Section 5: 510(k) Summary

JAN 6 2006

Device Information:

Category	Comments
Sponsor:	Estech 4135 Blackhawk Plaza Circle. Suite 150 Danville, CA 94506 Tel: 925-648-3500
Correspondent Contact Information:	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501 Tel: 510-337-0140 Fax: 510-337-0416
Device Common Name:	Electrosurgical Unit and Accessories
Device Classification & Code:	Class II, GEI (21 CFR 878.4400)
Device Classification Name:	Electrosurgical cutting and coagulation device and accessories
Device Proprietary Name:	Estech Cobra Cardiac Electrosurgical Unit Estech Cobra Cable

Predicate Device Information:

Predicate Devices:	Cobra Cardiac Electrosurgical System (K013873)
Predicate Device Manufacturers:	Boston Scientific
Predicate Device Common Name:	Electrosurgical Unit and Accessories
Predicate Device Classification:	21 CFR 878.4400
Predicate Device Classification & Code:	Class II, GEI

b. Date Summary Prepared

28 December 2005

c. Description of Device

The Estech Cobra Cardiac Electrosurgical Unit and Estech Cable comprise a system that is identical to the Boston Scientific Cobra Cardiac Electrosurgical System.

Both Systems are comprised of three components: the (radiofrequency) RF Probe, Electrosurgical Unit (ESU) and Instrument (Cobra) Cable. The Cable is an accessory to the ESU. The Estech RF Probes have been the subject of previous premarket notifications.

The ESU is a software controlled high frequency electronic instrument, provided with controls for set temperature, power limit, and number of active electrodes. The ESU delivers 460 kHz of RF energy to selected Probe electrodes. The ESU measures

temperatures from the Probe thermocouples and modulates the RF energy to keep all selected electrodes' temperatures essentially the same; it adjusts the power output to maintain the maximum temperature of all selected electrodes close to the set point. The ESU has readouts for temperature, time of energy delivery, and delivered power. Front panel connectors include connections for the Instrument Cable, and third party dispersive or indifferent (DIP) electrodes.

The Instrument Cable (Cobra Cable) connects the ESU to the RF Probe. It is supplied sterile to the user. The User can resterilize the Cable.

d. Intended Use

The Estech Cobra Cardiac Electrosurgical System is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery. The System can be used during general surgery to coagulate soft tissue. The System may also be used to coagulate blood and soft tissue to produce hemostasis.

e. Comparison to Predicate Device

The Estech Cobra Cardiac Electrosurgical Unit is identical in intended use, technology, design, materials, manufacture, and packaging to that of the Boston Scientific Cobra Cardiac Electrosurgical System (K013873). The Instrument/Cobra Cables are accessories to their respective ESU's. They, too, are identical to each other.

Estech concludes that the Estech Cobra Cardiac Electrosurgical Unit is substantially equivalent to the Boston Scientific ESU of the Cobra Cardiac Electrosurgical System.

f. Summary of Supporting Data

Supporting data is not necessary to support this submission since the Estech Cobra Cardiac ESU is identical to the predicate device, the Boston Scientific ESU of the Cobra Cardiac Electrosurgical System (K013873).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 1 2008

Estech, Endoscopic Technologies, Inc.
c/o Mr. Craig Coombs
Coombs Medical Device Consulting
1193 Sherman Street
Alameda, CA 94501

Re: K053326
Trade/Device Name: Estech Cobra Cardiac Electrosurgical Unit & Cable
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and Coagulation device and accessories.
Regulatory Class: II (two)
Product Code: OCL, GEI
Dated: November 30, 2005
Received: December 12, 2005

Dear Mr. Coombs:

This letter corrects our substantially equivalent letter of January 6, 2006.

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.

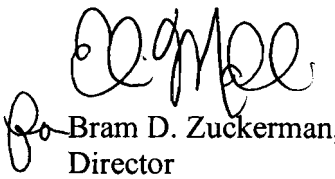
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Section 4: Indications for Use Statement

510(k) Number (if known): K053326

Device Name: Estech Cobra Cardiac Electrosurgical Unit; Cobra Cable

Indications For Use:

The Estech Cobra Cardiac Electrosurgical System is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery. The System can be used during general surgery to coagulate soft tissue. The System may also be used to coagulate blood and soft tissue to produce hemostasis.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bruemmer for MKM

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K053326