



September 12, 2019

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

Re: K191419

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: August 8, 2019  
Received: August 12, 2019

Dear Mr. 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

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

## Indications for Use

510(k) Number (if known)

K191419

Device Name

Revolution Peripheral Atherectomy System

Indications for Use (Describe)

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.

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)

**Submitter:** Rex Medical, L.P.  
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Conshohocken, PA 19428

**Contact Person:** Colin Valentis  
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**Date Prepared:** May 24<sup>th</sup>, 2019

**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:** K901206  
Rotablator Rotational Atherectomy System  
Heart Technologies (Acquired by Boston Scientific)

**Reference Device:** K082664  
Pathway Medical Jetstream System  
Pathway Medical Technologies (Acquired by Boston Scientific)

**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 and 60cm lengths with burr diameters of 1.33mm, 1.66mm, and 2.00mm.

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.

**Non-Clinical Performance Data:** To demonstrate the substantial equivalence of the Revolution™ Peripheral Atherectomy System to the selected predicate devices, 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
- Comparative Predicate Testing in Simulated Lesion
- Comparative Predicate Testing in Thrombus
- Debris Removal and Collection Testing
- Tensile & Torsional Testing
- Stall Torque Testing
- Luminal Gain Testing
- Heat Generation Testing
- Infusion and Aspiration Assembly Leak Testing
- Kink Resistance and Maximum Kink Radius
- Fatigue Testing
- Sheath Compatibility Testing
- Sheath Flow Rate Testing
- Motor Controller Software Testing
- Catheter Trackability in Below-the-Knee Anatomy
- Motor Control Board Testing
- Rotational Speed Testing
- Bit Coating Integrity Testing
- Tip Robustness Testing
- Guidewire Testing
  - Corrosion, Tensile, Flex, Fracture, Fatigue, and Coating Integrity
- Sterilization Validation
- Packaging and Shelf Life
- 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* thrombogenicity Study
- Non-Clinical Testing
  - Ovine study with acute and chronic (30-day) *in-vivo* comparison to the predicate Rotablator Rotational Atherectomy System using comparable sizes

**Clinical Summary:** The REVEAL clinical study was a prospective, multi-center, non-randomized, single-arm study to evaluate the safety and effectiveness of the Revolution™ Peripheral Atherectomy System in the treatment of infrainguinal lower extremity peripheral arterial occlusive disease.

A total of 121 patients were enrolled in the REVEAL study across 17 U.S. centers. The treated population consisted of subjects with symptomatic PAD with target lesions present in the superficial femoral, popliteal and tibial arteries who met all eligibility criteria. The primary disease had to be located in

reference vessel diameters of  $\geq 2.0\text{mm}$  -  $\leq 4.0\text{ mm}$ , not exceed 15cm in length, and have a  $\geq 70\%$  stenosis as measured by site-reported angiography.

The primary safety endpoint was evaluated in the Intent-to-Treat (ITT) population by assessing freedom from 30-day Major Adverse Events (MAE), defined as the composite of all-cause mortality, clinically-driven target lesion revascularization (TLR), major target limb amputation, target vessel perforation requiring endovascular or surgical repair, and clinically significant distal embolization in the target limb; as adjudicated by the independent Clinical Events Committee (CEC).

The primary effectiveness endpoint was assessed by technical success in the Per-Protocol (PP) population, defined as  $\leq 50\%$  diameter residual stenosis after atherectomy with the Revolution Peripheral Atherectomy System, prior to adjunctive therapy as evaluated by an independent Angiographic Core Laboratory.

Among the 121 enrolled subjects, the 30-day primary safety endpoint was evaluable in 113. The 30-day freedom from MAE rate was 97.3% (110/113) and technical success was achieved in 90.2% (111/123) of the lesions treated in the PP group with evaluable core laboratory measurements. Both primary endpoints met the predefined IDE study success criteria.

Secondary outcome measures were also favorable. Through 30 days, freedom from significant distal embolization was 98.2% (111/113), freedom from arterial perforation was 99.1% (112/113), and there were no deaths, CD-TLRs, or major amputations. The two distal embolizations were CEC-adjudicated as being procedure related, not device related.

Procedural success ( $< 30\%$  stenosis) at the conclusion of atherectomy and adjunctive therapy was achieved in 119/127 or 93.7% of PP lesions and 129/139 or 92.8% of ITT lesions with evaluable core laboratory post-adjunctive procedure angiographic measurements.

**Technological Characteristics:**

The proposed Revolution Peripheral Atherectomy System is substantially equivalent to the currently marketed Rotablator Rotational Atherectomy System (K901206) and Pathway Medical Jetstream System (K082664). 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 Revolution Peripheral Atherectomy System uses a mechanical means of conveyance to remove residual debris from the patient whereas the Jetstream systems uses an electronic pump. The Rotablator does not aspirate. Other differences include: working length, distal burr diameter, rotational speed, power source (pneumatic vs. electronic), sheath compatibility, and minimum vessel size for device use.

**Conclusion:**

Rex Medical, L.P. considers the proposed Revolution Peripheral Atherectomy System to be substantially equivalent to the currently marketed Rotablator Rotational Atherectomy System (K901206) and Pathway Medical Jetstream System (K082664) based on the intended use, technological characteristics, safety and performance testing included in this submission.