



Food and Drug Administration
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October 29, 2014

AtriCure, Inc.
Jonathan McElwee
Regulatory Engineer
6217 Center Park Drive
West Chester, Ohio 45069

Re: K142441
Trade/Device Name: CryoICE Cryo-Ablation Probe
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: October 20, 2014
Received: October 21, 2014

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. 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,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K142441

Device Name: AtriCure® cryoICE™ cryo-ablation probe (CRYO3)

Indications for Use:

AtriCure’s cryoICE cryo-ablation probe is a sterile, single use device intended for use in the cryosurgical treatment of cardiac arrhythmias. The probe freezes target tissues, creating an inflammatory response (cryonecrosis) that blocks the electrical conduction pathway.

Prescription Use **X**
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

I. Submitter

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

Contact Person: Jonathan McElwee, RAC
Regulatory Engineer

Alternate Contact: Dennis Hong, JD RAC
Sr. Director of Regulatory Affairs

Date Prepared: 08/29/2014

II. Device

Name of Device: AtriCure® cryoICE™ cryo-ablation probe
(CRYO3)

Common Name: Cryosurgical probe

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

Regulatory Class: Class II

Product Code: GEH

III. Predicate Device

The device proposed for modification in this submission is the AtriCure Cryo1 cryo-ablation probe cleared via 510(k) K082074 on March 2, 2009.

The predicate device has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. Device Description

AtriCure's cryoICE cryo-ablation probe (CRYO3) is a sterile, single use, cryosurgical device to be used in conjunction with the AtriCure Cryo Module [K111042, K112072, K121507, K140058] or ACC2 Cardiac Cryosurgical System [K811390] to freeze target tissue, blocking the electrical conduction pathways by creating an inflammatory response or cryonecrosis.

V. Indications For Use

AtriCure's cryoICE™ cryo-ablation probe is a sterile, single use device intended for use in the cryosurgical treatment of cardiac arrhythmias. The PROBE freezes 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 units
- 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 aluminum alloy cryotip and a different colored rigid shaft.

VII. Performance Data

The modified cryoICE cryo-ablation probe was tested on an animal model to confirm the modifications do not affect the ability to successfully ablate cardiac tissue. Additional testing per 21 CFR 820.30 and AtriCure's Quality System was performed to verify the modified cryo-ablation probe's conformance to design controls and specification. Testing determined that the modified cryo-ablation probe conformed to design controls and product specifications.

Non-clinical Bench Testing

- Mechanical Testing
- Reliability Testing
- Cryogen Performance Testing
- Validation Testing on an Animal Model

Biocompatibility Testing

The biocompatibility evaluation for the cryoICE cryo-ablation 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
- Hemolysis

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

VIII. Conclusions

The modified cryoICE cryo-ablation probe is equivalent to the previously cleared Cryo1 cryo-ablation probe as there is no change to intended use, the operating principle, or the basic design of the cryo-ablation probe. The modifications to the cryo-ablation probe do not affect the ability of the probe to successfully ablate cardiac tissue.