

**ATRICURE Cryo Module System 510(k) SUMMARY**

JAN 24 2014

**General Information**

Date Compiled	December 6, 2013
Classification	Class II
Product Code	GEH, 21 CFR 878.4350
Trade Name	AtriCure Cryo Module System (ACM, Cryo1, and cryoICE)
Manufacturer	AtriCure, Inc 6217 Centre Park Drive West Chester, OH 45069 (513) 755-4100 (513) 644-1354 (fax)
Contact	Karl Dahlquist VP of Quality Systems, Regulatory Affairs, and Legal

**Indications for Use**

The AtriCure Cryo Module System is intended for use in the cryosurgical treatment of cardiac arrhythmias. The System consists of the AtriCure Cryo Module (ACM)—a non-sterile, reusable device—used with the Cryo1 cryo-ablation probe—a sterile, single use device—and/or the cryoICE cryo-ablation probe—a sterile, single use device.

**Cleared Device**

The device proposed for modification in this submission is the AtriCure Cryo Module System (ACM, Cryo1, and cryoICE) (K111042, K112072, and K121507).

**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 an AtriCure cryo-ablation probe to create lines of ablation through cardiac tissue for the treatment of cardiac arrhythmias. The AtriCure cryo-ablation probe (Cryo1 or cryoICE) is a sterile, single use, cryosurgical device to be used in conjunction with the AtriCure Cryo Module or AtriCure ACC2 (Frigitronics CCS-200) Cardiac Cryosurgical System [K811390] to freeze target tissue, blocking the electrical conduction pathways by creating an inflammatory response or cryonecrosis.

**Materials**

All materials used in the manufacture of the AtriCure Cryo Module 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 cryo-ablation probes (Cryo1 and cryoICE).

**Testing**

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 ACM is substantially equivalent and in conformance international standards and device specifications. The standards and FDA Guidance used to determine substantial equivalence include, but are not limited to:

- UL 60601-1 1<sup>st</sup> Ed.: Medical Electrical Equipment, Part 1: General Requirements for Safety. (2003)
- EN
- IEC 60601-1-2: Collateral Standard- Electromagnetic Compatibility – Req. & Tests (2007)
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (Issued May 11, 2005)

**Summary of Technological Characteristics**

The modified AtriCure Cryo Module System has the following similarities to the technological characteristics of the previously cleared predicate AtriCure Cryo Module System (K111042, K112072, and K121507):

- Same intended use
- Same operating principle
- Same fundamental scientific technology
- Same cryo-ablation probes
- Same materials used
- Same module design
- Same electronic solenoid valves

**Summary of Substantial Equivalence**

The modified AtriCure *Cryo Module* System proposed in this submission is considered substantially equivalent to the AtriCure Cryo Module System cleared via K111042, K112072, and K121507. The indications for use, basic overall function, and materials used are substantially equivalent.



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

January 24, 2014

Atricure Inc.  
% Mr. Mark Job  
Third Party Reviewer  
Regulatory Technology Service LLC  
1394 25<sup>th</sup> Street NW  
Buffalo, MN 55313

Re: K140058  
Trade/Device Name: Atricure Cryo Module System  
Regulation Number: 21 CFR 879.4350  
Regulation Name: Cryosurgical Unit and Accessories  
Regulatory Class: Class II  
Product Code: GEH  
Dated: January 8, 2014  
Received: January 10, 2014

Dear Mr. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Owen D. Paris -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)

K140058

Device Name

AtriCure Cryo Module System (ACM, Cryo1, and cryoICE)

Indications for Use (Describe)

The AtriCure Cryo Module System is intended for use in the cryosurgical treatment of cardiac arrhythmias. The System consists of the AtriCure Cryo Module (ACM)—a non-sterile, reusable device—used with the Cryo1 cryo-ablation probe—a sterile, single use device—and/or the cryoICE cryo-ablation probe—a sterile, single use device.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Digitally signed by Owen  
P. Farris  
Date: 2014.01.24  
14:34:14+05'00'