December 23, 2020

AtriCure Inc.
Melissa Smallwood
Senior Regulatory Affairs Specialist
7555 Innovation Way
Mason, Ohio 45040

Re: K200697
Trade/Device Name: AtriCure CryoICE cryo-ablation probe (Cryo2), AtriCure CryoICE CryoSPHERE cryoablation probe (CryoS, CryoS-L)
Regulation Number: 21 CFR 882.4250
Regulation Name: Cryogenic Surgical Device
Regulatory Class: Class II
Product Code: GXH
Dated: March 13, 2020
Received: March 17, 2020

Dear Melissa Smallwood:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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.*

510(k) Number *(if known)*
K200697

Device Name
AtriCure® cryoICE® cryoablation probe (Cryo2)

Indications for Use *(Describe)*

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 visualization1 in adolescent patients of at least 12 years of age.

1Direct 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

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.*

510(k) Number *(if known)*
K200697

Device Name
AtriCure® cryoICE® cryoSPHERE™ cryoablation probe (CryoS, CryoS-L)

Indications for Use *(Describe)*

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 visualization1 in adolescent patients of at least 12 years of age.

1Direct 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.**

# 510(k) Summary

## I. Submitter


Manufacturer: AtriCure, Inc.
7555 Innovation Way
Mason, OH 45040
P: 513-644-4736
F: 513-755-4108

Contact Person: Melissa Smallwood, MHA
Senior Regulatory Affairs Specialist

Alternate Contact Person: Mary Galeano, RAC
Senior Regulatory Affairs Specialist


Date Submitted: 11/23/2020

## II. Device

Name of Devices: AtriCure® cryoICE® cryoablation probe (Cryo2)
AtriCure® cryoICE® cryoSPHERE™ cryoablation probe (CryoS, CryoS-L)

Common Name: Cryosurgical Probe

Classification Name: Cryogenic Surgical Device (21 CFR 878.4250)

Regulatory Class: Class II

Product Code: GXH

## III. Predicate Device

Predicate Device:
K180138 AtriCure® cryoICE® cryoablation probe (Cryo2)
K182565 AtriCure® cryoICE® cryoSPHERE™ cryoablation probe (CryoS, CryoS-L)

## IV. Device Description

Cryo2

The cryosurgical handpiece, or cryo-ablation probe, utilized in the AtriCure Cryosurgical System is a hand held, single use, cryosurgical instrument intended for the cryosurgical treatment of cardiac arrhythmias during cardiac surgery; it is also intended for use in blocking pain by temporarily ablating peripheral nerves. The cryosurgical handpiece utilizes a high-pressure cryogen (nitrous oxide, $N_2O$) to freeze target tissues, creating an inflammatory response, and ultimately, cryonecrosis. The cryosurgical handpiece provides probe temperatures below -40°C, the temperature at which intracellular ice formation occurs which is considered lethal to cells. When high pressure nitrous oxide is supplied to the cryoprobe via the AtriCure Cryo Module, rapid cooling is achieved via the Joule-Thompson effect. The end effector, or cryotip, of the probe is malleable to allow access to varying anatomy and anatomical sites.

The cryo-ablation probes are comprised of a cryotip end effector, shaft, handle, thermocouple, inlet tube, and exhaust tube. The cryotip consists of an aluminum boiler and three internal inlet orifices distributed throughout the cryotip internally to provide uniform cooling. The 4-mm diameter, cryotip is malleable throughout its 10-cm length. A supplied forming tool can be used to bend the cryotip into the desired form. The cryotip is attached to an insulated rigid shaft that allows the surgeon to adjust the length of the exposed cryotip up to 10 cm in therapeutic length. A thermocouple is affixed to the proximal external surface of the shaft to display real time temperatures on the console. The handle is attached to the shaft. Inlet and exhaust tubes and thermocouple wire pass through the handle and connect to the AtriCure Cryo Module (ACM).

The cryoICE PROBE is a sterile, single-use cryosurgical instrument.

The form tool facilitates bending of the malleable tip.

This PROBE was designed for treatment of cardiac arrythmias by achieving controlled temperatures down to -50° to -70°C; it can also be used to temporarily block pain by ablating peripheral nerves, and also intercostal nerves in adolescent patients of at least 12 years of age.

