October 26, 2023

AtriCure, Inc.
Erica Schwab
Senior Regulatory Affairs Specialist
7555 Innovation Way
Mason, Ohio 45040

Re: K233170
Trade/Device Name: cryoICE cryoSPHERE+ Cryoablation Probe (CRYOSP);
cryoICE cryoSPHERE+ Cryoablation Probe (CRYOSP-L);
cryoICE cryoSPHERE MAX Cryoablation Probe (CRYOSMAX);
cryoICE cryoSPHERE MAX Cryoablation Probe (CRYOSMAX-L)

Regulation Number: 21 CFR 882.4250
Regulation Name: Cryogenic Surgical Device
Regulatory Class: Class II
Product Code: GXH
Dated: September 27, 2023
Received: September 27, 2023

Dear Erica Schwab:

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.

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: 2023.10.26 11:59:12 -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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K233170

Device Name

cryoICE cryoSPHERE+ Cryoablation Probe (CRYOSP);
cryoICE cryoSPHERE+ Cryoablation Probe (CRYOSP-L);
cryoICE cryoSPHERE MAX Cryoablation Probe (CRYOSMAX);
cryoICE cryoSPHERE MAX Cryoablation Probe (CRYOSMAX-L)

Indications for Use *(Describe)*

FOR ADULT PATIENTS
AtriCure's cryoICE cryoSPHERE+ and cryoSPHERE MAX cryoablation probes are intended for use to temporarily block pain by ablating peripheral nerves performed by freezing target tissues, creating an inflammatory response (cryonecrosis).

FOR ADOLESCENT PATIENTS
The cryoICE cryoSPHERE+ and cryoSPHERE MAX cryo-ablation probes are intended for use to temporarily block pain by ablating intercostal nerves under direct visualization* in adolescent patients of at least 12 years of age.
*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.

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: Erica Schwab
Senior Regulatory Affairs Specialist
Phone: 513-755-4100

Date Prepared: October 26, 2023

Device Information

Proprietary Name: cryoICE cryoSPHERE+ cryoablation probe (CRYOSP)
cryoICE cryoSPHERE+ cryoablation probe (CRYOSP-L)
cryoICE cryoSPHERE MAX cryoablation probe (CRYOSMAX)
cryoICE cryoSPHERE MAX cryoablation probe (CRYOSMAX-L)

Common Name: Cryosurgical Probe

Classification: Cryogenic surgical device
Regulatory Class: Class II; per 21 CFR 878.4250
Product Code: GXH
Classification Panel: Neurodiagnostic and Neurosurgical Devices

Predicate Device: cryoICE cryoSPHERE cryoablation probe (CRYOS and CRYOS-L) (K200697, December 23, 2020)

Device Description

The cryoICE cryoSPHERE+ and cryoICE cryoSPHERE MAX cryoablation probes are sterile, single use devices that achieve cryoablation of peripheral nerves by allowing a surgeon to insert the probe through an incision to reach the target tissue, place the probe tip on the target site, and in conjunction with an AtriCure Cryo Module (ACM), temporarily freeze the tissue in contact with the probe tip by circulating a cryogenic agent, nitrous oxide, through the device. The cryoICE cryoSPHERE+ and cryoICE cryoSPHERE MAX device is offered in two probe length configurations: approximately 11” and 17” long. At the distal end, the ryoICE cryoSPHERE+ and cryoICE cryoSPHERE MAX probe features an 8mm or 10mm diameter ball tip shape for each length configuration. The flexible region of the probe is malleable and is capable of being bent by the end user using an included forming tool.

Intended Use / Indications for Use

FOR ADULT PATIENTS
AtriCure's cryoICE cryoSPHERE+ and cryoICE cryoSPHERE MAX cryoablation probes are intended for use to temporarily block pain by ablating peripheral nerves performed by freezing target tissues, creating an inflammatory response (cryonecrosis).

FOR ADOLESCENT PATIENTS
The cryoICE cryoSPHERE+ and cryoICE cryoSPHERE MAX cryoablation 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.

