



September 21, 2015

Boston Scientific Corporation
c/o Ms. Anne V. Rossi
Regulatory Affairs Manager
One Scimed Place
Maple Grove, MN 55311

Re: K151313

Trade/Device Name: ZelanteDVT Thrombectomy Set
Regulation Number: 21 CFR 870.5150
Regulation Name: Catheter, Embolectomy
Regulatory Class: Class II
Product Code: DXE, KRA
Dated: August 21, 2015
Received: August 24, 2015

Dear Ms. Rossi:

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 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K151313

Device Name

ZelanteDVT™ Thrombectomy Set

Indications for Use (Describe)

The ZelanteDVT™ Thrombectomy Set is intended for use with the AngioJet® Ultra Console to break apart and remove thrombus, including deep vein thrombus (DVT), from:

- Iliofemoral and lower extremity veins ≥ 6.0 mm in diameter and
- Upper extremity peripheral veins ≥ 6.0 mm in diameter.

The ZelanteDVT Thrombectomy Set is also intended for use with the AngioJet Ultra Power Pulse® technique for the controlled and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(k) Summary

per 21 CFR §807.92

Date Prepared	15 May 2015
Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Anne V. Rossi Regulatory Affairs Fellow Phone: 763-494-1094 Fax: 763-494-2222 Email: Anne.Rossi@bsci.com
Trade Name(s)	ZelanteDVT™ Thrombectomy Set
Common or Usual Name	Catheter, Embolectomy
Product Code	DXE
Secondary Product Code	KRA (Catheter, Continuous Flush)
Classification of Device	Class 2 according to 21 CFR 870.5150
Predicate Device(s)	Solent™ Omni Thrombectomy Set K111182 24 May 2011

Device Description

The ZelanteDVT™ Thrombectomy Set is one component of the AngioJet® Ultra Thrombectomy System (AngioJet Ultra System). The other component, packaged and sold separately, is the multiple-use AngioJet® Ultra Console. The ZelanteDVT Thrombectomy Set can only be used in conjunction with the AngioJet Ultra Console.

The ZelanteDVT Thrombectomy Set uses high-velocity saline to create a low pressure zone at the catheter tip. Thrombus is drawn into the catheter where it is fragmented by the jets and evacuated from the body. The waste tubing transports the thrombus debris from the catheter to the waste collection bag for ultimate disposal.

The 105 cm ZelanteDVT Thrombectomy Catheter is introduced through an 8F introducer sheath and tracks and operates over a 0.035" (0.89 mm) guidewire. The manifold is equipped with a port with an attached stopcock. This port can be used to inject contrast media and other fluids into the bloodstream.

Intended Use

The ZelanteDVT™ Thrombectomy Set is intended for the removal of thrombus from and infusion of fluids into the peripheral vasculature.

Indications for Use

The ZelanteDVT™ Thrombectomy Set is intended for use with the AngioJet® Ultra Console to break apart and remove thrombus, including deep vein thrombus (DVT), from:

- Iliofemoral and lower extremity veins ≥ 6.0 mm in diameter and
- Upper extremity peripheral veins ≥ 6.0 mm in diameter.

The ZelanteDVT Thrombectomy Set is also intended for use with the AngioJet Ultra Power Pulse® technique for the controlled and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

Comparison of Required Technological Characteristics

The ZelanteDVT Thrombectomy Set incorporates substantially equivalent design, packaging, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate AngioJet Solent Omni Thrombectomy Set (K111182).

Summary of Nonclinical Tests

Nonclinical testing was performed on the ZelanteDVT Thrombectomy Set 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 device testing.

The following biocompatibility tests were completed on the ZelanteDVT Thrombectomy Set:

Cytotoxicity	Acute Systemic Toxicity	In Vivo Thromboresistance
Sensitization	Direct Contact Hemolysis	Materials Mediated Pyrogenicity
Intracutaneous Reactivity	In Vitro Hemocompatibility	USP Physicochemical

The following in vitro performance tests were completed with the ZelanteDVT Thrombectomy Set:

Shaft Outer Diameter	Hemolysis Ratio	Device Tensile
Effective Length	Contrast Injection	Tip Compression
Guidewire Compatibility	Extended Use	Manifold Torque
Operating Pressure	Thermal Dose	Torsional Buckling Strength
Net Evacuation	Torque Transference	Proximal Saddle Torque
Infusion Rate	Corrosion & FM	Manifold Fluid Immersion
Particulate	Freedom from Leaks	U-Bend
Clot Removal	Guidewire Lumen Leak	Distal Pressure Test
		Packaging Bubble and Peel Tests

Additionally Acute and Chronic GLP studies were performed to evaluate the safety and performance of the ZelanteDVT Thrombectomy Set in peripheral veins.

Conclusion

Based on the indications for use, technological characteristics, safety and performance testing, the ZelanteDVT Thrombectomy Set is appropriate for the intended use and is considered to be substantially equivalent to the AngioJet Solent Omni Thrombectomy Set (K111182).
