



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

AtriCure Inc.,
Jonathan McElwee
Regulatory Engineer
6217 Centre Park Dr.
West Chester, OH 45069

Re: K142203
Trade/Device Name: AtriCure Cryosurgical System – AtriCure Cryo Module (ACM) and
AtriCure cryoICE cryo-ablation probes (CRY02)
Regulation Number: 21 CFR 882.4250
Regulation Name: Cryogenic Surgical
Regulatory Class: Class II
Product Code: GXH, GEH
Dated: October 30, 2014
Received: October 31, 2014

Dear Mr. Jonathan McElwee:

This letter corrects our substantially equivalent letter of November 25, 2014.

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

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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" (21CFR 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,



**Bram D.
Zuckerman -S**

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) K142203

Device Name: AtriCure Cryosurgical System, comprising:

- a) AtriCure Cryo Module (ACM)
- b) AtriCure cryoICE™ cryo-ablation probes (CRYO2)

Indications for Use:

AtriCure Cryo Module Indication for Use Statement: The AtriCure Cryo Module is a non-sterile, reusable device which delivers cryogenic energy, namely nitrous oxide, to AtriCure's cryo-ablation probes.

cryoICE™ Indication for Use Statement: 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.

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
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Contact Person: Jonathan McElwee, RAC
Regulatory Engineer

Alternate Contact: Dennis Hong, JD, RAC
Senior Director, Regulatory Affairs

Date Prepared: 08/8/2014

II. Device

Name of Device: AtriCure Cryosurgical System, comprising:
a) AtriCure Cryo Module (ACM)
b) AtriCure cryoICE™ cryo-ablation probes (CRYO2)

Common Name: Cryosurgical probe
Cryo Surgical Unit and Accessories
Cryoanalgesia System

Classification Name: Surgical, General and Plastic Surgery, 21 CFR 878.4350
Cryogenic Surgical Device, 21 CFR 882.4250

Regulatory Class: Class II

Product Code: GEH and GXH

III. Predicate Devices

AtriCure cryo-ablation probe K082074
AtriCure Cryo Module System K111042, K112072, K121507, and K140058
Cryomedical Instruments LTD. CryoStar™ System K031482

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

No reference devices were used in this submission.

IV. Device Description

The AtriCure Cryo Module (ACM) unit is a non-sterile reusable electro-mechanical and pneumatic cryogenic surgical system that delivers a cryogenic energy source, namely Nitrous Oxide, to the AtriCure cryo-ablation probes. The AtriCure's cryoICE cryo-ablation probe (CRYO2) is a sterile, single use, cryosurgical device to be used in conjunction with the AtriCure Cryo Module or ACC2 Cardiac Cryosurgical System [K811390] to freeze target tissue, blocking the electrical conduction pathways by creating an inflammatory response or cryonecrosis. The cryoICE™ probe can also be used to temporarily ablate peripheral nerves.

Model numbers:

AtriCure Cryo Module – ACM1

AtriCure cryoICE™ cryo-ablation probe – CRYO2

Materials:

All materials used in the manufacture of the AtriCure Cryosurgical System are safe and suitable for their intended use and suitable for their use with pressurized nitrous oxide. The ACM is not intended for patient contact. Testing has been previously conducted in accordance with ISO 10993-1 to ensure biocompatibility of all appropriate materials in the AtriCure cryoICE™ cryo-ablation probe (CRYO2).

V. Indications For Use

AtriCure Cryo Module Indication for Use Statement: The AtriCure Cryo Module is a non-sterile, reusable device which delivers cryogenic energy, namely nitrous oxide, to the AtriCure cryo-ablation probes.

cryoICE™ Indication for Use Statement: 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.

