May 7, 2020

Vesatek, LLC
Paul Gasser
Medical Device RA/QA Consultant
17171 Daimler Street
Irvine, California 92614

Re: K200120
Trade/Device Name: LiteSaber Wire Torque Assist Device
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: April 6, 2020
Received: April 6, 2020

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. 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,

for Lydia Glaw
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200120

Device Name
LiteSaber Wire Torque Assist Device

Indications for Use *(Describe)*
The LiteSaber WTAD is used to maneuver guidewires in the coronary and peripheral vasculature during interventional or diagnostic procedures. The LiteSaber WTAD 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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Traditional 510(k) Summary

Submitter: Vesatek, LLC
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USA

Contact: Brad Culbert
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Date Summary Prepared: May 6, 2020

Device Trade Name: LiteSaber Wire Torque Assist Device

Common Name: Torque Device

Classification Name: Catheter guide wire (21 CFR 870.1330)

Product Code: DQX

Predicate Device: Firebow Wire Torque Assist Device
(510(k) K170684)

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

The device consists of an ergonomically designed white case, onto which is attached a guidewire holder with a pin vise clamp. Once the pin vise is screwed open, the lumen is opened to permit the insertion of guidewires ranging in size from 0.009" – 0.018" in diameter into the holder. Screwing the pin vise clamp closed causes the inserted device to be firmly clamped into place.

The inside of the case contains a pack of three AAA batteries, a miniature brushed DC motor and a software driven electronic control unit (ECU). The outside of the case has a red button to turn the power on, a green light that illuminates when the unit is turned on, and a black 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 in the direction shown by the indicator (increase or decrease rotations). If the user requires that the rotations be halted mid-procedure, then either the power may be turned off using the red button, or the white clamp can be held. Both actions will stop the rotations from occurring.

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

Indications for Use:
The LiteSaber WTAD is used to maneuver guidewires in the coronary and peripheral vasculature during interventional or diagnostic procedures. The LiteSaber WTAD is not intended for use in the neurovasculature.

Statement of Equivalence:
The subject device and the predicate share the same intended use and have the same fundamental technological characteristics.

Key technological differences between the subject and predicate devices are reflected in the following table.

Design Features	Predicate Firebow Wire Torque Assist Device	Subject LiteSaber Wire Torque Assist Device
Overall design	Spring tension, push button clamp to grasp the guidewire, attached to a case containing two AAA batteries, a stepper motor and an electronic control unit (ECU)	Pin vise clamp to grasp the guidewire, attached to a case containing three AAA batteries, a brushed DC motor and an electronic control unit (ECU)
Torque assist provided by	Motor	Same
Power provided by	2 AAA batteries	3 AAA batteries
Activation strip	Present	None
Rotations	0 – 8	Same
Markings for number of rotations selected	None	Indicator showing which direction to turn to either increase or decrease the number of rotations
Guidewire compatibility (inches)	0.014 – 0.038	0.009 – 0.018
Materials	Plastic and stainless steel	Same

The LiteSaber Wire Torque Assist Device is substantially equivalent to the predicate device.

Summary of Non-Clinical Performance Data:
Device evaluation consisted of bench 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 design verification testing was performed to support the determination of substantial equivalence:

Power activation
Control knob functionality
Guidewire rotation
Manual torque override
Peak rotational speed
Rotations in CW and CCW directions
Torque output
Minimum battery life
Software validation
EMC and product safety

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

Sterilization Testing:
ISO 11135 is used to ensure continued compliance with sterilization requirements and to maintain 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 2A.

Shelf life testing was performed.

The data from the bench testing supports the substantial equivalence of the subject device to the predicate device.

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

Summary:
Based on the intended use and bench testing information provided in this premarket notification, the LiteSaber Wire Torque Assist Device is substantially equivalent to the predicate device.