JAN - 8 2014

SECTION 5 **510(k) SUMMARY**

510(k) Summary for Occluder™ Occlusion Balloon Catheter

A. Sponsor

Boston Scientific Corporation
Urology and Women's Health Division
100 Boston Scientific Way
Marlborough, MA 01756

B. Contact

Christine Shoemaker
Specialist II, Regulatory Affairs
508-683-4214
christine.shoemaker@bsci.com

Or

Lisa Sullivan
Manager, Regulatory Affairs
508-683-4745
lisa.sullivan@bsci.com

C. Device Name

Trade name: Occluder™ Occlusion Balloon Catheter
Common/usual name: Catheter, Ureteral, Gastro-Urology
Classification Name: EYB – Catheter, Ureteral, Gastro-Urology

D. Predicate Device

Trade name: Occluder™ Occlusion Balloon Catheter (Boston Scientific)
Common/usual name: Catheter, Urological
Classification Name: KOD – Catheter, Urological

Premarket Notification: Van-Tec Occlusion Balloon Catheter (submitted by Van-Tec, Inc.), K841941/A, August 8, 1984.

E. Device Description

Occluder Occlusion Balloon Catheters are designed for use for temporary occlusion of the ureter and applications including renal opacification, dislodgement of calculi and preventative calculi migration. The devices are provided sterile and are intended for single use.

The Occluder Occlusion Balloon Catheters are constructed of a soft compliant latex balloon mounted on the tip of a catheter shaft. Catheter shafts are radiopaque, maximizing fluoroscopic visibility.

The Occluder Occlusion Balloon Catheters have two lumens that are marked and color-coded. The balloon tubing, marked BALLOON is a balloon inflation lumen. The tubing marked DISTAL, is the essential lumen of the catheter, which terminates at the distal tip. This lumen is used to pass the catheter over a guidewire. This lumen can also be used for infusion of contrast medium.

F. Intended Use

The Occluder™ Occlusion Balloon Catheters are indicated for use for temporary Ureteral occlusion and applications including, renal opacification, dislodgment of calculi and preventative calculi migration.

G. Technological Characteristics

The Occluder Occlusion Balloon Catheters have the same technological characteristics and fundamental occlusion balloon catheter design as the predicate device. The proposed Occluder Occlusion Balloon Catheters are packed using a thermoformed, multi-product tray and supplied with a stopcock and syringe. A tray lid is applied to help secure the device inside the tray cavities. The lidded tray is then placed into a heal-sealed poly/Tyvek pouch. The pouch is labeled and placed into a labeled shelf carton along with a DFU.

H. Substantial Equivalence

A direct comparison of key characteristics has been performed and demonstrates that the proposed Occluder Occlusion Balloon Catheter is substantially equivalent to the predicate device in terms of intended use. The proposed device is substantially equivalent to the reference devices in terms of technological characteristics, types of materials and performance characteristics. The proposed Occluder Occlusion Balloon Catheter is as safe, as effective, and performs as well as the predicate device.

I. Performance Testing (Bench Evaluation)

Boston Scientific has conducted performance testing with samples aged at T=0 and 7-months Accelerated Aging in support of the balloon material and shaft material changes.

The results of the performance testing demonstrate equivalence of the Occluder Catheter to the predicate device. The Occluder Occlusion Balloon Catheter is considered safe and effective for its intended use.

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

January 8, 2014

Boston Scientific Corporation
Urology and Women's Health
Christine Shoemaker, MS, RAC
Specialist II, Regulatory Affairs
100 Boston Scientific Way
Marlborough, MA 01752

Re: K133750
Trade/Device Name: Occluder™ Occlusion Balloon Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EYB
Dated: December 11, 2013
Received: December 12, 2013

Dear Christine Shoemaker,

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 -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4 **INDICATIONS FOR USE**

Indications for Use Statement

510(k) Number : K133750

Device Name Occluder™ Occlusion Balloon Catheter

Indications For Use

The Occluder™ Occlusion Balloon Catheters are indicated for use for temporary Ureteral occlusion and applications including, renal opacification, dislodgment of calculi and preventative calculi migration.

Prescription Use __X____ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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