SECTION 6
510(K) SUMMARY (K140495)

APR 17 2014

1. Submitter:

Boston Scientific Corporation
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Contact: Matt Beauchane
Regulatory Affairs Specialist
Date Prepared: April 8, 2014

2. Device:

Trade Name:	LeVeen™ Standard Needle Electrode System and LeVeen™ CoAccess™ Needle Electrode System
Common Name:	Electrode, Electrosurgical
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulation Number:	878.4400
Product Code:	GEI
Panel:	General & Plastic Surgery
Classification:	Class II

3. Predicate Device:

Boston Scientific Corporation's LeVeen™ Standard Needle Electrode System (K982556)
Boston Scientific Corporation's LeVeen™ CoAccess™ Needle Electrode System (K012315)

4. Device Description:

LeVeen Standard Needle Electrode System:
The description of the proposed LeVeen Standard Needle Electrode System is the same as the predicate LeVeen Standard Needle Electrode System. The LeVeen Standard Needle Electrode System consists of a pre-shaped, multi-armed electrode array which is contained within a delivery cannula. The array is attached to a handle mechanism that deploys the array into targeted tissue. The device is connected to a generator so that RF energy passes from the array to a patient ground pad and heats the tissue surrounding the array.

LeVeen CoAccess Needle Electrode System:
The description of the proposed LeVeen CoAccess Needle Electrode System is the same as the predicate LeVeen CoAccess Needle Electrode System. The LeVeen CoAccess Needle Electrode System is a disposable, monopolar electrosurgical device used for the coagulation necrosis of soft tissue, including partial or complete ablation of nonresectable liver lesions.

The LeVeen CoAccess Needle Electrode System consists of the CoAccess Introducer (an insulated cannula with a locking stylet) and the LeVeen CoAccess Electrode (array with integrated deployment handle) capable of fixed coaxial placement within the insulated cannula. The LeVeen CoAccess Electrode also has an array of wires that is deployed into the targeted soft tissue.

5. Intended Use:

The LeVeen™ Needle Electrode Family (which includes the LeVeen™ Standard Needle Electrode System and the LeVeen™ CoAccess™ Need Electrode System) is intended to be used in conjunction with the RF3000 Generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver lesions.

6. Technological Characteristics:

The proposed LeVeen Standard Needle Electrode System and LeVeen CoAccess Needle Electrode System devices will have PEEK insulation. The currently cleared LeVeen Standard Needle Electrode System (K982556) and LeVeen CoAccess Needle Electrode System (K012315) insulation material is FEP. This change is identical to the LeVeen™ SuperSlim™ Needle Electrode System cannula insulation material change that received 510(k) clearance per K113090.

The proposed CoAccess Introducer will have a hub made of Lexan resin material. The currently cleared CoAccess Introducer (K012315) has a hub made of Eastalloy resin material.

7. Performance Data:

Performance bench testing, biocompatibility testing, and electrical testing were performed on the proposed LeVeen Standard Needle Electrode System and LeVeen CoAccess Needle Electrode System with PEEK insulation, which demonstrates the PEEK insulation met the required specifications for the completed design verification, biocompatibility tests, and electrical tests.

Also, performance bench testing and biocompatibility testing were performed on the proposed CoAccess Introducer with the Lexan hub to demonstrate that the Lexan hub met the required specifications for the completed design verification and biocompatibility tests.

The following performance bench tests were performed:

- LeVeen Standard Needle Electrode System:
  - Insulated Cannula Outer Diameter (OD)
  - Cannula Insulation Adhesion
  - Cannula Tensile
  - Cannula/Array Housing Handle Compression Strength

- LeVeen CoAccess Needle Electrode System:
  - Introducer Cannula Length
  - Insulated Introducer Cannula OD
  - Introducer Insulation Adhesion
  - Introducer Cannula Luminal Access
  - Introducer-Electrode Connection Strength
  - Introducer Tensile Strength
  - Introducer Cannula Compression Strength
  - Introducer Insulation
  - Stylet Protrusion from Introducer Cannula
  - Array Housing Protrusion from Introducer Cannula
  - Insulation Protrusion
  - Introducer Cannula Luer

The following biocompatibility tests were performed:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Latex

Testing was performed per the requirements of the following electrical standards:

- IEC 60601-1:2005 - *Medical Electrical Equipment, Part 1: General Safety Requirements*
- IEC 60601-2-2:2009 - *Medical Electrical Equipment, Part 2-2: Particular Requirements for the Safety of High Frequency Surgical Equipment*

8. Conclusion:

The LeVeen Standard Needle Electrode System and LeVeen CoAccess Needle Electrode System are substantially equivalent to the currently cleared LeVeen Standard Needle Electrode System (K982556) and LeVeen CoAccess Needle Electrode System (K012315) as they are similar to the predicate devices in Intended Use / Indications for Use, fundamental design, function, device materials, packaging, sterilization, operating principles, and fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 17, 2014

Boston Scientific Corporation
Mr. Matt Beauchane
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, Minnesota 55311

Re: K140495
Trade/Device Name: LeVeen™ Standard Electrode System and Leveen™ CoAccess™ Need Electrode System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 26, 2014
Received: February 27, 2014

Dear Mr. Beauchane:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 5
INDICATIONS FOR USE STATEMENT

510(k) Number:
K140495

Device Name:

LeVeen™ Standard Needle Electrode System
and
LeVeen™ CoAccess™ Need Electrode System

Indications for Use:
The LeVeen™ Needle Electrode Family (which includes the LeVeen™ Standard Needle Electrode System and the LeVeen™ CoAccess™ Need Electrode System) is intended to be used in conjunction with the RF3000 Generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver lesions.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/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)

Joshua C. Nipper -S