November 17, 2020

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

Re: K201998
Trade/Device Name: JETi AIO Peripheral Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEZ
Dated: October 9, 2020
Received: October 13, 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,

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)*
K201998

Device Name
JETi AIO Peripheral Thrombectomy System

Indications for Use *(Describe)*
The JETi AIO Peripheral Thrombectomy System is intended to:

- remove/aspirate fluid and break-up soft emboli and thrombus from the peripheral vasculature, and
- subselectively infuse/deliver diagnostics or therapeutics with or without vessel occlusion.

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

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Date Summary Prepared: July 10, 2020

Device Trade Name: JETi AIO Peripheral Thrombectomy System

Common Name: Embolectomy/Thrombectomy Catheter

Classification Name: Embolectomy Catheter (21 CFR 870.5150)

Product Code: QEZ

Predicate Device: JETi 88 Peripheral Thrombectomy System
(510(k) K183403)

Device Description:
The JETi All In One (AIO) Peripheral Thrombectomy System consists of one aspiration catheter, which is connected to the JETi Pump Set and JETi AIO Suction Tubing, one JETi AIO Peripheral Saline Drive Unit (SDU), and an Accessory Cart. A Non-Sterile Accessory Device is supplied. In use, thrombus enters the distal catheter tip via the suction force provided by the JETi AIO SDU internal vacuum pump. The peripheral SDU and pump set deliver a stream of sterile saline through the secondary lumen to break up and dilute the thrombus within the catheter. The diluted thrombus and saline are drawn back through the primary lumen and deposited into the disposable collection canister. No high pressure saline is injected into the patient during normal operation. The peripheral SDU, a height adjustable cart, a height adjustable canister mount, an IV pole, basket, and cart handle are contained on an accessory cart.

Indications for Use:
The JETi AIO Peripheral Thrombectomy System is intended to:

- remove/aspirate fluid and break-up soft emboli and thrombus from the peripheral vasculature, and

- subselectively infuse/deliver diagnostics or therapeutics with or without vessel occlusion.

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

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

Design Features	Predicate JETi 88 Peripheral Thrombectomy System	Subject JETi AIO Peripheral Thrombectomy System
Catheter		
Catheter working length (cm)	100	Same
Catheter connections and location	Multi-port Luer adapter on the proximal end of the catheter	Same
Pump Set		
Saline input tube length (feet)	6	Same
Saline Drive Unit		
IEC 60601-1-2 edition complied with	4th	Same
On/off control	Foot pedal	Handheld controller
Method to stop flow	Pinch valve	Handheld controller
Pinch valve control	Mode button	N/A
Aspiration method	Vacuum pump	Same, but internal to unit
Location	Mounted on cart outside sterile field	Same
Vacuum sensor connector	Standard RJ45	Same
Accessory Stand		
Height adjustable	No	Yes
Sterile Accessory Kit	Present	Replaced with suction tubing
Non-Sterile Accessory Device	Present	Modified to accommodate internal pump

The JETi AIO Peripheral Thrombectomy System is substantially equivalent to the predicate device.

Summary of Non-Clinical Performance Data:
Device evaluation consisted of *in vitro* testing performed pursuant to Walk Vascular'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 to support the determination of substantial equivalence:

Design validation
SDU life cycle
Software validation
60601-1 Product and electrical safety

Biocompatibility Testing:
Biocompatibility testing was not conducted, as the catheter and pump set materials are identical to the predicate device.

Sterilization Testing:
Sterilization testing was not conducted, as the catheter and pump set designs are comparable to the predicate device.

Transportation and Shelf Life Testing:
Transportation and shelf life testing was not conducted on the catheter and pump set, as the catheter and pump set are comparable to the predicate device. Shelf life testing was conducted for the SDU.

The data from the *in vitro* testing above 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 *in vitro* performance information provided in this premarket notification, the JETi AIO Peripheral Thrombectomy System is substantially equivalent to the predicate device.