



February 15, 2018

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

Re: K180137

Trade/Device Name: AtriCure cryoICE cryo-ablation probe (CRYO3), AtriCure cryoICE cryoFORM cryo-ablation probe (CRYOF)

Regulation Number: 21 CFR 878.4350

Regulation Name: Cryosurgical Unit And Accessories

Regulatory Class: Class II

Product Code: GEH

Dated: January 15, 2018

Received: January 17, 2018

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. 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.

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.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, appearing to read "M. Zuckerman", is written over a large, light blue, semi-transparent "FDA" watermark.

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)

Subject of this Special 510(k) submission                      K180137

Device Name

AtriCure® cryoICE® cryo-ablation probe (CRYO3), and  
AtriCure® cryoICE® cryoFORM® cryo-ablation probe (CRYOF)

Indications for Use (Describe)

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.

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.

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## 510(k) Summary

### I. Submitter

Manufacturer: AtriCure, Inc.  
7555 Innovation Way  
Mason, Ohio 45040  
P: 1 (513) 755-4100

Contact Person: Melissa Smallwood  
Regulatory Affairs Specialist

Alternate Contact: Jonathan McElwee  
Manager, Regulatory Affairs

Date Prepared: 01/12/2018

### II. Device

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

Common Name: Cryosurgical Probe

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

Regulatory Class: Class II

Product Code: GEH

### III. Predicate Device

The device proposed for modification in this submission is the AtriCure cryoICE cryo-ablation probe cleared via K142441 on October 29, 2014, and the AtriCure cryoICE cryoFORM cryo-ablation probe cleared via K152337 on March 22, 2016.

The following reference device was also used in this submission:

- K142203 AtriCure cryoICE cryoablation probe

### IV. Device Description

The cryosurgical handpieces, or cryo-ablation probes, utilized in the AtriCure Cryosurgical System are hand held, single use, cryosurgical instruments intended for the cryosurgical treatment of cardiac arrhythmias during cardiac surgery. The cryosurgical handpieces utilize a high-pressure cryogen (nitrous oxide, N<sub>2</sub>O) to freeze target tissues, creating an inflammatory response, and ultimately, cryonecrosis. The cryosurgical handpieces provide 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 cryoprobes via the AtriCure Cryo Module, rapid cooling is achieved via the Joule-Thompson effect. The end effector, or cryotip, of the probes are 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 or stainless-steel 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).

## V. Indications For 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.

## VI. Comparison Of Technological Characteristics With The Predicate Device

Minor modifications were made to the non-patient contacting tube-sets of the cryoICE cryo-ablation probes. The packaging was modified to align with AtriCure's current product lines.

- The devices have the same intended use, and;
- No changes were made in operating principle, or specifications of performance, and;
- Both the previously cleared and proposed CRYO3, and CRYOF probes use the same patient contacting materials, and;
- The results of the verification and validation testing:
  - Demonstrated equivalency in performance
  - Did not raise any new issues of safety

The modifications to the proposed AtriCure cryoICE cryo-ablation probe are intended to 1.) align components with the previously cleared cryoICE cryoFORM cryo-ablation probe, and 2.) align the device packaging with AtriCure's commercial product lines.

## VII. Performance Data

### Non-clinical Bench Testing

- Mechanical Reliability
- Transit
- Shelf-life
- Cryogen Performance/Thermal Insulation

## VIII. Conclusions

The modified AtriCure cryoICE cryo-ablation probe (CRYO3) and AtriCure cryoICE cryoFORM cryo-ablation probe are equivalent to the previously cleared CRYO3, and CRYOF probes as there is no change to intended use, operating principals, or function of the devices.