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Special 510(k) – AtriCure Bipolar System

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510(k) SUMMARY
ATRICURE COAGULATION SYSTEM
510(k) NOTIFICATION KXXXXX

K 020 919

General Information

Manufacturer:

AtriCure Incorporated
6033 Schumacher Park Drive
West Chester, OH 45069-3863
(513) 755-4100
Fax (513) 755-4108
Est. Reg. No. 3003502

Contact Person:

Mark L. Friedman, Ph.D.
Vice President of Quality Assurance & Regulatory Affairs
AtriCure Incorporated

Date Prepared:

[to be added after 510(k) process]

Device Description

Classification:

Class II

Trade Name:

AtriCure Bipolar System

Generic/Common Name:

Electrosurgical cutting and coagulation device and Accessories 21CFR 878.4400

Predicate Devices

1. AtriCure Inc. AtriCure Bipolar Coagulation System K011722
2. AtriCure Inc. AtriCure Bipolar Coagulation System K010122

Indication For Use Statement

The AtriCure Bipolar Coagulation System is intended to ablate and coagulate soft tissue during General, ENT, Thoracic, Gynecology, and Urology surgical procedures.

Product Description

The system is comprised of the Bipolar Handpiece (single patient use) with integral cable and the re-usable Ablation and Sensing Unit (ASU).

The ASU is a portable reusable device that produces and delivers RF bipolar energy near the AM frequency band to coagulate and ablate biological tissue. The device consists of a RF PCB (printed circuit board), microprocessor PCB, measurement PCB, display PCB, AC power supply, power entry module, volume control, footswitch Interface, and Handpiece interface. Front panel indicators include an LED temperature display, a LCD graphics conductance display, and LED lamps indicating power on, fault condition, ready state, RF on, and conductance state. The ASU limits the amount of voltage, current and time at which power is output to the Handpiece. Upon reaching a threshold conductance, the ASU will light a visual indicator and sound an audible tone signaling that the conditions for a complete ablation have been satisfied. A footswitch is included in the Ablation System to activate RF energy delivery.

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Special 510(k) – AtriCure Bipolar System

The system delivers Bipolar RF energy to tissue that is clamped between the Handpiece jaws. Pressing of the footswitch initiates the RF energy output. RF energy output is terminated by releasing the footswitch or upon expiration of the RF backup timer.

The Handpiece connects to the ASU and utilizes Bipolar RF energy to ablate tissue that is clamped between the instrument jaws. The Handpiece includes a set of jaws that are capable of grasping tissue up to 10mm in thickness. Each jaw is comprised of an electrode with surrounding insulators and imbedded temperature-sensing element allowing for the transfer of energy to tissue and the monitoring of temperature rise by the tissue. The handle includes a lever that applies a controlled force to the tissue in the jaws. At a predetermined force the jaws latch. A trigger is provided to release the latch at the end of the ablation.

The AtriCure Bipolar System meets the following performance industrial/international standards.

ANSI/AAMI HF 18	Electrosurgical Devices
ISO 10993/EN 30993	Biological Evaluation of Medical Devices
ISO 11607	Packaging for Terminally Sterilized Medical Devices
ISO 11135	Medical Devices, Validation and Routine Control of Ethylene Oxide Sterilization
IEC/EN 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC/EN 60601-1-1	Medical Electrical Equipment - Collateral Standard: Safety Requirements for Medical Device Systems
IEC/EN 60601-1-2	Medical Electrical Equipment - Part 1: General Requirements for Safety 2: Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC/EN 60601-2-2	Medical Electrical Equipment - Part 2-2: Particular Requirements for the Safety of High Frequency Surgical Equipment
IEC/EN 60601-1-4	Medical Electrical Equipment - Part 1-4: General Requirements for safety – Collateral Standard: Programmable Electrical Medical Systems
UL 2601-1	Standard for Safety: Medical Electrical Equipment

Summary

As contained in this 510(k) summary, the AtriCure Bipolar System is substantially equivalent to the predicate devices identified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mark L. Friedman, Ph.D.
Vice President of Quality Assurance
and Regulatory Affairs
AtriCure, Inc.
6033 Schumacher Park Drive
West Chester, Ohio 45069-3863

Re: K020919
Trade/Device Name: AtriCure Bipolar System
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 19, 2002
Received: March 21, 2002

Dear Dr. Friedman:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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 begin 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (~~if known~~): K020919

Device Name: AtriCure Bipolar System

Indications For Use:

"The AtriCure Bipolar System is intended to ablate and coagulate soft tissue during General, ENT, Thoracic, Gynecology and Urology surgical procedures."

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020919

(Optional Format 3-10-98)