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

February 21, 2017

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

Re: K163051
Trade/Device Name: ClearLumen II Peripheral Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: January 10, 2017
Received: January 11, 2017

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. 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.

510(k) Number *(if known)*
K163051

Device Name
ClearLumen II Peripheral Thrombectomy System

Indications for Use *(Describe)*
The ClearLumen II Peripheral Thrombectomy System is intended to remove/aspirate fluid and break-up soft emboli and thrombus from the peripheral vasculature.

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

Date Summary Prepared: October 28, 2016

Device Trade Name: ClearLumen II Peripheral Thrombectomy System

Common Name: Embolectomy/Thrombectomy Catheter

Classification Name: Embolectomy Catheter (21 CFR 870.5150)

Product Code: DXE

Predicate Device: Walk Vascular ClearLumen II Thrombectomy System (K161786)

Device Description:
The ClearLumen II Peripheral Thrombectomy System 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 high pressure saline via a displacement pump to the distal tip of the catheter, while aspirating thrombotic material macerated by the saline stream.

The ClearLumen II Peripheral Thrombectomy System consists of one aspiration catheter, which connects to the ClearLumen II Pump Set and the ClearLumen Peripheral Saline Drive Unit (SDU). In use, thrombus enters the distal catheter tip via the suction force provided by a 60 ml VacLok syringe, which is connected to the vacuum sensor. 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 is drawn back through the primary lumen and deposited into the syringe. No saline is injected into the patient during normal operation.

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, which is centered in the pump set, 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 Y-connector of the peripheral catheter and delivers the saline to the peripheral catheter.

The peripheral SDU is a reusable, IV pole mounted 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 vacuum sensor. Vacuum is achieved by a vacuum syringe (not provided), which is connected to the vacuum sensor. The vacuum sensor is connected to the aspiration lumen on the Y-connector of the peripheral catheter. The peripheral SDU contains a microprocessor controlled circuit and firmware that monitors various functions of the motor and vacuum to assure that the device is functioning as expected. Various colored LED lights on the front panel indicate to the user the current status of the SDU. Energy is provided by a 24 volt external power supply, which is connected to mains power.

Indications for Use:
The ClearLumen II Peripheral Thrombectomy System is intended to remove/aspirate fluid and break-up soft emboli and thrombus from the peripheral vasculature.

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

Key differences between the two are reflected in the table below.

Design Features	Predicate ClearLumen II Catheter	Subject ClearLumen II Peripheral Catheter
Intended use	Coronary and peripheral	Peripheral
Catheter overall length (cm)	135	115
Minimum guide catheter ID (inches)	0.070	0.113
Number of lumens	Tri-lumen	Dual-lumen
Proximal design	Saline lumen is bonded to the straight-away main port of the Y-site adaptor	Saline lumen is bonded to the side-branch port of the Y-site adaptor
Tip design	Beveled	Blunt, soft
Guidewire	Rapid exchange	Over the wire
SDU to be used with	Coronary SDU	Peripheral SDU

The ClearLumen II Peripheral Thrombectomy System is substantially equivalent to the predicate device with regard to its similar intended use, design, function, materials and sterilization method.

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:

Design Verification Testing:

Pull test of welded and glued joints
Leak
Pressure
Flow
Kink resistance
Torque strength
Guidewire compatibility
Deliverability in torturous model
Performance (simulated clot removal)

Biocompatibility Testing:
Biocompatibility testing was conducted on the peripheral catheter and pump set combination, as the two devices are used concurrently during the surgical procedure. Biocompatibility testing was conducted in accordance with ISO 10993-1.

Sterilization Testing:
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 *in vitro* testing above supports the substantial equivalence of the subject device to the predicate device.

Summary of Pre-Clinical and Clinical Data:
A pre-clinical study was conducted to evaluate the safety of the peripheral catheter. Histological evaluation established the safety of the peripheral catheter when used in peripheral arteries.

No clinical data were generated to establish substantial equivalence. Bench data and pre-clinical data are considered adequate to support a determination of substantial equivalence.

Summary:
Based on the intended use, *in vitro* performance and biocompatibility information provided in this premarket notification, the ClearLumen II Peripheral Thrombectomy System is substantially equivalent to the predicate device.