APR 1 4 2011

K110887

SECTION 6
510(k) SUMMARY

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4359
Fax: 508-683-5939

Contact: Ashley Pyle
Sr. Regulatory Affairs Specialist
Date Prepared: March 29, 2011

2. Proposed Device:

Trade Name: Injection Gold Probe™ Bipolar Electrohemostatis Catheter
Classification Name: Unit, Electrosurgical, Endoscopic (with Accessories)
Regulation Number: 876.4300
Product Code: KNS
Classification: Class II

3. Predicate Device:

Trade Name: Injection Gold Probe™ Bipolar Electrohemostatis Catheter
Manufacturer and Clearance Number: Boston Scientific Corporation, K961349
Classification Name: Unit, Electrosurgical, Endoscopic (with Accessories)
Regulation Number: 876.4300
Product Code: KNS
Classification: Class II

4. Proposed Device Description:

The Injection Gold Probe Catheter is an injection therapy and bipolar electrohemostasis catheter with irrigation capabilities. The Injection Gold Probe Catheter is available with two different style electrical connectors (plugs), Standard and Banana. The Injection Gold Probe Catheter is available in a working length of 210cm with outer diameter of 7Fr (2.3mm) and 10Fr (3.3mm) compatible with a minimum working channel of 2.8mm and 3.7mm.

I. Injection Therapy

Each Injection Gold Probe Catheter contains a 25gauge injection needle for injection therapy. The catheter handle contains the injection needle hub. Injection is performed by attaching a luerlock syringe to the "Injection" hub and advancing the needle.

II. Bipolar Electrohemostasis

The gold spiral electrode on the probe tip provides bipolar electrohemostasis. The Injection Gold Probe Catheter has a standard plug which adapts to Symmetry Endostat, Endostat II and Bicap bipolar electrosurgical generators or Banana plugs which are recommended for use with Valleylab bipolar electrosurgical generator containing female

Banana plug receptacles. The Valleylab generators should be used with the appropriate Valleylab accessories, reference the operating manuals for specifications.

III. Irrigation

Irrigation with saline or sterile water is performed by connecting the irrigation hub to the irrigation port of the bipolar generator for the Standard plug or to a 30ml (30cc) or 60ml (60cc) luer-lock syringe for the Banana plug.

5. Intended Use/Indications for Use:

The Injection Gold Probe™ Bipolar Electrohemostasis Catheter is indicated for use in endoscopic injection therapy (to deliver pharmacological injection agents, such as vasoconstrictors) and endoscopic electrohemostasis (cauterization of tissue and coagulation of blood) of actual or potential bleeding sites in the gastrointestinal tract. These sites include the following: Peptic Ulcers, Dieulafoy Lesions, Mallory-Weiss Tears, Bleeding Polyp Stalks, Arteriovenous Malformations (AVMs), Angiomata. The Injection Gold Probe Bipolar Electrohemostasis Catheter also has irrigation capability. Any other use is not recommended.

6. Description of Change for this Submission:

The following changes are being made to the proposed Injection Gold Probe Bipolar Electrohemostasis Catheter:

- The current gold thick film conductor paste is being replaced with a new gold thick film conductor paste.
- The Medi-Glide™ coating will be eliminated from the inside of the catheter and outside of the needle hub/hypo tube assembly of the device and replaced with Teflon coating on the outside of the needle hub/hypo tube assembly only.
- The current ceramic tip material is being replaced with a new ceramic tip material.
- The tolerance of the "radius" component has been slightly adjusted.
- The length of the hypotube component of the needle assembly was reduced.

7. Technological Characteristics:

The proposed Injection Gold Probe™ Bipolar Electrohemostasis Catheter has the same fundamental design, operating principal and intended use as the predicate Injection Gold Probe™ Bipolar Electrohemostasis Catheter (K961349). The proposed device has material differences and some modifications to needle subassembly when compared to the currently marketed Injection Gold Probe™ Bipolar Electrohemostasis Catheter (K961349).

8. Performance Data:

Biocompatibility Testing has been performed to demonstrate that the material changes made to the proposed device are biocompatible.

Bench Testing has been performed on the proposed Injection Gold Probe™ Bipolar Electrohemostasis Catheter to demonstrate that the modified device meets the required specifications of the completed tests.

9. Conclusion:

All biocompatibility tests conducted on the proposed Injection Gold Probe™ Bipolar Electrohemostasis Catheter passed. Therefore, the Injection Gold Probe™ Bipolar Electrohemostasis Catheter is considered biocompatible.

All device bench tests results were acceptable. The data demonstrate that the Injection Gold Probe™ Bipolar Electrohemostasis Catheter meets design specifications and is suitable for its intended use.

Boston Scientific Corporation has demonstrated that the proposed Injection Gold Probe™ Bipolar Electrohemostasis Catheter is substantially equivalent to Boston Scientific Corporation's currently marketed Injection Gold Probe™ Bipolar Electrohemostasis (K961349).

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Ms. Ashley Pyle
Sr. Regulatory Affairs Specialist
Boston Scientific Corporation
Endoscopy Division
100 Boston Scientific Way
MARLBOROUGH MA 01752

APR 14 2011

Re: K110887
Trade/Device Name: Injection Gold Probe™ Bipolar Electrohemostasis Catheter
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KNS
Dated: March 29, 2011
Received: March 30, 2011

Dear Ms. Pyle:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 5
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~To Be Determined~~ K110887

Device Name: Injection Gold Probe™ Bipolar Electrohemostasis Catheter

Indications For Use: The Injection Gold Probe™ Bipolar Electrohemostasis Catheter is indicated for use in endoscopic injection therapy (to deliver pharmacological injection agents, such as vasoconstrictors) and endoscopic electrohemostasis (cauterization of tissue and coagulation of blood) of actual or potential bleeding sites in the gastrointestinal tract. These sites include the following:

- Peptic Ulcers
- Dieulafoy Lesions
- Mallory-Weiss Tears
- Bleeding Polyp Stalks
- Arteriovenous Malformations (AVMs)
- Angiomata

The Injection Gold Probe Bipolar Electrohemostasis Catheter also has irrigation capability. Any other use is not recommended.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110887