events are reported, to whom, and the time frame in which it is done.

Page 1 of IDE Study May Proceed letter (example)




DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service


Food and Drug Administration
 10903 New Hampshire Avenue
 Document Control Center - WO66-G609
 Silver Spring, MD 20993-0002

 November 13, 2015



IDE number

Re: G#####


Trade/Device Name: 

Dated: October 15, 2015

Received: October 16, 2015

CMS Category: B4

Annual Report Due: One Year from the Date of This Letter

Dear :

The Food and Drug Administration (FDA) has reviewed your Investigational Device Exemption (IDE) application regarding your feasibility study for a significant risk device. FDA has determined you have provided sufficient data to support initiation of a human clinical study; this means that there are no subject protection concerns that preclude initiation of the investigation. Your application is therefore approved, and you may begin your investigation after you have obtained institutional review board (IRB) approval. Your investigation is limited to 12 US institutions and 200 US subjects.

We would like to point out that approval of an IDE application does not ensure that the results of this investigation will provide a reasonable assurance of the safety and effectiveness of your device or assure a determination of clearance/approval for your premarket submission.

FDA will waive those requirements regarding submission and prior FDA approval of a supplemental application and receipt of certification of institutional review board (IRB) approval for investigational sites ([21 CFR 812.35\(b\)](#)) provided that the total number of investigational sites does not exceed the limit identified in this letter. As a reminder, you must submit a supplemental IDE application, and receive FDA approval, prior to expanding the investigation beyond the site limit specified in this letter. In addition, you must maintain current records as required by [21 CFR 812.140](#) and submit reports as required by [21 CFR 812.150](#). If a reviewing IRB requires any significant changes in the investigational plan or in the informed consent that may increase the risks to subjects or affect the scientific soundness of the study, then this change must be submitted to FDA for review and approval prior to initiating the study at that investigational site ([21 CFR 812.35](#)). Minor changes requested by the IRB may be made without prior FDA approval.

Provide a brief description of the device.

The description may include:

- Physical, chemical, and/or biological processes/principles used by the device to generate device output (if applicable)
- Physical and biological characteristics of the device output (if applicable)
- An explanation of the user interface and/or how the device interacts with other devices or with the user (medical professional and/or patient)

Additional details, such as pictures or engineering drawings, can be uploaded in the device labeling section.

Provide the proposed rationale for choice of the device (compared to other devices that could have been used).

Explain why the device is being used in this research.

Summarize the potential adverse effects (including serious warnings and more common adverse effects).

Provide a snapshot of the *most common* adverse effects; these may be summarized by grouping AEs into general categories (e.g., “mild to moderate short-term GI side effects”), as opposed to listing individual symptoms. Do not copy a comprehensive list of potential risks from the device labeling.

Provide documentation of all applicable FDA approvals/exemptions for the investigational or research use of the devices. Copies of any correspondence to and from the FDA must be provided to the IRB. Final IRB approval cannot be granted until regulatory status is confirmed.

UPLOADED FILES

No files have been uploaded.

Click [Select Files](#) to add files to this form.
For files greater than 20MB, please see [instructions for large files](#).

SELECT FILES

Provide any other applicable correspondence from the FDA pertaining to the SR investigation.

Provide a copy of the device manufacturer's approved labeling (e.g., package insert, device label, descriptive and informational literature, operations manual, etc.).

UPLOADED FILES

No files have been uploaded.

Click **Select Files** to add files to this form.
For files greater than 20MB, please see [instructions for large files](#).

SELECT FILES

Provide labeling, descriptive information, user manuals, etc. so that the IRB can evaluate the intended use and potential risks of the device. If the device is still in development, a robust description of these items must be provided. As applicable, upload pictures or engineering drawings.

Promotional brochures alone are not sufficient.

Page 1 of device labeling (example)

Note: Device labeling & user manuals will vary; unlike drugs, there is not a universal format.



7F Freezor® Cardiac Cryoablation Catheter Instructions For Use

Device Description

The 7F Freezor® Cardiac Cryoablation Catheter and CCT.2 CryoConsole System consists of a CryoConsole, the Freezor® Catheter, connection components and accessories.

The Freezor® Catheter is a flexible, steerable device specifically designed for tissue cryomapping and cryoablation. Electrodes at the tip surface provide temperature-reading capabilities. Freezor® Catheters are introduced into the vasculature by traditional minimally invasive techniques. The distal end of the Freezor® Catheter reaches temperatures as cold as -75°C when refrigerant is injected from the console to the tip of the catheter.

Indications for Use

The 7F Freezor® Cardiac Cryoablation Catheter and CCT.2 CryoConsole System and related accessories are indicated for the cryoablation of the conducting tissues of the heart in the treatment of patients with atrioventricular nodal reentrant tachycardia (AVNRT).

Contraindications

This device is contraindicated:

- In patients with active systemic infection.
- In conditions where manipulation of the catheter would be unsafe (e.g. intracardiac mural thrombus).
- In patients with cryoglobulinemia

Warnings

- Additional studies are needed to fully characterize the impact of cryomapping with respect to patient outcomes.
- The Freezor® Catheter contains pressurized refrigerant during operation. Release of this gas into the circulatory system due to equipment failure or misuse could result in gas embolism.
- If an unanticipated event occurs, stop the procedure at any time by pushing the RED button on the console control panel.
- Do not pull on the Freezor® Catheter, umbilicals or CryoConsole while the catheter tip is frozen to the endocardial tissue, as this could lead to cardiac or vascular damage.
- Do not connect the Freezor® Catheter to any radio frequency generator or use the Freezor® Catheter to deliver RF ablation energy, because this could cause catheter malfunction and / or patient harm.
- Introducing any catheter into the circulatory system entails the risk of gas embolism, which can occlude vessels and lead to tissue infarction with serious consequences.
- Catheter procedures may mechanically induce arrhythmias.
- The use of fluoroscopy during catheter ablation procedures presents the potential for significant x-ray exposure to both patients and laboratory staff. Extensive exposure can result in acute radiation injury and increased risk for somatic and genetic effects. Only perform catheter ablation after giving adequate attention to the potential radiation exposure associated with the procedure, and taking steps to minimize this exposure. Give careful consideration before using the device in pregnant women.
- Careful catheter manipulation must be performed in order to avoid cardiac damage such as perforation or tamponade.
- Catheter advancement should be performed under fluoroscopic guidance. Do not use excessive force to advance or withdraw the Freezor® Catheter, especially if resistance is encountered. Ensure the appropriate intravascular tip positioning.
- Catheter entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures. The potential for catheter entrapment may be increased when the catheter is

Alternatives to Participation

Other than choosing not to participate, are there any alternatives to participating in the research?

Yes

No

List the specific alternatives to participation, including available procedures or treatments that may be advantageous to the subject.

Alternatives to participating in a therapeutic study may include the following:

- **Receiving different approved device(s) or other treatment**
- **Receiving the device(s) at a frequency and/or route of administration determined by one's physician (as opposed to the protocol)**
- **Enrolling in a different clinical trial**

There may or may not be alternatives to participating in non-therapeutic studies.

Risks, Harms & Discomforts

Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Discuss severity and likelihood of occurrence. As applicable, include potential risks to an embryo or fetus if a woman is or may become pregnant.

General study risks go here. Do not duplicate risks of devices listed elsewhere or copy a comprehensive list of side effects from device labeling.

Describe how risks, harms, and/or discomforts will be minimized.

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