K110117
pg. 1 of 2

APR - 8 2011

ATRICURE BIPOLAR SYSTEM 510(k) SUMMARY

General Information

Date Compiled	January 13, 2011
Classification	Class II (Surgical device, for ablation of cardiac tissue)
Product Code	OCL
Trade Name	AtriCure Bipolar System
Manufacturer	AtriCure, Inc 6217 Centre Park Drive West Chester, OH 45069
Contact	James L. Lucky VP of Quality Assurance and Regulatory Affairs (513) 755-5754

Indications for Use

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

Predicate Devices

The predicate devices for the AtriCure Bipolar System include the AtriCure Bipolar System (K020919), the AtriCure Transpolar System (K052893), the AtriCure Ablation System (K063630), the AtriCure Bipolar System (K043579), and the AtriCure Bipolar System including Isolator Synergy Dual Electrode Clamps (K101174).

Device Description

The AtriCure Bipolar System includes a hand held, single use, bipolar radiofrequency (RF) surgical instrument (Isolator Transpolar Clamps or Isolator Synergy Clamps) intended for the ablation of cardiac tissue and an accessory instrument guide (Glidepath™ Tape). The clamp handpieces are connected via an integral cable to the AtriCure re-usable Ablation and Sensing Unit (ASU2) and an Isolator Switch Matrix (ASB3) console. This 510(k) specifically seeks approval of a modification to AtriCure Bipolar System to include the Synergy Access Clamp. The only changes incorporated in the Synergy Access Clamp is the addition of mechanical features allowing for more surgical options due to surgeon preference and varying patient body habitus including a hinged jaw assembly allowing jaw position to be locked at the preferred angle and a passive proximal jaw allowing wider jaw aperture. There are no changes being made to the current Isolator Synergy Clamps, the Ablation and Sensing Unit or the Isolator Switch Matrix as part of this 510(k).

Materials

All materials used in the manufacture of the AtriCure Bipolar System are suitable for their intended 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.

Testing

Appropriate product testing was conducted to evaluate conformance to product specification and substantial equivalence to predicate devices. In-vitro and in-vivo testing demonstrated that the proposed AtriCure Bipolar System is able to ablate cardiac tissue as safely and effectively as the previously approved AtriCure Bipolar System. Additionally, complete design verification testing was performed including but not limited to mechanical testing, electrical safety and compliance testing, reliability testing per the device design life, transit, and aging to ensure the design outputs meets the design input specifications.

Summary of Substantial Equivalence

The AtriCure Bipolar System is equivalent to the predicate products as shown through the device descriptions and provided performance data. The indications for use, basic overall function, and materials used are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AtriCure, Inc.
C/O James Lucky, RAC
6217 Centre Park Drive
West Chester, OH 45069

APR - 8 2011

Re: K110117
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
Product Code: OCL
Dated: January 13, 2011
Received: January 11, 2011

Dear Mr. Lucky:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,

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) K110117

Device Name: AtriCure Bipolar System

Indications for Use:

The AtriCure Bipolar System is intended for the ablation of caridac 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)

(Division Sign-Off)
for Division of Cardiovascular Devices

510(k) Number K110117