510(k) Summary

NOV 1 2 2010

General Information

Date Compiled	April 26, 2010
Classification	Class II, 21 CFR § 878.4400 Product code OCL
Trade Name	AtriCure Bipolar System including Isolator Synergy Dual Electrode clamps
Submitter	AtriCure, Inc. 6217 Centre Park Drive West Chester, Ohio 45069 Tel: 513-755-4100 Fax: 513-644-1354
Contact	James L. Lucky VP of Quality Assurance and Regulatory Affairs Tel: 513-755-5754 Fax: 513-644-1354

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

Predicate Devices

AtriCure Bipolar System (including Isolator Single Electrode clamps) Manufactured by AtriCure, Inc.	K043579
AtriCure Bipolar System (including Isolator Synergy Dual Electrode clamps) Manufactured by AtriCure, Inc.	K063630

Device Description
The AtriCure Bipolar System includes hand held, single use, dual electrode, bipolar radiofrequency (RF) surgical instruments (Isolator Synergy™ Clamps) intended for the ablation of cardiac tissue. The clamp handpieces are connected via an integral cable to the AtriCure re-useable Ablation and Sensing Unit (ASU2) and the accessory Isolator Switch Matrix (ASB3).

Materials
All materials used in the manufacture of the AtriCure Bipolar System including Isolator Synergy Dual Electrode clamps are suitable for this use and are identical to the predicate product.

Testing
All appropriate testing has been performed and all components, subassemblies, and/or full devices met the required specifications for the completed tests.

Pre-Clinical: Chronic and acute animal studies were performed to show equivalency to the predicate device and for verification and validation of design.

Clinical: Clinical study data has proven lesion transmurality using the AtriCure Bipolar System including Isolator Synergy Dual Electrode clamps via assessment of pulmonary vein isolation.

Summary of Substantial Equivalence

AtriCure, Inc. believes the AtriCure Bipolar System including Isolator Synergy Dual Electrode Clamps is substantially equivalent to the predicate product. The intended use, method of operation, methods of construction and materials used, are either identical or substantially equivalent to existing legally marketed predicate product.

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

NOV 1 2 2010

Re: K101174
Trade/Device Name: AtriCure Bipolar System including Isolator Synergy Dual Electrode Clamps, Models OSL2, OLL2, EMR2, EML2
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: OCL
Dated: November 3, 2010
Received: November 4, 2010

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

4. Indications for Use Statement

NOV 1 2 2010

510(k) Number (if known): This application

Device Name: AtriCure Bipolar System including Isolator Synergy Dual Electrode Clamps

Indications for Use: The AtriCure Bipolar System including Isolator Synergy Dual Electrode Clamps is intended for the ablation of cardiac tissue during surgery.

Prescription Use _X_ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (Per 21 CFR 801 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)
Division of Cardiovascular Devices

510(k) Number K101174