February 13, 2026

Medinice S.A.
℅ Melissa DeHass
Regulatory Consultant
MEDIcept
200 Homer Ave
Ashland, Massachusetts 01721

Re: K251928
Trade/Device Name: CoolCryo - Cryoapplicator for cardiac cryoablation; CoolCryo - Control console for cardiac cryoablation with liquid nitrogen reservoir
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: January 16, 2026
Received: January 16, 2026

Dear Melissa DeHass:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these

requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
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Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251928

Device Name

CoolCryo - Cryoapplicator for cardiac cryoablation
CoolCryo - Control console for cardiac cryoablation with liquid nitrogen reservoir

Indications for Use *(Describe)*

The CoolCryo cryoapplicator is a single use, sterile device indicated for the cryosurgical treatment for ablation of arrhythmic cardiac tissue by freezing target tissues, inducing an inflammatory response (cryonecrosis) that blocks the electrical conduction pathway.

The CoolCryo cryoapplicator can be used in adults and is intended for use in the clinical environment by trained healthcare professionals.

The CoolCryo control console is a nonsterile, reusable device which delivers cryogenic energy, namely liquid nitrogen, to the CoolCryo cyroapplicator. The CoolCryo control console can be used in adults and is intended for use in the clinical environment by trained healthcare professionals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K251928
510(k) Summary

I. SUBMITTER

510(k) Holder: Medinice S.A.
S.K. Hankiewicza
Warsaw, Poland 02-103

Contact Person: Melissa DeHass
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MEDIcept, Inc.
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Date Prepared: June 23, 2025

II. DEVICE

Name of the Device:	CoolCryo - Cryoapplicator for cardiac cryoablation CoolCryo - Control console for cardiac cryoablation with liquid nitrogen reservoir
Common Name or Usual Name:	Cryosurgical probe
Classification Name:	Cryosurgical unit and accessories
Regulatory Class:	Class II
Product Code:	GEH – Unit, Cryosurgical, Accessories

III. PREDICATE DEVICE

K152337 Atricure cryoICE cryoFORM cryoablation probe is the predicate device and has not been subject to a design-related recall.

The reference device is K142203 AtriCure Cryosurgical System – AtriCure Cryo Module (ACM) and AtriCure cryoICE cryo-ablation probes (CRY02).

IV. DEVICE DESCRIPTION

The CoolCryo is a sterile, single-use cryogsurgical device to freeze target tissue, blocking electrical conduction pathways by creating an inflammatory response or cyronecrosis.

The CoolCryo comprises a cryoapplicator and a control console with a liquid nitrogen reservoir:

- CC01-01 Cryoapplicator for cardiac cryoablation,
- CC01-21 Control console for cardiac cryoablation with liquid nitrogen reservoir.

V. INTENDED USE/INDICATIONS FOR USE

The CoolCryo cryoapplicator is a single use, sterile device indicated for the cryosurgical treatment for ablation of arrhythmic cardiac tissue by freezing target tissues, inducing an inflammatory response (cryonecrosis) that blocks the electrical conduction pathway.

The CoolCryo cryoapplicator can be used in adults and is intended for use in the clinical environment by trained healthcare professionals.

The CoolCryo control console is a nonsterile, reusable device which delivers cryogenic energy, namely liquid nitrogen, to the CoolCryo cyroapplicator. The CoolCryo control console can be used in adults and is intended for use in the clinical environment by trained healthcare professionals.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

In accordance with the *510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* issued July 28, 2014, the comparison between the predicate and the subject devices is shown to be substantially equivalent by comparing the indications for use, principles of operation, technological characteristics, and performance testing similarities and differences. (Table 1) The technological characteristic differences rationale demonstrates that the subject device is safe and effective as the legally marketed device and does not raise different questions of safety and effectiveness than the predicate device.

Table 1. Substantial Equivalence Subject Device CoolCryo Cryoapplicator and CoolCryo Console Compared to the Predicate

Characteristic	**Subject Device CoolCryo - Cryoapplicator for cardiac cryoablation and CoolCryo - Control console for cardiac cryoablation with liquid nitrogen reservoir**	**Predicate Device AtriCure cryoFORM cryoICE Cryoablation Probe (K152337)**	**Equivalence Comparison**
Intended Use/ Indications for Use	The CoolCryo - Cryoapplicator for cardiac cryoablation is a single use, sterile device indicated for the cryosurgical treatment for ablation of arrhythmic cardiac tissue by freezing target tissues, inducing an inflammatory response (cryonecrosis) that blocks the electrical conduction pathway.	AtriCure's cryoICE cryoFORM cryoablation probes are sterile, single use devices intended for use in the cryosurgical treatment of cardiac arrhythmias by freezing target tissues, creating an inflammatory response (cryonecrosis) that blocks	**Same**

