JUL - 5 2007

510(k) Summary

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General Information

Classification	Device, Electrosurgical, Cutting and Coagulation and Accessories (21CFR878.440)
Trade Name	AtriCure Bipolar System
Manufacturer	AtriCure, Inc. 6033 Schumacher Park Drive West Chester, OH 45069
Contact	Elsa Abruzzo Vice President, Clinical and Regulatory Affairs

Intended Use

The AtriCure Bipolar (Transpolar) System is intended for the ablation of cardiac tissue during surgery.

Predicate Devices

The predicate devices for the AtriCure Bipolar System are the Atricure Bipolar System (K020919), the Medtronic Cardioblate Pen (K013392), the Boston Scientific Cobra Cardiac Surgical Probe (K013873), the CryoCath SurgiFrost Cryosurgical Device with FrostByte Clamp (K040690), the AFx Microwave Ablation System (K003978) and the Epicor Medical Ultracinch Tissue Ablation Device (K040641).

Device Description

The Atricure Bipolar System is comprised of a bipolar clamping hand-piece with integral cable (Isolator™), and a re-useable generator, (Ablation and Sensing Unit, ASU).

Materials

All materials used in the manufacture of the AtriCure Bipolar System are suitable for this use and have been used in numerous previously cleared products. Testing was conducted in Accordance with ISO 10993-1 to ensure appropriate biocompatibility of all materials.

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Testing

Appropriate preclinical product testing was conducted to evaluate conformance to the product specification and demonstrate substantial equivalence to predicate devices. Clinical data demonstrating the device's acute safety and ability to create lines of electrical conduction block in the heart as assessed intraoperatively were also provided in support of this submission.

Summary of Substantial Equivalence

The AtriCure Bipolar System is equivalent to the predicate products. The indications for use, basic overall function, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

Atricure, Inc.
c/o Ms. Elsa C. Abruzzo
Vice President of Regulatory and Clinical Affairs
6033 Schumacher Park Dr.
West Chester, OH 45069

Re: K043579
Trade/Device Name: Atricure Bipolar System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II (two)
Product Code: OCL
Dated: March 30, 2007
Received: April 6, 2007

Dear Ms. Abruzzo:

This letter corrects our substantially equivalent letter of July 5, 2007.

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 (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.

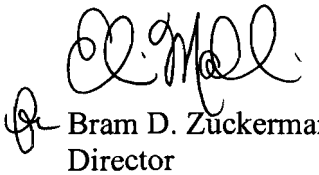
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); 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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

Indications for Use

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510(k) Number (if known) K043579

Device Name: AtriCure Bipolar (Transpolar) System

Indications for Use:

The AtriCure Bipolar (Transpolar) System is intended for the ablation of cardiac tissue during surgery.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CRF 801 Subpart D) (21 CRF 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M.S. Hillebrenner for Bram Zuckerman

(Division Sign-Off)
Division of Cardiovascular Devices

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