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

June 29, 2017

Vesatek, LLC
% Paul Gasser
Medical Device RA/QA Consultant
13612 Rushmore Lane
Santa Ana, California 92705

Re: K170684
Trade/Device Name: Firebow Wire Torque Assist Device
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: May 30, 2017
Received: May 31, 2017

Dear Paul Gasser:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

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

Indications for Use

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

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510(k) Number *(if known)*

K170684

Device Name
Firebow Wire Torque Assist Device

Indications for Use *(Describe)*
The Firebow Wire Torque Assist Device is used to maneuver guidewires in the coronary and peripheral vasculature during interventional or diagnostic procedures. The Firebow Wire Torque Assist Device is not intended for use in the neurovasculature.

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.

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K170684

Traditional 510(k) Summary

Submitter: Vesatak, LLC
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Irvine, CA 92614

Contact: Brad Culbert
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Vesatek, LLC
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Date Summary Prepared: March 3, 2017

Device Trade Name: Firebow Wire Torque Assist Device

Common Name: Torque Device

Classification Name: Catheter guide wire (21 CFR 870.1330)

Product Code: DQX

Predicate Devices: Distal Access Torque Device (K141054)
Merit Medical SeaDragon Torque Device (K936032)

Device Description:
The Firebow Wire Torque Assist Device is an electrically driven device that delivers a controlled, predictable number of rotations to guidewires.

The device consists of an ergonomically designed black case, onto which is attached a green guidewire holder with a white spring tension, push button clamp. Once the push button clamp is depressed, the lumen is opened to permit the insertion of guidewires ranging in size from 0.014" – 0.038" in diameter into the holder. Releasing the push button on the clamp causes the inserted device to be firmly clamped into place.

The inside of the case contains two AAA batteries, a miniature stepper motor and a software driven electronic control unit (ECU). The outside of the case has a white button to turn the power on, a green light that illuminates when the unit is turned on, and a white adjustment knob at the bottom of the case to control the number of rotations. The number of rotations can be adjusted from 0 – 8 by rotating the knob. If the user requires that the rotations be halted mid-procedure, then either the power may be turned off using the white button, or the green clamp can be held. Both actions will stop the rotations from occurring.

In order to ensure that the batteries are at full capacity and that the power to the device is not accidentally turned on during shipping, an activation strip is positioned through the case and in between one of the batteries and the battery terminal to prevent completion of the electrical circuit.

The device is provided sterile and is intended for single use.

Indications for Use:
The Firebow Wire Torque Assist Device is used to maneuver guidewires in the coronary and peripheral vasculature during interventional or diagnostic procedures. The Firebow Wire Torque Assist Device is not intended for use in the neurovasculature.

Statement of Equivalence:
The subject device and the predicates share the same intended use and compatibility with procedural accessories (e.g., use with guidewires).

The subject device and the predicates share the same technological characteristics (materials of construction, sterilization method, single use, ability to provide torque to a guidewire).

The key technological difference between the subject device and the predicates is that the subject device is battery powered, while the predicate devices are manually operated.

The Firebow Wire Torque Assist Device is substantially equivalent to the predicate devices with regards to its intended use, design, function, materials and sterilization method.

Summary of Non-Clinical Performance Data:
Device evaluation consisted of design verification testing performed pursuant to Vesatek's risk analysis. All data met the acceptance criteria and fell within pre-determined product specifications and external standard requirements. The following testing was performed:

Design Verification Testing:

- Software
- Electromagnetic compatibility
- Electrical safety
- Visual
- Seal peel
- Dye penetration
- Activation strip functionality
- ECU functionality
- Guidewire compatibility/wire grip integrity
- Rotational output
- Device manual override
- Minimum battery life
- Torque

Biocompatibility Testing:
Biocompatibility testing was not conducted, as the subject device has no patient contact.

Sterilization Testing:
Sterilization validation was conducted in accordance with ISO 11135 to ensure a sterility assurance level (SAL) of 10^{-6}.

A sterilization adoption assessment was conducted in accordance with AAMI TIR 28 in order to support the ability of the current sterilization cycle to adequately sterilize the subject device.

Transportation and Shelf Life Testing:
Shipping and distribution testing was conducted in accordance with ISTA P2A.

Shelf life testing was performed.

The data from the design verification testing above supports the substantial equivalence of the subject device to the predicate devices.

Summary of Pre-Clinical and Clinical Data:
No pre-clinical or clinical data were generated to establish substantial equivalence. Bench data is considered adequate to support a determination of substantial equivalence.

Summary:
Based on the intended use and design verification testing information provided in this premarket notification, the Firebow Wire Torque Assist Device is substantially equivalent to the predicate devices.