APR - 2 2003

510(K) SUMMARY

Category:	Comments
Sponsor:	Boston Scientific Corporation/EP Technologies, Inc. 2710 Orchard Parkway San Jose, CA 95134
Correspondent:	April Malmborg Specialist II, Regulatory Affairs 2710 Orchard Parkway San Jose, CA 95134
Contact Numbers:	Phone: 408.895.3637 Fax: 408.895.2202 Email: malmbora@bsci.com
Device Common Name	Electrosurgical Probe
Device Proprietary Name	Cobra Bipolar System
Device Classification	21 CFR 878.4400; Class II
Predicate Device	Cobra Electrosurgical Probe
Predicate Device Manufacturer(s)	BSC/ EP Technologies, Inc.
Predicate Device Proprietary Name(s)	Eelectrosurgical Probes
Predicate Device Classification(s)	21 CFR 8778.4400; Class II

Date Summary Was Prepared:

April 3, 2003

Description of the Device:

The Cobra Bipolar System device is comprised of two components; a reusable surgical clamp and an associated coagulating device BSC/ EP Technologies has named the Cobra Bipolar Insert. The Bipolar Insert is a sterile, single use device that transmits radiofrequency (RF) energy to coagulate soft tissues. The Bipolar Clamp will be used with a Cobra Electrosurgical Unit (ESU). The ESU delivers 460 kHz RF energy to selected Bipolar Clamp electrodes, modulates the RF energy to keep all selected Bipolar Clamp electrodes' temperatures essentially the same, and adjusts the power output to maintain the maximum temperature of all selected electrodes close to the set point.

Intended Use:

The Cobra Bipolar System (System) is intended for the coagulation of soft tissue during general surgery. The System may also be used to coagulate blood and soft tissue to produce hemostasis.

Comparison to Predicate Devices:

	Predicate Device	Modified Device
510(k) Reference	K013783	K023288
Intended Use	Coagulation of soft tissues	Same
Device Description	Electrosurgical Probe	Same
Single Use?	Yes	Same
EO Sterilized?	Yes	Same
Manufacturer	BSC/ EP Technologies	Same
Device Classification	Class II, GEI; 21 CFR §878.4400	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2003

Ms. April Malmborg
Regulatory Affairs Specialist II
Boston Scientific
2710 Orchard Parkway
San Jose, California 95134

Re: K023288
Trade/Device Name: Cobra Bipolar System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 30, 2002
Received: January 2, 2003

Dear Ms. Malmborg:

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), 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) you may obtain. 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,

Miriam C. Provost

for 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

INTENDED USE STATEMENT

510(k) Number: K023288

Device Name: Cobra Bipolar System

Indication for Use:

The Cobra Bipolar System (System) is intended for the coagulation of soft tissue during general surgery. The System may also be used to coagulate blood and soft tissue to produce hemostasis.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IS NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR Over-the Counter Use** _____

(Per 21 CFR §801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023288