December 9, 2019

Walk Vascular, LLC
℅ Mr. Paul Gasser
Medical Device RA/QA Consultant
13612 Rushmore Lane
Santa Ana, California 92705

Re: K192439
Trade/Device Name: JETi Peripheral Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ
Dated: November 19, 2019
Received: November 21, 2019

Dear Mr. 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

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K192439

Device Name
JETi Peripheral Thrombectomy System

Indications for Use *(Describe)*
The JETi 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

**Submitter:** Walk Vascular, LLC
17171 Daimler Street
Irvine, CA 92614
USA

**Contact:** Brad Culbert
VP, Engineering
Walk Vascular LLC
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Email: bsculbert@yahoo.com

**Date Summary Prepared:** September 6, 2019

**Device Trade Name:** JETi 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 Peripheral Thrombectomy System consists of one aspiration catheter, which is connected to the JETi Pump Set, one JETi Peripheral Saline Drive Unit (SDU), one Peristaltic Pump, and an Accessory Stand. A Sterile Accessory Kit and Non-Sterile Accessory Device are supplied. In use, thrombus enters the distal catheter tip via the suction force provided by the peristaltic 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 peristaltic pump receptacle. No saline is injected into the patient during normal operation. The peripheral SDU, peristaltic pump, an adjustable mounting arm, an accessory basket, and an IV pole are contained on an accessory stand.

The peripheral catheter is a multi-lumen device that allows for simultaneous hydro-mechanical thrombus disruption and thrombus aspiration. It is designed to simultaneously deliver a stream of saline via a displacement pump within the distal tip of the catheter, while aspirating thrombotic material macerated by the saline stream.

The peripheral catheter has the ability to infuse fluid through the aspiration lumen and saline lumen.

For infusion through the aspiration lumen, an appropriate sized syringe filled with fluid is infused to the treatment area by passing through the side arm of the rotating hemostasis valve (RHV) that is attached to the catheter.

For infusion through the saline lumen, a clamp is used on the suction tubing to cut off aspirate flow.

The proximal end of the pump set consists of a spike and an in-line drip chamber that is used to pierce the saline bag and connect the pump set to the saline source. The cassette contains a piston pump and is mounted onto the peripheral SDU. The cassette is powered by the motor contained in the peripheral SDU. The distal end of the pump set has a connector, which mounts to the proximal end of the multi-port Luer adapter of the peripheral catheter and delivers the saline to the peripheral catheter.

The peripheral SDU is a reusable device. The fork drive of the peripheral SDU is designed to run the piston pump contained in the pump set to deliver the stream of saline to the peripheral catheter, when activated by the foot pedal. Aspiration is achieved with a peristaltic pump that is connected to the SDU and is also turned on/off with the foot pedal. The pressure sensor is connected to the suction tubing, which is connected to the multi-port connector of the peripheral catheter. The peripheral SDU contains a microprocessor controlled circuit and firmware that monitors various functions of the motor and pressure to assure that the device is functioning as expected. Various colored LED lights on the front panel indicate to the user what the current status is of the SDU. Energy is provided by a 24 volt external power supply, which is connected to mains power.

**Indications for Use:**
The JETi 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 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 | Same |
| Method to stop flow | Pinch valve | Peristaltic pump |
| Pinch valve control | Mode button | N/A |
| Location | Mounted on cart outside sterile field | Same |
| Vacuum sensor connector | Standard RJ45 | Same |
| **Aspiration** | | |
| Aspiration Method | Vacuum pump | Peristaltic pump |
| Aspiration Flow Rate | 650 mL/min | 450 mL/min |
| Pressure – Free Flow | - 23.6 inHg | - 12.9 inHg |
| Pressure – Engaged in Clot | < - 27 inHg | Same |
| **Accessory Stand** | Present | Re-designed to accommodate the peristaltic pump |
| **Sterile Accessory Kit** | Four components | Three components |
| **Non-Sterile Accessory Device** | Present | Tubing section added |

The JETi 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 Verification Testing:

SDU/peristaltic pump software and functional performance
SDU/peristaltic pump/accessory stand validation
Peristaltic pump life cycle
Aspiration source comparison
Clot removal
Software validation
60601-1 Product and electrical safety

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

**Sterilization Testing:**
Sterilization testing was not conducted, as the catheter and pump set are identical 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 identical to the predicate device. Transportation /shelf life testing was not repeated for the SDU, sterile accessory kit, non-sterile disposable accessory device, and accessory stand, as the design differences between the predicate and subject devices are not considered sufficiently significant to justify repeating those studies. Shelf life testing was conducted for the peristaltic pump.

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 Peripheral Thrombectomy System is substantially equivalent to the predicate device.