January 30, 2018

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

Re: K173389
Trade/Device Name: Rex Medical Aspiration Pump
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: January 12, 2018
Received: January 16, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173389

Device Name
Rex Medical Aspiration Pump

Indications for Use *(Describe)*
The Aspiration Pump is intended for general suction use in hospitals or clinics.

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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510(k) Summary

This summary of 510(k) is being submitted in accordance with the requirements of SMDA I990 and 21 CFR §807.92.

The assigned 510(k) number is: K173389

Submitter: Rex Medical, L.P.
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Contact Person: Ms. Susan D. Goldstein-Falk
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Date Prepared: January 30, 2018

Trade Name: Rex Medical Aspiration Pump

Common Name: Pump, Portable, Aspiration (Manual or Powered)

Regulation Name: Pump, Portable, Aspiration (Manual or Powered)
Regulation Number: 21 CFR 878.4780
Product Code: BTA
Device Class: Class II

Predicate Device(s): Primary: K051758, Penumbra Aspiration Pump
Reference: K971749, EasyGo Aspirator, Precision Medical, Inc.

Device Description
The Aspiration Pump is a portable suction / aspirator / vacuum system which is used to remove debris, blood and other bodily fluids through the application of continuous negative pressure. The Aspiration Pump includes two suction / aspiration / vacuum ports on the input side, each with individual flow control valves and standard 6% Luer taper connectors. A 500cc collection bag is attached to the output side of the Aspiration Pump for collection of removed debris, blood and bodily fluids.

Patient Contacting Components:

There are no patient contacting components for the Rex Medical Aspiration Pump. The pump connects to a catheter and is never place directly into the body of vasculature. The pump only aspirates and does not infuse any substances into the body.

The Aspiration Pump is used in conjunction with suction tubes, catheters, etc. to remove surgical fluids, tissues, bodily fluids and infectious materials from a wound, patient's airway or espiratory system during surgery. During procedural use, the collection bag is kept on the same surface as the Aspiration Pump so that they are at the same elevation. The Aspiration Pump has two flow control valves that can be attached to other devices with a standard luer connection. The Aspiration Pump is activated by pressing the ON/OFF switch and deactivated by pressing the switch again.

The Aspiration Pump contains an over-pressure safety device which will cease device operation during an over-pressure situation. An over-pressure situation can occur if fluid contained within the collection bag exceeds the collection bag's maximum capacity. A red L.E.D. will illuminate during an over-pressure situation and will remain illuminated until the over-pressure state is resolved.

Indication for Use:
The Rex Medical Aspiration Pump is intended for general suction use in hospitals or clinics.

Comparison to the 510(k) Cleared Device:

The Rex Medical Aspiration Pump is substantially equivalent to the Penumbra Aspiration Pump (K051758).

Discussion of Similarities:

The Rex Medical Aspiration Pump and Penumbra Aspiration Pump are both design to connect to other devices such as catheters and sheaths with a standard luer connection and provide general suction. Both pumps provide a continuous suction through the creation on negative pressure in a closed system.

The Rex Medical Aspiration Pump and EasyGo Aspirator are both compact, portable pumps with similar indications for use. Both pumps are powered with batteries (DC) and provide continuous suction with comparable vacuum pressure.

Discussion of Differences:

The Rex Medical Aspiration Pump is a compact, portable, single use device that is powered by a 12V DC battery. Contrarily, the Penumbra pump is a large, reusable pump that is powered by 110V AC and plugged into a standard wall outlet. The collection cannister and aspiration tubing are single use disposable and are replaced for each use.

The Rex Medical Aspiration Pump differs with the EasyGo Aspirator in a few key aspects. The Rex Medical Pump is a single use disposable pump as opposed to re-usable. The Rex Medical Aspiration Pump feature an inline pressure switch as opposed to a floating valve. Additionally, the EasyGo Aspirator can be recharged.