Characteristic	Subject Device CoolCryo - Cryoapplicator for cardiac cryoablation and CoolCryo - Control console for cardiac cryoablation with liquid nitrogen reservoir	Predicate Device AtriCure cryoFORM cryoICE Cryoablation Probe (K152337)	Equivalence Comparison
	The CoolCryo - Cryoapplicator for cardiac cryoablation can be used in adults and is intended for use in the clinical environment by trained healthcare professionals. The CoolCryo - Control console for cardiac cryoablation with liquid nitrogen reservoir is a nonsterile, reusable device which delivers cryogenic energy, namely liquid nitrogen, to the CoolCryo - Cryoapplicator for cardiac cryoablation. The CoolCryo - Control console for cardiac cryoablation with liquid nitrogen reservoir can be used in adults and is intended for use in the clinical environment by trained healthcare professionals.	the electrical conduction pathway.	
Target population	Adults	Adults	**Same**
Cooling system location	Integrated, reusable, dewar of liquid nitrogen [non-removable by the user]. To be refilled by the qualified professional.	System of reusable gas cylinder of nitrous oxide, hose, heater band. To be refilled by the qualified professional.	**Similar**
Operating mode	Standby, freeze, defrost. Pre-programmed default operating mode	Ready, freeze, defrost. Pre-programmed default operating mode	**Same**
Defrost	Active	Active	**Same**
Operating principle during freezing	Flow of liquid nitrogen	Joule-Thompson effect	**Different**

Characteristic	Subject Device CoolCryo - Cryoapplicator for cardiac cryoablation and CoolCryo - Control console for cardiac cryoablation with liquid nitrogen reservoir	Predicate Device AtriCure cryoFORM cryoICE Cryoablation Probe (K152337)	Equivalence Comparison
User parameters controlled	Automatic treatment mode (setting the ablation time), operated from the footswitch or buttons on the cryoapplicator. Ablation timer setting	Automatic treatment mode (setting the ablation time), operated from the footswitch or panel. Ablation timer setting	**Same**
Software controls	Valves, pumps, heaters	Valves, heaters	**Similar**
Parameters monitored by the software	The controller constantly monitors the status of buttons, freezing part temperature, ablation timer, cryogen level, valves, buttons, cryoapplicator pressure, cryogen pressure, and presence of the cryoapplicator.	The controller constantly monitors the status of: buttons, freezing part temperature, ablation timer, cryogen level, valves, buttons, probe pressure, cryogen pressure.	**Similar**
System display	Operating mode, cryogen level, ablation time, current temperature of the probe, error codes, messages	Operating mode, cryogen level, ablation time, current temperature of the probe, error codes.	**Similar**
Freezing part characteristics	Material: Aluminum alloy Construction: Smooth malleable probe Dimensions: 5.7 mm, 100 mm working length	Material: Stainless Steel Construction: Corrugated malleable probe Dimensions: 3.9 mm, 100 mm working length	**Similar**
Probe connection to the system	Cryoapplicator (Probe) is connected to the control console.	Probe is connected to the cryo module (console).	**Same**
Screen/Display	Touch Screen mounted on the control console. Additional screen on the cryoapplicator.	Two alphanumeric displays on the cryo module (console).	**Similar**
Console dimensions	Height: 115 cm / 45.3 in Depth: 58 cm / 22.8 in Width: 80 cm / 31.5 in	Height: 11.4 cm / 4.5 in Depth: 68.6 cm / 27.0 in Width: 44.5 cm / 17.5 in	**Different**
Cryogen	Liquid Nitrogen	Nitrous Oxide	**Different**
Use environment	Hospital – operating room	Hospital – operating room	**Same**

The reference device K142203 AtriCure Cryosurgical System – AtriCure Cryo Module (ACM) and AtriCure cryoICE cryo-ablation probes (CRY02) was used to demonstrate that the different technological characteristics, operating principle during freezing, cryogen, and console dimensions, do not raise different questions of safety and effectiveness.

VII. PERFORMANCE DATA

Non-clinical performance testing was conducted to verify the subject device performance. The following performance data was provided in support of the substantial equivalence determination.

Biocompatibility testing
In accordance with the *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process": Guidance for Industry and Food and Drug Administration Staff,* the type of tissue contact and duration of contact for the subject device is external communicating device: circulating blood ≤ 24 hours. The biological effect for evaluation were cytotoxicity, sensitization, irritation, acute systemic and pyrogenicity, genotoxicity and hemocompatibility.

Electrical safety and electromagnetic compatibility (EMC)
In accordance with the *Electromagnetic Compatibility (EMC) of Medical Devices: Guidance for Industry and Food and Drug Administration Staff,* the subject device complies with the IEC 60601-1 standard for electrical safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing
In accordance with the *Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff* software documentation was provided for Enhanced documentation level.

Bench Testing
In accordance with *Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions: Guidance for Industry and Food and Drug Administration Staff*, the following testing was conducted

- Functional Testing
- Visual Inspection
- Cryogen Performance Testing
- LAL Testing
- Sterilization validation
- Shelf Life
- Usability

Animal Study
Animal testing was conducted a GLP animal study to evaluate the performance of the subject device in a live porcine thigh tissue model and to compare performance to the predicate device AtriCure cryoFORM cryoICE cryoablation probe. Lesions were created by each of the cryoablation probes on porcine thigh muscle. The lesions were assessed using histopathology

and morphometric measurements and the results demonstrated statistical equivalence via two one-sided tests (TOST) for lesion width and depth.

Clinical Study
Clinical testing was not completed and is not part of the substantial equivalence demonstration.

VIII. CONCLUSIONS

The substantial equivalence tables, bench testing and animal testing results demonstrate that the subject device, CoolCryo - Cryoapplicator for cardiac cryoablation and CoolCryo - Control console for cardiac cryoablation with liquid nitrogen reservoir, is substantially equivalent to the predicate device, K152337 AtriCure cryoICE cryo-ablation probe (CRYO2).