

OCT 17 2002

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**Attachment 4  
510(k) Summary**

<b>Category:</b>	<b>Comments</b>
<b>Sponsor:</b>	Boston Scientific Corporation 2710 Orchard Parkway San Jose, CA 95134
<b>Correspondent:</b>	Andrea L. Ruth, RAC Senior Associate, Regulatory Affairs 2710 Orchard Parkway San Jose, CA 95134
<b>Contact Information:</b>	E-mail: rutha@bsci.com Phone: 408.895.3625 Fax: 408.895.2202
<b>Device Common Name</b>	Electrosurgical Probe
<b>Device Proprietary Name</b>	Cobra® Cooled Surgical Probe
<b>Device Classification</b>	21 CFR § 878.4400, class II, product code GEI
<b>Predicate Device</b>	Electrosurgical Probe
<b>Predicate Device Manufacturer(s)</b>	Boston Scientific Corporation/EP Technologies, Inc.
<b>Predicate Device Proprietary Name(s)</b>	Cobra® Surgical Probe
<b>Predicate Device Classification Number</b>	Class II
<b>Predicate Device Classification(s)</b>	21 CFR § 878.4400, product code GEI

**Date Summary Was Prepared:**

September 20, 2002

**Description of the Device:**

The Boston Scientific Corporation Surgical Probe is a sterile, single use electrosurgical device intended to be used to coagulate soft tissues. The surgical probe transmits radiofrequency energy from electrodes which are connected to an Electrosurgical unit (non-sterile; re-useable) through an Instrument Cable (sterile; re-useable).

**Intended Use:**

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

**Comparison to Predicate Device:**

	<b>Predicate Device</b>	<b>Modified Device</b>
510(k) Reference	K981981; K010956	Current Submission
Intended Use	Coagulation of tissue	Same
Device Description	Electrosurgical Probe	Same
Single Use?	Yes	Same
EO Sterilized?	Yes	Same
Manufacturer	Boston Scientific Corporation/EP Technologies, Inc.	Same
Device Classification	Class II, 21 CFR §878.4400, code GEI	Same

**Summary of the Non-clinical Data:**

Where appropriate, testing conformed to the requirements of 21 CFR Part 58 (Good Laboratory Practices (GLP)). Specifically, non-clinical tests conducted for the Device included Fluid Path Integrity, Bond Joint Tensile Strength, Bond Joint Torsional Strength, Distal Section Fatigue, Shaft to Handle Tensile Strength, Biocompatibility and, both acute and chronic, *In vivo* performance.



FEB 21 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Boston Scientific Corporation  
c/o Ms. Andrea L. Ruth  
Senior Associate, Regulatory Affairs  
2710 Orchard Parkway  
San Jose, CA 95134

Re: K023291  
Trade/Device Name: Cobra® Cooled Cardiac Surgical Probe, Model 1596X  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical probe  
Regulatory Class: Class II (two)  
Product Code: OCL, GEI  
Dated: October 1, 2002  
Received: October 2, 2002

Dear Ms. Ruth:

This letter corrects our substantially equivalent letter of October 17, 2002.

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.

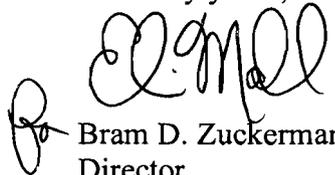
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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

