K113475

MAR 2 0 2012

SECTION 5: 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Information:

Category	Comments
Sponsor:	ESTECH, Inc. 2603 Camino Ramon Suite 100 San Ramon, CA 94583 Tel: 925-543-2110
Correspondent:	Tamer Ibrahim Vice President ESTECH, Inc
Contact Information:	Tel: 925-543-2110 Fax: 925-866-7117
Device Common Name:	Surgical Device, For Ablation of Cardiac Tissue
Device Proprietary Name:	Estech COBRA Adhere XL 2
Device Classification:	Class II, OCL (21 CFR 878.4400)

Predicate Device Information:

Predicate Devices:	Estech COBRA Adhere XL (K051749) Estech COBRA Bipolar Recording Electrode (K051749)
Predicate Device Manufacturers:	Endoscopic Technologies, Inc (dba Estech)
Predicate Device Common Name:	Surgical Device, For Ablation of Cardiac Tissue
Predicate Device Classification:	21 CFR 878.4400
Predicate Device Classification Number:	Class II, OCL

Predicate Device Information:

Predicate Devices:	Multifunctional Linear Pen (K100501)
Predicate Device Manufacturers:	AtriCure, Inc.
Predicate Device Common Name:	Surgical Device, For Ablation of Cardiac Tissue
Predicate Device Classification:	21 CFR 878.4400
Predicate Device Classification Number:	Class II, OCL

b. Date Summary Prepared

21 November 2011 (Updated 22Feb2012)

c. Description of Device

The Estech COBRA Adhere XL 2 is a sterile, single use device intended for the ablation of cardiac tissue. It is designed to deliver RF energy to the target tissue via electrodes in the device when connected to the COBRA Electrosurgical Unit (ESU).

When the COBRA Adhere XL 2 is connected to an auxiliary temporary external pacemaker or recording device it can be used to provide temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery. The COBRA Adhere XL 2 must be disconnected from the ESU and connected to a temporary external pacemaker or recording device using the accessory cable provided.

d. Intended Use

The ESTECH COBRA Adhere XL 2 is intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy when connected directly to the Estech Electrosurgical unit (ESU).

The ESTECH COBRA Adhere XL 2 may be used for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external cardiac pacemaker or recording device.

e. Comparison to Predicate Device and Summary of Technological Characteristics

The ESTECH COBRA Adhere XL2 has the identical intended use and the same technological characteristics as the predicate devices. There have been no significant changes in technological characteristics with respect to the predicate device including materials, design, energy sources, or other features from the predicate device.

The COBRA Adhere XL 2 and predicate COBRA Adhere XL both comprise a vacuum stabilizer to maintain contact between the ablation probe and target tissue to be ablated. These vacuum stabilizers are flexible. The COBRA Adhere XL 2 further comprises an internal ribcage which gives the device the ability to conform into various shapes while providing the flexible suction stabilizer with structural integrity. The predicate COBRA Adhere XL has a vacuum stabilizer with a centrally located series of electrodes. The COBRA Adhere XL 2 has a vacuum stabilizer with a laterally located series of electrodes. As the vacuum stabilizers form a seal with the tissue, tissue is drawn into the device creating contact between tissue to be ablated and the electrodes.

Both the COBRA Adhere XL2 and predicate COBRA Adhere XL include temperature controlled RF energy. Predicate and application devices each have multiple active RF electrodes that are individually selectable and controlled by the ESU (generator). Predicate and application devices each have two (2) thermocouples attached to each active RF electrode. The COBRA Adhere XL2 also comprises an integrated indifferent electrode. With the COBRA Adhere XL 2, RF energy is directed from the active electrode to the integrated indifferent electrode or to the indifferent electrode placed on the patient's back, depending on the mode the device is in, as selected by the surgeon. The surgeon depresses the button on the device handle and the switch in the handle illuminates the mode and enables or disables the integrated indifferent electrode.

The COBRA Adhere XL 2 also provides transient pacing/sensing capability when connected to an auxiliary temporary external pacemaker or recording device like the predicate devices.

f. Summary of Nonclincal Testing

Appropriate testing, included in this application, has been performed to ensure that the ESTECH COBRA Adhere XL 2 meets its product specifications. The data demonstrates substantial equivalence to the predicate devices. In-vitro and in-vivo testing demonstrate that the COBRA Adhere XL2 is able to pace, sense, and stimulate and ablate cardiac tissue as safely and effectively as the predicate devices.

The patient contacting materials of the ESTECH COBRA Adhere XL 2 have been tested in accordance with ISO 10993: *Biological Evaluation of Medical Device* to ensure biocompatibility. The safety of the electrical design has been tested per and is in conformance with the pertinent sections of IEC 60601-1-2, (Second Edition, 2001), *Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests* and IEC 60601-2-2*: Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment.*

g. Summary of Substantial Equivalence

Estech concludes that the COBRA Adhere XL 2 is substantially equivalent to the predicate devices. The indications for use, basic overall function, materials, packaging, and sterilization methods are identical or substantially equivalent.

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

MAR 2 0 2012

Endoscopic Technologies, Inc.
C/O Mr. Tamer Ibrahim
2603 Camino Ramon, Suite 100
San Ramon, CA 94583

Re: K113475
Trade/Device Name: ESTECH Cobra Adhere XL 2
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: OCL
Dated: February 21, 2012
Received: February 22, 2012

Dear Mr. Ibrahim:

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,

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): K113475

Device Name: ESTECH Cobra Adhere XL 2

Indications For Use:

The ESTECH Cobra Adhere XL2 is intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy when connected directly to the Estech Electrosurgical Unit (ESU).

The ESTECH Cobra Adhere XL 2 may be used for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external pacemaker or recording device.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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
5 [illegible] Number K113475