December 15, 2021

Rex Medical, L.P.
Colin Valentis
Project Leader and Senior Developement Engineer
555 East North Lane, Suite 5035
Conshohocken, Pennsylvania 19428

Re: K212351
Trade/Device Name: Revolution™ Peripheral Atherectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: November 23, 2021
Received: November 24, 2021

Dear Colin Valentis:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212351

Device Name
Revolution Peripheral Atherectomy System

Indications for Use *(Describe)*
Atherectomy of the peripheral vasculature and to break apart and remove thrombus from the peripheral arteries in patients with occlusive atherosclerotic disease.

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

(Per 21 CFR 807.92)
K212351

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Contact Person:
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Date Prepared: July 30th, 2021

Trade Name: Revolution™ Peripheral Atherectomy System

Common Name: Peripheral Atherectomy Catheter

Classification Name: Intraluminal Artery Stripper (21 CFR 870.4875)

Product Code: MCW

Regulatory Class: Class II

Predicate Device:
K191419
Revolution™ Peripheral Atherectomy System
Rex Medical, L.P.

Device Description:
The Revolution Peripheral Atherectomy System is sterile, single-use device designed for atherectomy of the peripheral vasculature and to break apart and remove thrombus from the peripheral arteries in patients with occlusive atherosclerotic disease.

The Revolution device incorporates a flexible drive shaft designed to track over the Revolution guidewire. Attached to the distal end of the drive shaft is a diamond coated spheroid shaped burr which rotates at high speed to ablate occlusive material and restore luminal patency. Power is derived from a mains source and converted using the reusable power supply. During treatment, the rotating burr ablates material into fine particles. This particulate is conveyed proximally by a mechanical means through the catheter and handle into a collection receptacle that resides outside the patient. The device is available in 145cm, 200cm, and 60cm lengths with burr diameters of 1.33mm, 1.66mm, 2.00mm, and 2.33mm.

The Revolution Peripheral Atherectomy System consists of the following components:

1. Single-use Revolution Device (provided sterile)
2. Single-use Revolution .014” Guidewire (provided sterile)
3. Single-use infusion assembly (provided sterile)
4. Single-use collection receptacle (provided sterile)
5. Single-use guidewire clip (provided sterile)
6. Reusable power supply (provided non-sterile)

Indication for Use:
The Revolution Peripheral Atherectomy System is intended for atherectomy of the peripheral vasculature and to break apart and remove thrombus from the peripheral arteries in patients with occlusive atherosclerotic disease.

Technological Characteristics Comparison:

The proposed Revolution Peripheral Atherectomy System is substantially equivalent to the currently marketed Revolution Peripheral Atherectomy System (K191419). The subject and predicate devices share the following technological characteristics:

- Intended Use
- Fundamental Cutting Mechanism
- Fundamental Scientific Technology
- Principles of Operation
- Conditions of Use
- Sterilization Method

The differences between the subject and predicate device include the addition of several product codes and modifications to the construction and materials of certain components.

Changes in catheter material and drive wire construction were implemented in order to reduce the total stiffness of the system to improve performance in highly tortuous anatomy.

The additional product code offerings include a 2.33mm bit, a 200cm length, and low-profile sheath options for the 1.66mm and 2.00mm bits which reduces the sheath compatibility to 6F.

Description	Revolution Peripheral Atherectomy System (Predicate)	Revolution Peripheral Atherectomy System (Subject)
510(k) Number	K191419	K212351
Indications for Use	Atherectomy of the peripheral vasculature and to break apart and remove thrombus from the peripheral arteries in patients with occlusive atherosclerotic disease.	Unchanged
Cutting Mechanism	Spheroid diamond coated burr	Unchanged
Device Type	Rotational	Unchanged
Burr Advancement	Direct-Push Type	Unchanged
Debris Collection	Continuous collection and removal of excised debris via mechanical conveyance	Unchanged
Max. Rotational Speed	140,000 RPM	Unchanged
Guidewire Exchange	Over-the-Wire	Unchanged
Guidewire Compatibility	0.014” x 335cm	0.014” x 335cm 0.014” x 445cm
Sheath Compatibility	4F – 7F	Unchanged
Catheter Working Length	60cm 145cm	60cm 145cm 200cm
Crossing Profile	1.33mm 1.66mm 2.00mm	1.33mm 1.66mm 2.00mm 2.33mm
Capital Equipment	No	Unchanged
Rotation Profile	Axial, Rotational	Unchanged
Infusion	Yes, Saline	Unchanged
Sterilization	Ethylene Oxide	Unchanged
Single-Use	Yes	Unchanged

Non-Clinical Performance Data:

To demonstrate the substantial equivalence of the Revolution™ Peripheral Atherectomy System to the selected predicate device, the performance and technological characteristics will be evaluated in an anatomically correct model and under simulated biological conditions, when necessary, in the following tests:

- Dimensional Verification Testing
- Testing in Simulated Lesion
- Plaque Removal Efficiency and Embolization Analysis
- Fatigue Testing
- Tensile & Torsional Testing
- Stall Testing
- Heat Generation Testing
- Kink Bend Radius Testing
- Corrosion Resistance Testing
- Flow Rate Testing
- Coating Integrity Testing
- Comparative Surface Assessment
- Guidewire Testing
    - Corrosion, Tensile, Flex, Fracture, and Fatigue
- Sterilization Validation
- Shelf Life
- Simulated Distribution
- Electrical and EMC Testing
    - EN 60601-1
    - EN 60601-1-2
- Biocompatibility Testing
    - Cytotoxicity Study Using the ISO Elution Method
    - ASTM Hemolysis Study
    - USP Rabbit Pyrogen Study, Material Mediated
    - ISO Systemic Toxicity Study in Mice
    - ISO Intracutaneous Study in Rabbits
    - ISO Maximization Sensitization Study - Extract
    - C3a Complement Activation Assay
    - SC5b-9 Complement Activation Assay
    - In Vivo Thromboresistance Study
    - Partial Thromboplastin Time
    - Heparinized Blood Platelet and Leukocyte Count

Conclusion:

Rex Medical, L.P. considers the proposed Revolution Peripheral Atherectomy System to be substantially equivalent to the currently marketed Revolution Peripheral Atherectomy System (K191419) based on the intended use, technological characteristics, and performance testing included in this submission.