

FEB 18 2004

SPECIAL 510(K) SUBMISSION  
Cobra Adhere Surgical System

K040104

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**3. 510(k) Summary of Safety and Effectiveness**

**a. General Information**

**Modified Device Information**

<b>Category:</b>	<b>Comments:</b>
Sponsor:	Boston Scientific Corporation 2710 Orchard Parkway San Jose, Ca 95134
Correspondent:	April I. Malmborg Senior Specialist, Regulatory Affairs Boston Scientific Corporation 2710 Orchard Parkway San Jose, Ca 95134
Contact Information:	E-mail: <a href="mailto:malmbora@bsci.com">malmbora@bsci.com</a> Phone: (408) 895-3637 Fax: (408) 895-2202
Device Common Name:	Electrosurgical Probe
Device Proprietary Name:	Cobra Adhere Surgical System
Device Classification:	21 CFR §878.4400

**Predicate Device Information**

Predicate Device:	Cobra Cooled Surgical Probe (K032207)
Predicate Device Manufacturer:	Boston Scientific Corporation
Predicate Device Common Name:	Electrosurgical Probe
Predicate Device Classification:	21 CFR §878.4400
Predicate Device Classification Number:	Class II

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**b. Date Summary Prepared**

January 16, 2004

**c. Description of Device**

The Cobra Adhere Surgical System is an Electrosurgical Probe, with either a malleable or flexible shaft, used in conjunction with the Cobra Electrosurgical Unit (ESU). The system is intended for use by surgeons for the coagulation of cardiac and soft tissues during open surgical procedures.

**d. Intended Use**

The intended use for the Cobra Adhere Surgical System is as follows:

*The Cobra Adhere Surgical System (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 tissues. The System may also be used to coagulate blood and soft tissue to produce hemostasis.*

**e. Comparison to Predicate Device**

See Table I- Comparison of Device Characteristics to Predicate on the following page.

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Table 1 - Comparison of Device Characteristics to Predicate

	Cobra® Cooled Surgical Probe	Cobra Adhere Surgical Probe
Device Manufacturer & Name	Boston Scientific Corporation	Same
Device Description	Electrosurgical Probe	Same
510(k) Number	K032207	
Regulatory Class	II	Same
Device Classification	21 CFR §878.4400	Same
Intended Use	Coagulation of Cardiac Tissue during Cardiac surgery and Soft Tissue during General Open Surgical Procedures	Same
Single Use?	Yes	Same
EO Sterilized?	Yes	Same
Shaft Size	9F	Same
Mandrel -Length and Distal tip OD	6.5 inches 0.036 inches	11.73 inches; 0.035 inches
Tip Material	Polycarbonate	Same
Length	15-35 cm	15-37 cm
Electrode Size	6 to 12.5 mm	Same
9F Hypotube Length	12 inches	8 inches
Electrode Number	2 to 7	Same

f. *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 showed the device met its design-input criteria, and was safe and effective for its intended use.



FEB 21 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Boston Scientific Corporation  
c/o Ms. April I. Malmborg  
Senior Specialist, Regulatory Affairs  
2710 Orchard Parkway  
San Jose, CA 95134

Re: K040104  
Trade/Device Name: Cobra Adhere Surgical System  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: II (two)  
Product Code: OCL, GEI  
Dated: January 16, 2004  
Received: January 20, 2004

Dear Ms. Malmborg:

This letter corrects our substantially equivalent letter of February 18, 2004.

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.

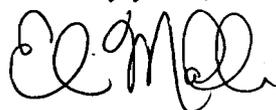
Page 2 - Ms. April I. Malmborg

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" (21 CFR 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

**4. Premarket Notification -Indication for Use Statement**

**Device Name:** Cobra Adhere Surgical System

**Indication for Use:**

The intended use for Cobra Adhere Surgical System is as follows:

*The Cobra Adhere Surgical System (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 tissues. 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)**

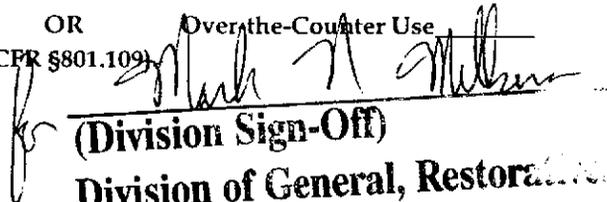
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

OR

Over-the-Counter Use

(Per 21 CFR §801.109)

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

510(k) Number K040104