Comparison of Technological Characteristics

- The devices include the same intended use and indications for 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
    - Did not raise any new issues of safety

Modifications included in the cryoICE cryoSPHERE+ and cryoICE cryoSPHERE MAX probe end-effectors were for differing body habitus and surgeon preference for the use of the device specifically intended to blocking pain.

#	Feature	Predicate Device – CRYOS and CRYOS-L per K200697	Proposed Device – CRYOSP, CRYOSP-L, CRYOSMAX and CRYOSMAX-L
1	Marketed Product Name	cryoICE cryoSPHERE cryoablation probe	cryoICE cryoSPHERE+ cryoablation probe cryoICE cryoSPHERE MAX cryoablation probe
2	Intended Use	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.	FOR ADULT PATIENTS AtriCure's cryoICE cryoSPHERE+ and cryoSPHERE MAX cryoablation probes are intended for use to temporarily block pain by ablating peripheral nerves performed by freezing target tissues, creating an inflammatory response (cryonecrosis). 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.

#	Feature	Predicate Device – CRYOS and CRYOS-L per K200697	Proposed Device – CRYOSP, CRYOSP-L, CRYOSMAX and CRYOSMAX-L
3	Operating Principle	Joule-Thompson Effect	Joule-Thompson Effect
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.
5	Energy Used	Nitrous Oxide	Nitrous Oxide
6	Operating Temperature	Below -40°C	Below -40°C
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.
5	Ball Tip	Material: Aluminum Alloy	Material: Aluminum Alloy
		Construction: smooth spherical ball welded onto the shaft.	Construction: smooth spherical ball threaded (with epoxy adhesive) onto the shaft.
		Diameter: Ball Tip – 8mm (CRYOS and CRYOS-L)	Diameter: Ball Tip – 8mm (CRYOSP and CRYOSP-L) and 10mm (CRYOSMAX and CRYOSMAX-L)
6	Insulative Shaft	Rigid Region: Material: Makrolon Polycarbonate (black) Construction: smooth rigid shaft	Rigid Region: Material: Double Wall Vacuum Insulated Stainless Steel covered with Shrink Tube (black) Construction: smooth rigid shaft
		Flexible Region: Material: Clear LDPE sheath with black braids) Construction: Smooth Aluminum	Flexible Region: Material: Double Wall Vacuum Insulated Stainless Steel covered with Shrink Tube (black) Construction: Corrugated Stainless Steel
7	Exposed Shaft Length	Standard: 28cm (11”) (CRYOS) Long: 46cm (18”) (CRYOS-L)	Standard: Same Long: 43cm (17”) (CRYOSP-L and CRYOSMAX-L)
8	Nose Cone	Overall Length: Less than 1 inch Material: Polycarbonate Resin Color: Translucent Blue	Overall Length: Less than 2 inches Material: Polycarbonate Resin, Color: Blue
9	Device Flow Rate	Minimum flow rate value	Specified flow rate range
10	Probe Thermocouple	Material: Cu-Constantan w/Kapton Location: Distal end of the Rigid Shaft	Material: Type t (cu-constantan) Location: Distal Cap, proximal to ball tip.
11	Biocompatibility	Biocompatible patient contacting materials	Biocompatible patient contacting materials
12	Packaging	Sterile - single use, disposable device	Sterile - single use, disposable device
13	Sterilization	Gamma Irradiation	Gamma Irradiation
14	Power Source	Mains Powered	Mains Powered

Performance Data

The following bench testing was conducted for design and performance elements deemed appropriate to demonstrate equivalence to the previously cleared cryoICE cryoSPHERE devices. The cryoICE cryoSPHERE+ and cryoICE cryoSPHERE MAX devices met the predetermined acceptance criteria ensuring substantial equivalence to the previously cleared cryoICE cryoSPHERE devices. No new safety or performance issues were raised during testing.

Non-clinical Bench Testing:

- Reliability Testing
- Transit
- Shelf-life
- Cryogen Performance/Thermal Insulation
- Mechanical testing
- Biocompatibility
- Sterility
- EMC

Conclusions

AtriCure has demonstrated that the cryoICE cryoSPHERE+ and cryoICE cryoSPHERE MAX cryoablation probes are substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principal, and intended use/ indication for use as the previously cleared devices: cryoICE cryoSPHERE cryoablation probes.