K140273

510(k) Summary

per 21 CFR §807.92

JUL 22 2014

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	13 June 2014
Proprietary Name	Equalizer™ 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)	Equalizer™ Occlusion Balloon Catheter K021721 20 June 2002
Device Description	The Equalizer™ Occlusion Balloon Catheter is constructed of a soft compliant latex balloon mounted near the tip of a dual-lumen nylon catheter shaft. Radiopaque markers are placed adjacent to the balloon to provide visual reference points for balloon positioning within the vessel. The catheter shaft is radiopaque, maximizing fluoroscopic visibility. Proximal to the bifurcation, the two lumens of the catheter are marked to differentiate their use. The tubing marked 'BALLOON' is the balloon inflation lumen. The tubing marked 'DISTAL' is the central lumen of the catheter, which terminates at the distal tip. This lumen is used to pass the catheter over a guidewire. The lumen can also be used for the infusion of contrast media or therapeutic drugs. Each lumen ends in a luer fitting hub for attachment to ancillary devices.
Intended Use/ Indications for Use of Device	Equalizer Occlusion Balloon Catheter is indicated for use for temporary vessel occlusion in applications including arteriography, preoperative occlusion, emergency control of hemorrhage, chemotherapeutic drug infusion and renal opacification procedures. Any use for procedures other than those indicated in the instructions is not recommended.
Comparison of Technological Characteristics	The Equalizer™ 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. The following biocompatibility and bench testing were completed on the Equalizer 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 Equalizer 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 Equalizer™ Occlusion Balloon Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Equalizer™ Occlusion Balloon Catheter (K021721 cleared 20 June 2002).

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

July 22, 2014

Boston Scientific Corp.
Diane Nelson
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K140273
Trade/Device Name: Equalizer Occlusion Balloon Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: June 13, 2014
Received: June 16, 2014

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 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" (21 CFR 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,

FDA Kenneth J. Cavanaugh -S

for 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): K140273

Device Name: **Equalizer™ Occlusion Balloon Catheter**

Indications for Use:

Equalizer™ Occlusion Balloon Catheter is indicated for use for temporary vessel occlusion in applications including arteriography, preoperative occlusion, emergency control of hemorrhage, chemotherapeutic drug infusion and renal opacification procedures.

Any use for procedures other than those indicated in the instructions is not recommended.

Prescription Use ___X____ (Part 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kenneth J. Cavanaugh -S