K132990

510(k) Summary

per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Diane Nelson Regulatory Affairs Specialist Phone: 763-255-0813 Fax: 763-494-2222 e-mail: diane.nelson@bsci.com
Date Prepared	21 October 2013
Proprietary Name	Occlusion Balloon Catheter
Common Name	Vascular Clamp
Product Code	MJN – Catheter, Intravascular Occluding, Temporary
Classification	Class II, 21 CFR Part 870.4450 – Vascular Clamp
Predicate Device(s)	Occlusion Balloon Catheter K062202 October 20, 2006
Device Description	The Occlusion Balloon Catheters are a compliant latex balloon mounted on the distal tip of a dual lumen, radiopaque catheter shaft to which two luer fittings are attached proximally. In addition to the balloon inflation lumen, the central lumen is used to pass the catheter over the guidewire as well as infusion of contrast medium, and in the case of the Berenstein™ Occlusion Balloon Catheter, coaxial delivery of small catheters or embolic agents.
Intended Use/ Indications for Use of Device	The Occlusion Balloon Catheters are indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, emergency control of hemorrhage, chemotherapeutic drug infusion and renal opacification procedures. The Occlusion Balloon Catheter product line consists of two specific designs – Standard Occlusions Balloon Catheters and Berenstein Occlusion Balloon Catheter. Only the Berenstein Occlusion Balloon Catheter has been designed for coaxial delivery of small catheters or embolic agents.
Comparison of Technological Characteristics	The Occlusion Balloon Catheter will incorporate a substantially equivalent design, packaging, fundamental technology, manufacturing, sterilization and intended use as those featured in the predicate Occlusion Balloon Catheter.
Performance Data	Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing and, therefore, these devices may be considered substantially equivalent to the predicate devices.

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The following biocompatibility and bench testing were completed on the Occlusion Balloon Catheter:

Biocompatibility

Cytotoxicity
Sensitization
Intracutaneous Reactivity
Acute Systemic Toxicity
Materials Mediated Pyrogenicity
Hemocompatibility: Direct Hemolysis, Partial Thromboplastin Time (PTT), Complement Activation, In Vitro Hemocompatibility
USP Physicochemical Tests for Plastics

The following in-vitro performance tests were completed on the Occlusion Balloon Catheter:

Bench

Deflated Balloon Profile
Proximal Bond Tensile
Inflated Balloon O.D.
Balloon Deflation Time
Multiple Inflation, Challenge
Balloon Burst, Challenge
Sheath Compatibility

Conclusion

Based on the Indications for Use, technological characteristics, safety and performance testing, the Occlusion Balloon Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Occlusion Balloon Catheter (K062202 cleared October 20, 2006).

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

October 22, 2013

Boston Scientific Corporation
C/O Diane Nelson, Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K132990
Trade/Device Name: Occlusion Balloon Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Catheter, Intravascular Occluding, Temporary
Regulatory Class: Class II
Product Code: MJN
Dated: September 23, 2013
Received: September 24, 2013

Dear Ms. Nelson:

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,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132990

Device Name: **Occlusion Balloon Catheter**

Indications for Use:

Occlusion Balloon Catheters are indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, emergency control of hemorrhage, chemotherapeutic drug infusion and renal opacification procedures.

The Occlusion Balloon Catheter product line consists of two specific designs – Standard Occlusions Balloon Catheters and Berenstein™ Occlusion Balloon Catheter.

Only the Berenstein Occlusion Balloon Catheter has been designed for coaxial delivery of small catheters or embolic agents.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Bram D. Zuckerman -S
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