July 29, 2020

Rex Medical, L.P.
% MDI Consultants, Inc.
Susan Goldstein-Falk
55 Northern Boulbevard
Great Neck, New York 11021

Re: K141617
Trade/Device Name: Cleaner Rotational Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW, KRA

Dear Susan Goldstein-Falk:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 14, 2014. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2020.07.29 19:20:18 -04'00'

Gregory O'Connell
Assistant Director
Plaque Modification Devices Team
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

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

November 14, 2014

Rex Medical, L.P.
% Susan Goldstein-Falk
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K141617
Trade/Device Name: Cleaner Rotational Thrombectomy System
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: October 6, 2014
Received: October 7, 2014

Dear Ms. Goldstein-Falk,

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 yours,

Kenneth J. Cavanaugh -S

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)*

K141617

Device Name

Cleaner™ Rotational Thrombectomy System

Indications for Use *(Describe)*

The Cleaner™ Rotational Thrombectomy System is indicated for mechanical declotting of native vessel dialysis fistulae and synthetic dialysis access grafts.

The Cleaner™ Rotational Thrombectomy System is indicated for mechanical declotting and controlled and selective infusion of physician-specified fluids, including thrombolytics, in the peripheral vascular.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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."

510(k) Summary

The assigned 5l0(k) number is: K141617

Submitter: Rex Medical, L.P.
555 East North Lane, Suite 5035
Conshohocken, PA 19428

Contact Person: Colin Valentis
Development Engineer
Phone: (610) 940-0665 x106
Fax: (610) 940-1590
Email: cvalentis@rexmedical.com

Date Prepared: September 19th, 2014

Trade Name: Cleaner™ Rotational Thrombectomy System

Common Name: Thrombectomy catheter

Classification Name: Continuous Flush Catheter (21 CFR 870.1210, Product Code KRA)
Peripheral Atherectomy Catheter (21 CFR 870.4875, Product Code MCW)

Predicate Device(s):

K013635	Trellis Peripheral Infusion System
K950907	Pulse*Spray Infusion System
K091029	Cleaner™ Rotational Thrombectomy System
K120346	Cleaner™ Rotational Thrombectomy System

Device Description:

The Cleaner™ Rotational Thrombectomy System is a percutaneous infusion system that utilizes a rotating sinusoidal wire to increase the dispersion of delivered solution. The devices employ mechanical rotation of a flexible "S" shaped dispersion wire at 4000 RPM which creates a fluid vortex within the treatment site. Contrast media and physician specified solutions, including thrombolytics, may be infused through the catheter lumen to a side hole at the distal end. The dispersion wire uses mechanical rotation to allow the infused solution to penetrate the clot increasing the effectiveness of the treatment. Any residual clot can be aspirated through an introducer sheath prior to restoration of flow. The distal soft tip is a radiopaque a-traumatic tip on the distal end of the dispersion wire. The devices are sterile and single-use disposable.

Intended Use:

The Cleaner™ rotational thrombectomy system is indicated for mechanical declotting of native vessel dialysis fistulae and synthetic dialysis access grafts.

The Cleaner™ Rotational Thrombectomy System is indicated for mechanical declotting and controlled and selective infusion of physician-specified fluids, including thrombolytics, in the peripheral vasculature.

Technological Characteristics:

The Cleaner™ Rotational Thrombectomy System is similar with regard to materials, intended use, principles of operation and technological characteristics to the predicate device. Any differences that may exist do not significantly affect the safety and efficacy of the device. Results of bench testing and animal studies demonstrate Cleaner™ Rotational Thrombectomy System is as safe and effective as the legally marketed predicate device.

Non-Clinical Performance Testing:

The expanded indications for use to include controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature. are based on the bench testing and animal data presented in the performance section of the submission. A GLP animal study was conducted utilizing the Cleaner Rotational Thrombectomy System to assess device performance at restoring vessel patency in the peripheral vasculature. The results of the animal testing show the Cleaner Rotational Thrombectomy System successfully restores patency to occluded vessels. Bench testing included: infusion testing of the predicate device to the proposed device, Electrical Safety, and EMC testing.

Conclusions:

Rex Medical considers the Cleaner™ Rotational Thrombectomy System to be substantially equivalent to the predicate devices listed above. The conclusions are based on performance testing and similarities in indications for use, materials, technological characteristics, principle of operation and design features.