November 9, 2018

AtriCure, Inc.
Jonathan McElwee
Regulatory Affairs Manager
7555 Innovation Way
Mason, Ohio 45040

Re: K182565
Trade/Device Name: AtriCure cryoICE cryoSPHERE cryoablation probe
Regulation Number: 21 CFR 882.4250
Regulation Name: Cryogenic Surgical Device
Regulatory Class: Class II
Product Code: GXH
Dated: September 17, 2018
Received: September 18, 2018

Dear Jonathan McElwee:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Matthew C. Krueger -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182565

Device Name
cryoICE® cryoSPHERE™ cryoablation probe

Indications for Use *(Describe)*
AtriCure's cryoICE cryoSPHERE cryoablation probes are sterile, single use devices intended for use in blocking pain by temporarily ablating peripheral nerves.

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

I. Applicant Information

Manufacturer: AtriCure®, Inc.
7555 Innovation Way
Mason, Ohio 45040
P: 513-644-4736
F: 513-895-9013

Contact Person: Jonathan McElwee, RAC
Manager, Regulatory Affairs

Date Prepared: 9/17/2018

II. Device Information

Proprietary Name: cryoICE™ cryoSPHERE® cryo-ablation probe (CRYOS)

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)
(K180138, February 15, 2018)

Reference Device: cryoICE cryoablation probe (CRYO2)
(K142203, November 25, 2014)

III. Device Description

The cryoICE cryoSPHERE cryoablation (CRYOS) 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.

IV. Intended Use/ Indications for Use

AtriCure's cryoICE cryoSPHERE cryoablation probes are sterile, single use devices intended for use blocking pain by temporarily ablating peripheral nerves.

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V. Comparison of Technological Characteristics (CRYO2 K180138)

- The devices include 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
  - Did not raise any new issues of safety

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

	CRYO2 (Predicate)	CRYOS (Subject)
Market Product Name	cryoICE cryoablation probe	cryoICE cryoSPHERE cryoablation probe
510(k) Number	K180138	Subject of this Submission
Intended Use	AtriCure's cryoICE cryo-ablation 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 probe is also intended for use in blocking pain by temporarily ablating peripheral nerves.	AtriCure's cryoICE cryoSPHERE cryoablation probes are sterile, single use devices intended for use blocking pain by temporarily ablating peripheral nerves.
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 Construction: smooth malleable cylindrical linear probe Diameter: 4 mm Length: 10cm	Material: aluminum alloy Construction: smooth spherical ball welded to a malleable cylindrical aluminum shaft. Diameter: ball - 8mm; aluminum shaft – 5mm Length: reference the "end-effector" length
End-effector Length – Shaft and Cryotip	28 cm	28cm (CRYOS) 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

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VI. Performance Data

The following bench testing was conducted for design and performance elements deemed appropriate to demonstrate equivalence to the previously cleared CRYO2 device. The CRYOS device met the predetermined acceptance criteria ensuring substantial equivalence to the previously cleared CRYO2 device. No new safety or performance issues were raising during testing.

Non-clinical Bench Testing:

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

VII. Conclusions

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