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K053128

Summary of Safety and Effectiveness

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

General Information

Submitter: Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
508-683-4003

Contact Person: Nicholas Condakes

General Provisions

Trade Name: Soloist™ Single Needle Electrode

Classification Name: Electrode, Electrosurgical

Name of Predicate Devices

LeVeen™ Needle Electrode

Classification

Class II

Performance Standards

The Soloist™ Single Needle Electrode has been designed to comply with the applicable sections of:

- ANSI/AAMI HF-18: 2001, Electrosurgical Devices
- EN 60601-2-2: 2000, Medical Electrical Equipment - Part 2-2: Particular Requirements for the Safety of High Frequency Surgical Equipment
- EN 60601-1:1990/Amd.1:1993/Amd.11:1993/Amd.12:1993/Amd.2: 1995/Amd 13:1996, Medical Electrical Equipment Part 1 General Requirements for Safety
- EN ISO 10555-5: 1997/Amd 1: 2000, Sterile single use intravascular catheters
- EN 1707: 1996, Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment. Lock fittings.

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Intended Use and Device Description

Soloist™ Single Needle Electrode is intended to be used in conjunction with a Boston Scientific radiofrequency (RF) generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver lesions.

The Soloist™ Single Needle Electrode is a disposable, monopolar, electrosurgical device. The device consists of an electrode tip, an insulated delivery needle with handle, and cable.

The Soloist™ Single Needle Electrode is connected to Boston Scientific radiofrequency (RF) generator so that energy passes into the electrode tip and heats the surrounding tissue. The device is also compatible with and may be used in conjunction with the Boston Scientific Coaccess™ Introducer.

Summary of Substantial Equivalence

The Soloist™ Single Needle Electrode has been tested and compared to the predicate device. All data gathered demonstrate this device as substantially equivalent. No new issues of safety or efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2005

Nicholas Condakes
Sr. Regulatory Affairs Specialist
Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K053128
Trade/Device Name: Soloist™ Single Needle Electrode
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: November 7, 2005
Received: November 8, 2005

Dear Mr. Condakes:

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 (240) 276-0115. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known) K053128

Device Name: Soloist™ Single Needle Electrode

Indications for Use Soloist™ Single Needle Electrode is intended to be used in conjunction with a Boston Scientific radiofrequency (RF) generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver lesions.

Prescription Use X
(Per 21 CFR 801 Subpart D)

OR

Over-The-Counter Use
(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)

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

510(k) Number K053128