CryoS, CryoS-L

The cryoICE cryoSPHERE cryoablation (CRYOS/CRYOS-L) probe is a single use device that achieves 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 CRYOS probe is offered in two probe length configurations: approximately 11" and 18" long. The probe is malleable and is capable of being bent by the end user. At the distal end, the CRYOS device features an 8 mm diameter ball tip shaped probe.

The PROBE is a single-use device offered in two configurations: standard length probe shaft (CRYOS), and extended length probe shaft (CRYOS-L). The probe shaft is malleable and supports forming by the user via the supplied TOOL. The PROBE features a spherical 8mm cryoablation tip.

PACKAGE CONTENTS
1.One (1) PROBE
2.One (1) TOOL
The PROBE and TOOL are supplied STERILE and NON-PYROGENIC in unopened, undamaged package. For single use only. Do not re-sterilize. Do Not Re-Use.

## V. Indications for Use

Cryo2

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 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.

CryoS, CryoS-L

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.

## VI. Comparison of Technological Characteristics with the Predicate Device

AtriCure's cryoICE cryoablation probes (Cryo2, CryoS and CryoS-L) have no changes in technological characteristics as compared to the predicate.

Modifications included in the cryoICE cryoablation probes include the expanded indication for use in adolescent patients to temporarily block pain by ablating intercostal nerves under direct visualization.

| Summary of Technical Characteristics | | |
|---|---|---|
| | CRYO2 | CRYOS/CRYOS-L |
| Market Product Name | cryoICE cryoablation probe | cryoICE cryoSPHERE cryoablation probe |
| Intended Use | For Adult Patients<br>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.<br>The cryoICE cryo-ablation probes are also intended for use to temporarily block pain by ablating peripheral nerves.<br><br>For Adolescent Patients<br>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.<br>[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<br>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.<br><br>For Adolescent Patients<br>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.<br><br>[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. |
| Operating Principle | Joule-Thompson Effect | Joule-Thompson Effect |
| 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. |
| Energy Used | Nitrous Oxide | Nitrous Oxide |
| Operating Temperature | -50°C to 70°C | -50°C to 70°C |
| Human Factors | Hand-held device containing cryogen with activation button on console or footswitch. | Hand-held device containing cryogen with activation button on console or footswitch. |
| Cryotip | Material: aluminum alloy<br>Construction: smooth malleable cylindrical linear probe<br>Diameter: 4 mm<br>Length: 10cm | Material: aluminum alloy<br>Construction: smooth spherical ball welded to a malleable cylindrical aluminum shaft.<br>Diameter: ball - 8mm; aluminum shaft – 5mm<br>Length: reference the "end-effector" length |
| End-effector Length – Shaft and Cryotip | 28 cm | 28cm (CRYOS)<br>46cm (CRYOS-L) |
| Biocompatibility | Biocompatible patient contacting materials. | Biocompatible patient contacting materials. |
| Probe Packaging | Sterile – Single Use disposable device | Sterile – Single Use disposable device |
| Sterilization | Gamma Irradiation | Gamma Irradiation |
| Power Source | Mains Powered | Mains Powered |

## VII. Performance Data

Clinical Evidence

AtriCure partnered with UCSF Stanford Pediatric Device Consortium (PDC) to evaluate Clinical Evidence in support of the cryoICE cryoablation probes (Cryo2, CryoS and CryoS-L) Indication for Use. The clinical evidence, including clinical publications demonstrated that use of the cryoICE cryoablation probes (Cryo2, CryoS and CryoS-L) in intercostal nerve ablation for temporarily pain block was as safe and effective when used in patients aged ≥ 12 years as compared to use of the cryoICE cryoablation probes (Cryo2, CryoS and CryoS-L) for equivalent procedures in adults, based on the following endpoints:

- Intraoperative or post-operative complications for patients receiving cryoanalgesia during Nuss procedure
- Adverse events observed for patients receiving cryoanalgesia
- Cryoablation associated numbness
- Neuropathic pain
- Chest wall numbness
- Post-operative pneumothorax

## VIII. Conclusions

The Clinical Evidence reviewed in the 510(k) submission demonstrates that AtriCure's cryoICE cryoablation probes (Cryo2, CryoS, CryoS-L), as labeled per the Indication for Use do not present any new or additional questions of safety and effectiveness.