Table 1: Comparison Chart

Design Feature	**Proposed Device** **Rex Medical** **Aspiration Pump**	**Predicate Device** **Penumbra** **Aspiration Pump** **K051758**	**Comments**	**Alternate Predicate Device** **Precision Medical** **EasyGo Aspirator** **K971749**	**Comments**
Indications for Use	Intended for general suction use in hospitals or clinics.	Intended for general suction use in hospitals or clinics.	SAME	Intended for use in the homecare or hospital environment.	SIMILAR
Closed System	YES	YES	SAME	YES	SAME
Fluid Collection Disposal	Disposable, collection bag	Disposable collection canister.	Rex Medical Aspiration Pump utilizes a bag as opposed to a container. The bag is more beneficial to shipping and packaging but does not affect product safety or efficacy.	Disposable collection canister.	Rex Medical Aspiration Pump utilizes a bag as opposed to a container. The bag is more beneficial to shipping and packaging but does not affect product safety or efficacy.
Product Code	BTA	BTA, JCX	SIMILAR	BTA	SAME
FDA Regulation, 21 CFR	878.4780	878.4780	SAME	878.4780	SAME
Dimensions - Mobile Unit	6" X 4.125" X 2.5"	Est. 16” X 10” X 8”	Smaller unit to take up less operating table space and become less intrusive to the physician.	12” X 9.5” X 10.2”	Smaller unit to take up less operating table space and become less intrusive to the physician.
Weight -Mobile Unit	1.5 lbs	Unknown	From the size of the pump, it can be assumed that it is substantially heavier.	11 lbs	Rex Medical Aspiration Pump is lighter as it requires smaller battery & pump for operation.
Electrical Requirements	12V DC powered, standalone	100-115V AC	Uses wall outlet vs. battery powered.	12V DC powered, re-chargeable. AC adapter for re-charging.	SAME (When Portable)
Suction Source	Integrated vacuum pump	Integrated vacuum pump	SAME	Integrated vacuum pump	SAME

Mobile Unit Vacuum Range	5-28 inHG, depending on diameter of attached suction tubing	29inHG Max, varies depending on diameter of attached suction tubing	SIMILAR	2-21 inHG depending on diameter of attached suction tubing & vacuum control knob.	The vacuum pressure generates adequate flow rates to aspirate materials and fluids with varied diameters of tubing. A higher maximum vacuum pressure increases the effectiveness with small diameter catheters.
Flow Rate	22 - 650 mL/min H_2O depending on catheter used	42 - 480 mL/min depending on catheter used	SIMILAR	14 Lpm Air, Under AC Power	The aspiration flow rate is sufficient to effectively aspirate material and fluids.
Run Time	45min Minimum	Infinite	AC powered does not have a runtime.	45min Minimum	SAME
Vacuum Regulator	None	Regulator Valve	Rex Medical Aspiration Pump's vacuum is based on flow and volumetric load. Maximal vacuum is regulated by designed supplied voltage parameter which is non-adjustable.	Regulator Valve	Rex Medical Aspiration Pump's vacuum is based on flow and volumetric load. Maximal vacuum is regulated by designed supplied voltage parameter which is non-adjustable.
Fluid Suction Filter	None	Inline Filter	Rex Medical Aspiration Pump does not require a filter, as the collection unit is downstream of the pump.	Bacterial Filter	Rex Medical Aspiration Pump does not require a filter, as the collection unit is downstream of the pump.
Single Patient Use	Single	Single use cannister and aspiration tubing. Reusable pump.	Rex Medial Aspiration Pump is designed and marketed as a onetime use device.	Reusable	Rex Medial Aspiration Pump is designed and marketed as a onetime use device.
Holding Container Capacity	500 mL	1000 mL	-	800 mL	-
Suction Mode	Continuous	Continuous	SAME	Continuous	SAME
OTC or Prescription	Prescription	Prescription	SAME	Prescription	SAME
Overflow Prevention Mechanism	Integrated Pressure Switch	None	Rex Medical Aspiration Pump utilizes a pressure switch which ceases device operation when a positive	Float Shut-off	Rex Medical Aspiration Pump utilizes a pressure switch which ceases device operation when a positive

			pressure of 3psi (±10%) is reached on the output side of the pump. This prevents system operation if a downstream tube is kinked or if the volume of fluid within the collection bag exceeds 500 mL.		pressure of 3psi (±10%) is reached on the output side of the pump. This prevents system operation if a downstream tube is kinked or if the volume of fluid within the collection bag exceeds 500 mL.
Suction Inlet Port Dimensions	.125" ID with Luer Connector	0.071” – 0.110” ID with Luer Connector	SIMILAR	.125” ID	Rex Medical Aspiration Pump is compatible with Luer fittings commonly found on catheters used within the surgical field.

