October 2, 2020

Boston Scientific Corporation
Vanessa Fowler
Senior Regulatory Affairs Specialist
3 Scimed Place
Maple Grove, Minnesota 55311

Re: K202218
Trade/Device Name: ZelanteDVT™ Thrombectomy System
ZelanteDVT™ ClotHunter™ Helical Rotation Device
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: August 5, 2020
Received: August 6, 2020

Dear Vanessa Fowler:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202218

Device Name
ZelanteDVT™ Thrombectomy System
ZelanteDVT™ ClotHunter™ Helical Rotation Device

Indications for Use *(Describe)*
The ZelanteDVT Thrombectomy System, which includes the ZelanteDVT Thrombectomy Set and the ClotHunter Helical Rotation Device, 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 System 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.

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510(k) Summary for K202218
Per 21 CFR §807.92

Sponsor	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, Massachusetts 01752 USA
Contact Name and Information	Vanessa Fowler Sr Regulatory Affairs Specialist 3 Scimed Place Maple Grove, MN 55311-1566 Phone: 763-494-2537 Fax: 763-494-2222 e-mail: Vanessa.Fowler@bsci.com
Date Prepared	August 5, 2020
Proprietary Name	ZelanteDVT™ Thrombectomy System ZelanteDVT™ ClotHunter™ Helical Rotation Device
Common Name	Catheter, Embolectomy; Catheter, Continuous Flush
Product Code	QEW, KRA
Classification	Class II, 21 CFR Part 870.5150
Predicate Device	ZelanteDVT Thrombectomy Set (K151313), cleared 21 September 2015
Reference Device	Amplatz Super Stiff Guidewire (K843012), cleared 29 November 1984
Device Description	The AngioJet™ ZelanteDVT Thrombectomy System is a component of the AngioJet Ultra Thrombectomy System (AngioJet Ultra System or System). The ZelanteDVT Thrombectomy System can only be used in conjunction with the AngioJet Ultra Console. The AngioJet ZelanteDVT Thrombectomy System is comprised of the single-use ZelanteDVT Thrombectomy Set and the single-use ClotHunter Helical Rotation Device. Both components are packaged and sold separately. The ClotHunter Helical Rotation Device can only be used in conjunction with the ZelanteDVT Thrombectomy Set. The Thrombectomy Set uses this pressurized, 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 bag for ultimate disposal. The ClotHunter Helical Rotation Device consists of a distal helical-shaped wire portion attached to a control handle that is used with the ZelanteDVT Thrombectomy Set. The Helical Rotation Device deflects the distal tip of the Catheter and improves clot removal due to increased luminal coverage. The ClotHunter Helical Rotation Device extends beyond the distal tip of the Catheter to provide a transition between the Catheter and the vessel wall.
Intended Use of Device	The ZelanteDVT™ Thrombectomy System is intended for removal of thrombus from and infusion of fluids into the peripheral vasculature
Indications for Use	The ZelanteDVT Thrombectomy System, which includes the ZelanteDVT Thrombectomy Set and the ClotHunter Helical Rotation Device, 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 System 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 Technological Characteristics	The ZelanteDVT Thrombectomy System incorporates substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the ZelanteDVT Thrombectomy Set (K151313).
Performance Data	Bench, animal, 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. The following biocompatibility tests were completed on the ZelanteDVT ClotHunter Helical Rotation Device or leveraged from the reference device, the Amplatz Super Stiff Guidewire: • Cytotoxicity • Sensitization • Intracutaneous Reactivity • Acute Systemic Toxicity • Materials Mediated Pyrogenicity • Extract and Direct Contact Hemolysis • Complement Activation • Partial Thromboplastin Time • In Vitro Hemocompatibility • Platelet and Leukocyte Counts The following *in-vitro* performance tests were completed for the ZelanteDVT Thrombectomy System. • Clot Removal • Catheter Withdrawal • Handle Attach/Detach • Distal Emboli • Catheter Advance • Insertion Force • Rotation Force • Wire Tip Tensile • Wire to Handle Torsional Force • Handle / Wire Tensile Strength • Gear Slip Force • Corrosion • Coating Integrity • Wire Whip Force (Wire Torque) • Infused Volume • Radiopacity • Particulate Evaluation • Rotator Disengagement Force • Rotational Fatigue • Exposed Wire Length • Wire Shape Retention • Trapped Wire Rotation • Thumbwheel Breakage • Column Strength • Handle Function Post Fluid Exposure Additionally, a GLP animal study was performed to evaluate the safety and performance of the ZelanteDVT Thrombectomy System.

Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the ZelanteDVT Thrombectomy System, consisting of the ZelanteDVT Thrombectomy Set and the ZelanteDVT ClotHunter Helical Rotation Device, has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the ZelanteDVT Thrombectomy Set (K151313).