VI. Comparison Of Technological Characteristics With The Predicate Devices

When used for the intended use of "cryosurgical treatment of cardiac arrhythmias", the AtriCure Cryosurgical System has the following similarities to the technological characteristics of the previously cleared predicate AtriCure Cryo Module System (K082074, K111042, K112072, K121507, and K140058):

- Same intended use
- Same operating principle
- Same fundamental scientific technology
- Same cryo-ablation probes
- Same materials used
- Same module design
- Same electronic solenoid valves
- Same 3 year age shelf life of the cryo-ablation probes

When used for the intended use of “blocking pain by temporarily ablating the peripheral nerve”, the AtriCure Cryosurgical System has the following similarities to the technological characteristics of the previously cleared predicate CryoStar™ System K031482:

	CryoStar™ Predicate	AtriCure Device
Manufacturer	Cryomedical Instruments LTD. (now Kryo Science LTD)	AtriCure
Market Product Name	CryoStar™ System (Cryostar™ console, 1 & 2mm cryoprobe, convenience procedure kit for the probe placement)	AtriCure Cryosurgical System (ACM and cryoICE™ (CRYO2) cryo-ablation probe)
510(k) Number	K031482	Subject of this Submission
Intended Use	Cryoanalgesia device intended for use in blocking pain by temporarily ablating the peripheral nerves.	The AtriCure Cryosurgical System is intended for use in blocking pain by temporarily ablating the peripheral nerves.
Target Population	Adults	Adults
Operating Principle	Joule-Thompson Effect	Joule-Thompson Effect
Technology	The system consists of a range of cryoprobes that are used for freezing nerves to block pain by temporary ablation. A console is used to house and control the supply of gas to the cryoprobe and to provide an electrical nerve location device.	The system consists of cryoprobes that are used for freezing target tissue to treat cardiac arrhythmias and for freezing nerves to block pain by temporary ablation. A console is used to control the supply of gas to the cryoprobe.
Energy Used	Nitrous Oxide	Nitrous Oxide
Operating Temperature	-40C to -70C	-50°C to 70°C
Peripheral Nerve Stimulation	Included as part of the system	Not included in the system.
Human Factors	Hand-held device containing cryogen with footswitch.	Hand-held device containing cryogen with activation button on console or footswitch.
Gas Purge System	Automatic	Automatic
Freeze Timer	Manual or automatic	Manual or automatic
Patient Contacting Materials	Hemispherical and trocar-tip stainless steel 1mm & 2mm diameter cryoprobe	Closed-tip aluminum 4mm cryoprobe
Cryotip	Rigid	Malleable
Biocompatibility	Biocompatible patient contacting materials.	Biocompatible patient contacting materials.
Probe Packaging	Non-Sterile – Reusable device	Sterile – Single Use disposable device
Sterilization	Steam Autoclave; EtO; or Sterrad	Gamma Irradiation
Power Source	Mains Powered	Mains Powered

VII. Performance Data

Appropriate product testing was conducted to evaluate conformance to product specification and substantial equivalence to predicate devices. Design verification and validation, software validation, and electrical safety testing were completed to show that the AtriCure Cryosurgical System is substantially equivalent and in conformance with international standards and device specifications.

Non-clinical Bench Testing

Name	Description	Results
CRYO2 Comparison testing to Predicate Device	Bench testing	Passed
CRYO2 Mechanical Reliability	Bench testing	Passed
CRYO2 Performance testing	Bench testing	Passed
CRYO2 Acute Animal Verification Lab	Bench testing	Passed
CRYO2 ASTM Testing	Bench testing	Passed
Evaluation Against Similar Product	Bench testing	Passed
ACM Software Validation	Software testing	Passed
ACM Display Board Verification	Bench testing	Passed
ACM Controller Board Verification	Bench testing	Passed
Handpiece Connector Board Verification	Bench testing	Passed
ACM Power Board Verification	Bench testing	Passed
ACM Reliability Testing	Bench testing	Passed
ACM Simulated Use	Bench testing	Passed

VIII. Conclusions

When used for the intended use of “cryosurgical treatment of cardiac arrhythmias”, the proposed AtriCure Cryosurgical System is equivalent to the previously cleared AtriCure Cryo Module System, as the intended use, overall function, and materials used are the same.

When used for the intended use of “blocking pain by temporarily ablating the peripheral nerve”, the proposed AtriCure Cryosurgical System is equivalent to the previously cleared CryoStar™ System, as the intended use, basic overall function, and materials used are substantially equivalent.