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

OCT 18 2016

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

Re: K161786
Trade/Device Name: ClearLumen II Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: September 13, 2016
Received: September 14, 2016

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 and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions device's labeling:

> The safety and effectiveness of this device for use in the treatment of ST-Elevation Myocardial Infarction (STEMI) have not been established. Complications from the use of this device in this manner could lead to death, permanent impairment, and/or the need for emergency medical intervention.

Furthermore, the indication to remove/aspirate fluid and break-up soft emboli and thrombus from the coronary vasculature must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

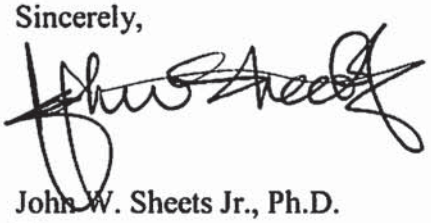
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



John W. Sheets Jr., Ph.D.
Director
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)*
K161786

Device Name
ClearLumen II Thrombectomy System

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional 510(k) Summary – K161786

Submitter: Walk Vascular, LLC
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Irvine, CA 92614

Contact: Brad Culbert
VP, Engineering
Walk Vascular LLC
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Date Summary Prepared: June 27, 2016

Device Trade Name: ClearLumen II Thrombectomy System

Common Name: Embolectomy/Thrombectomy Catheter

Classification Name: Embolectomy Catheter (21 CFR 870.5150)

Product Code: DXE

Predicate Device: Walk Vascular ClearLumen Thrombectomy System (K140296)

Device Description:
The ClearLumen II 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 system is comprised of three components: The ClearLumen II Catheter, the ClearLumen II Pump Set, and the ClearLumen Saline Drive Unit (SDU). Additional off-the-shelf accessory components are required for device operation and include a vacuum syringe, one way stopcock, aspiration extension tubing and a vacuum sensor.

The 6 Fr, 135 cm, multi-lumen thrombectomy catheter delivers pressurized saline, within the distal catheter inner diameter, to assist in the break-up and removal of soft emboli and thrombus. The distal catheter's 0.014" wire compatible rapid exchange lumen extends and ends in a soft atraumatic tip. The proximal in-line Luer port connects to the pump set, while the Y-connector connects to the vacuum sensor, extension tube, stopcock, vacuum syringe assembly (supplied separately).

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 SDU. The cassette is powered by the motor contained in the SDU. The distal end of the pump set has a connector, which mounts to the proximal end of the Y-connector of the catheter and delivers the saline to the catheter.

The SDU is a reusable, IV pole mounted device. The fork drive of the SDU is designed to run the piston pump contained in the pump set to deliver the stream of saline to the 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 catheter. The 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 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 ClearLumen II Thrombectomy System is intended to remove/aspirate fluid and break-up soft emboli and thrombus from the coronary and peripheral vasculature.

Statement of Equivalence:
The subject device and the predicate share the same intended use and compatibility with procedural accessories (e.g., 0.014" guidewire and 6 F guiding catheter use).

The subject device and the predicate share the same technological characteristics (distal catheter design, materials of construction, sterilization method and aspiration catheter with saline stream).

Key technological differences between the two include: The predicate is one unit compared to the subject device's three part component construction, the predicate can be placed in the sterile field compared to the subject device's SDU being pole mounted with the catheter and pump set being placed in the sterile field, the predicate's use of three pre-charged vacuum bottles for aspiration compared to the subject device's use of a syringe, the predicate is battery operated compared to the subject device's use of mains power.

The ClearLumen II Thrombectomy System is substantially equivalent to the predicate device with regards to its 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 testing
Pressure testing
Flow testing
Kink testing
Embolic analysis
Saline stream containment
60601-1 Product and electrical safety testing

Biocompatibility Testing:
Biocompatibility testing was not conducted on the catheter, as the materials were of sufficiently similar construction so as to not warrant repeat testing. Biocompatibility testing was conducted on the pump set in accordance with ISO 10993-1.

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

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:
No pre-clinical or clinical data were generated to establish substantial equivalence. Bench data is considered adequate to support a determination of substantial equivalence, as no patient contacting portion of the device has been modified or performs differently than the predicate.

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