April 10, 2025

AtriCure, Inc.
Ronit Shah
Regulatory Affairs Specialist
7555 Innovation Way
Mason, Ohio 45040

Re: K250371
Trade/Device Name: cryoICE cryoXT cryoablation probe (cryoXT)
Regulation Number: 21 CFR 882.4250
Regulation Name: Cryogenic Surgical Device
Regulatory Class: Class II
Product Code: GXH
Dated: February 10, 2025
Received: February 10, 2025

Dear Ronit Shah:

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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2025.04.10 13:41:24 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine 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)*

K250371

Device Name

cryoICE® cryoXT™ cryoablation probe (cryoXT)

Indications for Use *(Describe)*

AtriCure's cryoICE cryoXT cryoablation probes are intended for use to temporarily block pain by ablating peripheral nerves performed by freezing target tissues, creating an inflammatory response (cryonecrosis).

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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510(k) Summary

Applicant Information

Manufacturer: AtriCure, Inc.
7555 Innovation Way
Mason Ohio 45040
P: 513-755-4100

Contact Person: Ronit Shah
Regulatory Affairs Specialist
P: 409-434-7267

Date: April 10, 2025

Device Information

Proprietary Name: cryoICE® cryoXT™ cryoablation probe

Common Name: Cryosurgical Probe

Classification: Cryogenic surgical device
Regulatory Class: Class II; per 21 CFR 882.4250
Product Code: GXH
Classification Panel: Neurodiagnostic and Neurosurgical Devices

Predicate Device: cryoICE® cryoablation probe (CRYO2) (cleared via 510(k) K200697, March 17, 2020)

Reference Device: cryoICE® cryoSPHERE® cryoablation probe (CRYOS) (cleared via 510(k) K200697, March 17, 2020)

Device Description

The cryoICE® cryoXT™ probe is a sterile, single-use device designed to enable cryoablation of target nerves by allowing surgeons to surround exposed peripheral nerves with its blunt prong-shaped distal tip, and in conjunction with an AtriCure cryoICE BOX (ACM), temporarily freeze the tissue in contact with the probe tip by circulating a cryogenic agent, nitrous oxide, through the device. cryoXT is offered in one single probe length of approximately 11" (28 cm) long. The device has a flexible tubeset that consists of a gas supply tube and exhaust tube, a handle, a malleable probe which is covered by an insulating sheath and has a prong-shaped distal tip at the distal end.

Intended Use / Indications for Use

AtriCure's cryoICE® cryoXT™ cryoablation probes are intended for use to temporarily block pain by ablating peripheral nerves performed by freezing target tissues, creating an inflammatory response (cryonecrosis).

Comparison of Technological Characteristics

- The devices have the same intended use, and;
- No changes were made in operating principle, or specifications of performance, and;
- The results of the verification and validation testing:
  - Demonstrated equivalency in performance, and
  - Did not raise any new issues of safety.

The cryoICE® cryoXT™ cryoablation probe's blunt prong-shaped distal tip is being introduced based on physicians' feedback to provide a distal tip design to gently and efficiently surround the targeted exposed peripheral nerves.