Non-Clinical Performance Testing:
Testing information demonstrating safety and effectiveness of the Rex Medical Aspiration Pump in the intended environment of use is supported by testing that was conducted in accordance with Guidance on the Content of Premarket Notification Submissions for portable aspiration pumps.

The following table provides the in vitro testing that was performed for the Rex Medical Aspiration Pump to show substantial equivalence to the predicate device:

Table 2: In Vitro Testing

Report Title	Pass / Fail
Aspiration Pump Pressure Study Technical Report	Pass
Aspiration Pump Battery Life Study Technical Report	Pass
Aspiration Pump Voltage Comparison Study Technical Report	Pass
Distal Assembly IPA Resistance Study Technical Report	Pass
EPEC Engineered Technologies Battery Sample Study Technical Report	Pass
Flow Rate of Rex Medical Aspiration Pump and Predicate Device Technical Report	Pass
Battery Life of Rex Aspiration Pump and Predicate Device	Pass
Maximum Volume of Rex Medical Aspiration Pump and Predicate Device Technical Report	Pass
UL Test Report for Disposable Aspiration Pump, NT-Pump	Pass
Aspiration Pump Backflow Report	Pass

Summary of Aspiration Pump Backflow Testing:

The Rex Medical Aspiration Pump uses a liquid aspiration pump to aspirate fluid from the patient and into the collection bag. The liquid aspiration pump is designed to prevent back flow through the pump. The objective of the test is to verify that backflow does not occur. The acceptance criteria for the test is no backflow when a 45psi minimum back pressure is applied. Two liquid aspiration pumps were each tested three times. All tests passed. The liquid aspiration pump did not allow any backflow of fluids.

The following table provides the in vivo testing that was performed for the Rex Medical Aspiration Pump to show substantial equivalence to the predicate device:

Table 3: In Vivo Testing

Report Title	Pass / Fail
Aspiration Pump in vivo Fluid Flow Study Technical Report	Pass
Aspiration Pump in vivo Efficacy Study Technical Report	Pass

Testing to Standards:
The following national and international standards were utilized for testing the subject device:

Table 2: Standards

Report Title	Pass / Fail
ISO 14161 (2009) Sterilization of Health Care Products– "Biological Indicators - Guidance for The Selection, Use and Interpretation of Results"	Pass
BS EN ISO 11737-2 (2009) "Sterilization of Medical Devices - Microbiological Methods - Part 2: Tests of Sterility Performed in The Definition, Validation and Maintenance of A Sterilization Process"	Pass
AAMI/ANSI/ISO 11135 (2014) "Sterilization of Health-Care Products - Ethylene Oxide - Requirements for The Development, Validation and Routine Control of a Sterilization Process For Medical Devices"	Pass
ISO 11737-1 (2009) "Sterilization of Health Care Products - Microbiological Methods - Part 1: Determination Of The Population of Microorganisms On Product"	Pass
ISO 10993-7 (1995) "Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals"	Pass
ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) "Medical Electrical Equipment - Part 1: General Requirements for Basic Safety And Essential Performance"	Pass
AAMI ANSI IEC 60601-1-2 (2007/(R)2012) "Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests"	Pass
ASTM F 88 (2015) "Standard Test Method for Seal Strength of Flexible Barrier Materials"	Pass
ASTM D 4169 (2016) "Standard Practice for Performance Testing of Shipping Containers and Systems"	Pass
ASTM F1886 (2016) "Standard Test Method for Determining Integrity of Seals for Flexible Packaging By Visual Inspection"	Pass
ASTM F 2096 (2013) "Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)"	Pass
ISTA 2A (2012) "Packaged Products Weighting 150(lbs) or Less"	Pass

Clinical Performance Testing:

No clinical testing was conducted for this device.

Conclusion:
Conclusions based on aforementioned testing and information demonstrate the Rex Medical Aspiration Pump is substantially equivalent to the predicate device.