DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 22, 2016

Atricure, Inc
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K152337
Trade/Device Name: cryoFORM cryoICE Cryoablation Probe
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH, OCL
Dated: March 7, 2016
Received: March 8, 2016

Dear Mark Job:

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. 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.

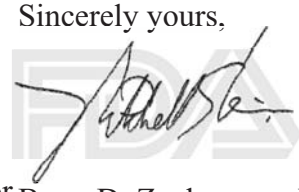
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152337

Device Name
AtriCure® cryoICE™ cryoFORM cryo-ablation probe (CRYOF)

Indications for Use *(Describe)*
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 the electrical conduction pathway.

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."

510(k) Summary

I. Submitter

Manufacturer: AtriCure, Inc.
6217 Centre Park Dr.
West Chester, OH 45069
P: 513-755-4100
F: 513-755-4108

Contact Person: Jonathan McElwee, RAC
Senior Regulatory Specialist

Alternate Contact: Jim Taufen
Director of Regulatory Affairs

Date Prepared: 08/11/2015

II. Device

Name of Device: AtriCure® cryoICE™ cryoFORM™ cryoablation probe (CRYOF)

Common Name: Cryosurgical probe

Classification Name: Unit, Cryosurgical, Accessories
Surgical, General and Plastic Surgery, 878.4350

Surgical Device, For Cutting, Coagulation, And/Or Ablation Of Tissue, Including Cardiac Tissue, 878.4400

Regulatory Class: Class II

Product Code: GEH and OCL

III. Predicate Device

The primary predicate device, AtriCure cryoICE cryoablation probe (CRYO2), was cleared via 510(k) K142203 on December 8, 2014 under the Product Code GEH.

A secondary predicate device, Heartport Maze System: Cryoprobe Set, was cleared via 510(k) K970496 on May 9, 1997 under the Product Code OCL.

The predicate devices have not been subject to a design-related recall.

No reference devices were used in this submission.

IV. Device Description

AtriCure's cryoICE cryoFORM cryoablation probe (CRYOF) is a sterile, single use, cryosurgical device to be used in conjunction with the AtriCure Cryo Module [K111042, K112072, K121507, K140058, K142203] to freeze target tissue, blocking the electrical conduction pathways by creating an inflammatory response or cryonecrosis.

V. Indications For Use

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 the electrical conduction pathway.

VI. Comparison Of Technological Characteristics With The Predicate Device

- Same intended use and;
- Same operating principle
- Same fundamental scientific technology
- Used with the same cryo module unit
- The basic design of the proposed device and the previously cleared devices are the same. The devices are disposable, single-use instruments including a cryotip end effector, shaft, handle, thermocouple, inlet tube, and exhaust tube.
- The modifications to the proposed cryoICE probe are designed to provide increased options for surgeons based on patient body habitus and surgeon preference. Major modifications compared to the predicate include a more malleable corrugated stainless steel cryotip, more flexible tubing, and a different colored rigid shaft.

The AtriCure cryoFORM cryoICE cryoablation probe has the following similarities to the technological characteristics of the previously cleared predicate AtriCure cryoICE cryoablation probe K142203:

Feature	AtriCure cryoICE™ cryoablation probe (CRYO2) (K142203)	AtriCure cryoFORM cryoICE cryoablation probe (CRYOF) (Proposed Device)
Manufacturer	AtriCure, Inc.	Same
Proprietary Name	AtriCure cryoICE cryoablation probe	AtriCure cryoFORM cryoICE cryoablation probe
Product Code(s)	CRYO2	CRYOF
510k Reference	K142203	Subject of this submission
Intended Use	AtriCure's 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 probe is also intended for use in blocking pain by temporarily ablating peripheral nerves.	AtriCure's cryoFORM 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.
Device Description	The probe is comprised of a cryotip end effector, shaft, handle, thermocouple, inlet tube, and exhaust tube.	The probe is comprised of a cryotip end effector, shaft, handle, thermocouple, inlet tube, and exhaust tube.
Cryotip	Material: Aluminum alloy Construction: Smooth malleable probe	Material: Stainless Steel Construction: Corrugated malleable probe
Method of Cryogen Activation	Switch on AtriCure Cryo Module	Switch on AtriCure Cryo Module
Cryogen	Nitrous Oxide	Nitrous Oxide
Packaging	Sterile - single use, disposable device	Sterile - single use, disposable device
Biocompatibility	Biocompatible patient contacting materials	Biocompatible patient contacting materials
Sterilization	Gamma Irradiation	Gamma Irradiation

VII. Performance Data

The modified cryoICE cryoablation probe was successfully tested on an animal model to confirm the modifications do not affect the ability to successfully ablate cardiac tissue.

Thigh Prep Study Testing
AtriCure conducted a GLP animal study to evaluate the performance of the CRYOF device in a live porcine thigh tissue model and to compare performance to the predicate CRYO2 device. 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.

Additional testing per 21 CFR 820.30 and AtriCure's Quality System was performed to verify the modified cryoablation probe's conformance to design controls and specification. Testing determined that the modified cryoablation probe conformed to design controls and product specifications.

Non-clinical Bench Testing
- Mechanical Testing
- Reliability Testing
- Cryogen Performance Testing
- Bench Testing on an Animal Model
- Sterilization Validation
- LAL Testing
- Accelerated Aging Testing
- Transit Testing

Biocompatibility Testing
The biocompatibility evaluation for the cryoICE cryoablation probe was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process" as recognized by FDA. The battery of testing included the following tests:
- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Material Mediated Pyrogenicity

The cryoICE cryoFORM cryoablation probe is considered an "External Communicating Device," contact for "Tissue/Bone" and contact duration for "under 24 hours."

VIII. Conclusions

The proposed cryoICE cryoFORM cryoablation probe (CRYOF) is substantially equivalent to the previously cleared cryoICE cryoablation probe (CRYO2) as there is no change to intended use, the operating principle, or the basic design of the cryoablation probe. The totality of evidence supports a decision that the modifications to the cryoablation probe have been successfully evaluated for its intended use.