#	Feature	**Predicate Device –** CRYO2 per K200697	**Reference Device** – CRYOS per K200697	**Proposed Device** – cryoXT	**Equivalence**
1	Marketed Product Name	cryoICE cryoablation probes	cryoICE cryoSPHERE cryoablation probe	cryoICE cryoXT cryoablation probe	N/A
2	Intended Use	FOR ADULT PATIENTS AtriCure's Cryo2 cryoICE 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 the electrical conduction pathway. The Cryo2 cryoICE cryo-ablation probes are also intended for use to temporarily block pain by ablating peripheral nerves. FOR ADOLESCENT PATIENTS The Cryo2 cryoICE cryo-ablation probes are intended for use to temporarily block pain by ablating intercostal nerves under direct visualization[1] in adolescent patients of at least 12 years of age. [1]Direct visualization, in this context, requires that the surgeon is able to see the targeted tissue for cryoablation directly or with assistance from a camera, endoscope or other similar optical technology.	FOR ADULT PATIENTS AtriCure's cryoICE cryoSPHERE cryoablation probes are sterile, single use devices intended for use performed by freezing target tissues, creating an inflammatory response (cryonecrosis) for blocking pain by temporarily ablating peripheral nerves. FOR ADOLESCENT PATIENTS The cryoICE cryoSPHERE cryo-ablation probes are intended for use to temporarily block pain by ablating intercostal nerves under direct visualization[1] in adolescent patients of at least 12 years of age. [1]Direct visualization, in this context, requires that the surgeon is able to see the targeted tissue for cryoablation directly or with assistance from a camera, endoscope or other similar optical technology.	AtriCure's cryoICE cryoXT cryoablation probes are intended for use to temporarily block pain by ablating peripheral nerves performed by freezing target tissues, creating an inflammatory response (cryonecrosis).	Equivalent The pain block indication statement is the same as the predicate device. The cryoXT is not intended for cardiac arrythmias or adolescents. Note: The 'what' and 'how' of the indications for use was re-arranged to make the sentence flow better. The 'what', blocking pain, was moved to read before the 'how', by ablating peripheral nerves performed by freezing target tissues, creating an inflammatory response (cryonecrosis). The key aspects all remain within the indications for use between the predicate and proposed devices. Elimination of 'sterile, single use devices' as this information is identified within multiple areas of the Instructions For Use and is not a part of the device's indication or intended use.
3	Operating Principle	Joule-Thompson Effect	Joule-Thompson Effect	Joule-Thompson Effect	Same
4	Technology	The system consists of cryoprobes that are used for freezing target tissue. A console is used to control the supply of gas to the cryoprobe.	The system consists of cryoprobes that are used for freezing target tissue. A console is used to control the supply of gas to the cryoprobe.	The system consists of cryoprobes that are used for freezing target tissue. A console is used to control the supply of gas to the cryoprobe.	Same
5	Energy Used	Nitrous Oxide	Nitrous Oxide	Nitrous Oxide	Same

#	Feature	**Predicate Device –** CRYO2 per K200697	**Reference Device** – CRYOS per K200697	**Proposed Device** – cryoXT	**Equivalence**
6	Operating Temperature	Below -40°C	Below -40°C	Below -40°C	Same
7	Human Factors	Hand-held device connected to a console which circulates the cryogen through the device in a closed loop system via the activation button or footswitch.	Hand-held device connected to a console which circulates the cryogen through the device in a closed loop system via the activation button or footswitch.	Hand-held device connected to a console which circulates the cryogen through the device in a closed loop system via the activation button or footswitch.	Same
7	Distal Tip	Linear, cylindrical probe, Aluminum	Ball-shaped probe, Aluminum	Linear, prong-shaped probe with cylindrical arms, Aluminum	Equivalent
8	Exposed Shaft Length	28cm (11”)	28cm (11”)	28cm (11”)	Same
9	Biocompatibility	Biocompatible patient contacting materials	Biocompatible patient contacting materials	Biocompatible patient contacting materials	Same
10	Packaging	Sterile - single use, disposable cryoablation probe.	Sterile - single use, disposable cryoablation probe.	Sterile - single use, disposable cryoablation probe.	Same
11	Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Same
12	Forming Tool	Forming Tool Supplied	Forming Tool Supplied	No Forming tool will be supplied	Equivalent

Performance Data

The following bench testing was conducted for design and performance elements deemed appropriate to demonstrate equivalence to the previously cleared cryoICE cryoablation probes (CRYO2, CRYOS). The cryoICE® cryoXT™ cryoablation probe met the predetermined acceptance criteria ensuring substantial equivalence to the previously cleared cryoICE cryoablation probes (CRYO2, CRYOS). No new safety or performance issues were raised during testing.

Non-clinical Bench Testing:

- Cryogenic Performance Test
- Iceball Performance Test
- Mechanical Reliability Test
- Pressure Cycle Withstand Test
- Drop Test
- Dimensional Verification Test
- BiocompatibilityTest
- Sterility Test

Conclusions

AtriCure has demonstrated that the cryoICE® cryoXT™ cryoablation probe is substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principle, and intended use / indication for use as the previously cleared cryoICE cryoablation probes (CRYO2) and cryoICE cryoSPHERE cryoablation probes (CRYOS) cleared via K200697.