



December 20, 2018

Volcano AtheroMed Inc.
Ms. Jean Chang
Senior Director, Operations
1530 O'Brien Drive, Suite A
Menlo Park, California 94025

Re: K182972

Trade/Device Name: Phoenix® Atherectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: December 3, 2018
Received: December 4, 2018

Dear Ms. Jean Chang:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

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,

Gregory O'Connell
2018.12.20 11:33:16 -05'00'
For
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K182972

Device Name

Phoenix® Atherectomy System

Indications for Use (Describe)

The Phoenix Atherectomy System is intended for use in atherectomy of the peripheral vasculature. It is not intended for use in coronary, carotid, iliac or renal 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
PRASStaff@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."

9 510(k) Summary

Submitter Information:

Date of 510(k) Summary Preparation: December 14, 2018

Name and Address of Manufacturer: Volcano AtheroMed, Inc.
1530 O'Brien Drive, Suite A.
Menlo Park, CA 94025

Contact Person: Jean Chang
Sr Director, Operations
Phone: (650) 352 5255

Subject Device:

Device Trade Name: Phoenix® Atherectomy System

Common Name: Peripheral Atherectomy Catheter

Regulation Description: Intraluminal Artery Stripper

Regulation Number: 21 CFR 870.4875

Product Code: MCW

Device Class: Class II

Classification Panel: Cardiovascular

Predicate Device:

Trade Name: Phoenix Atherectomy System

510(k) Numbers: Primary: K140944
Secondary: K151145, K172386

Manufacturer: Volcano AtheroMed, Inc.

Device Description:

The Phoenix Atherectomy System is a sterile, single-use device designed for atherectomy of the peripheral vasculature. The Phoenix Atherectomy System has two main components: the Phoenix Catheter and the Phoenix Handle.

The Phoenix Catheter is a flexible, over-the-wire (OTW), front-cutting Catheter that continuously captures and clears debulked plaque proximally through the Catheter and Handle into a collection reservoir that resides outside the patient. For use, the Phoenix Catheter is inserted into the Phoenix Handle. The Handle incorporates a self-contained battery-powered motor designed to drive and rotate the cutter of the Phoenix Atherectomy Catheter at its specified rotational speed. The device is activated by an ON/OFF slider switch on the top of the Handle. A Wire Support Clip is used to hold a guidewire in a fixed position relative to the Handle and prevent guidewire rotation during the procedure. The Catheter, Handle, and Wire Support Clip are packaged as sterile, single-use components of the Phoenix Atherectomy System.

There are multiple models of the Phoenix Catheter. The current Phoenix Tracking Catheter models track directly over the guidewire with no tip deflection capability. These Tracking Catheter models are available in 1.8 mm, 2.2 mm and 2.4mm tip diameter sizes. The controls for cutter tip rotation are housed in the Phoenix Handle when the Catheter is inserted into the Handle. All Phoenix Catheter models are compatible with commercially available 0.014" exchange length (260 cm or greater) guidewires, and all use the same Phoenix Handle.

This 510(k) includes modifications to the predicate 2.2 mm X 130cm Phoenix Tracking Catheter to add a new model, i.e., a 2.2mm X 130cm Deflecting Phoenix Catheter, that includes two modifications: (1) a minor modification to the distal cutter design to improve cutter efficiency, and (2) a modification to add a shaped tip at the distal end of the catheter shaft (similar in design to the currently marketed 2.4 mm Phoenix Deflecting Catheter) to enable debulking to a larger lumen diameter. Table 9-1 summarizes the subject modifications relative to the predicate device.

Indications for Use:

The Phoenix® Atherectomy System is intended for use in atherectomy of the peripheral vasculature. It is not intended for use in coronary, carotid, iliac or renal vasculature.

Testing Summary:

To demonstrate the substantial equivalence of the proposed 2.2mm X 130cm Phoenix Deflecting Atherectomy System to the predicate 2.2mm X 130cm Phoenix Tracking Atherectomy System, the performance and technological characteristics were evaluated by completion of the following testing:

- Dimensional and Visual Inspection
- Simulated Use
- Simulated Use -Volume Debris
- Cutter Torque Chain Torque-to-Failure Test
- Functional Outer Shaft Torque Test
- Knob to Shaft Testing
- Catheter Drive Train Stress Test
- Cutter Stall Test
- Temperature Rise of Catheter During Simulated Use
- Kink Bend Radius Test
- Catheter Trackability in Below-the-Knee Anatomy
- Minimum Debulking Diameter for Deflection Catheter (Large Vessel Debulking Diameter)
- Comparative Predicate Testing in Simulated Lesion
- Guidewire Compatibility
- Packaging and Shelf Life

Furthermore, testing of specific device attributes of the subject device demonstrated better or equivalent performance when compared to that of the secondary predicate devices (K151145, K172386). The results from this testing demonstrate that the performance and technological characteristics of the proposed 2.2mm X 130cm Phoenix Deflecting Atherectomy System meet pre-defined design requirements and that the modified Phoenix Atherectomy System performs in a manner equivalent to the predicate Phoenix Atherectomy System with the identical intended use.

Table 9-1: Technological Characteristics Comparison Summary of the Predicate 2.2mm X 130cm Phoenix Tracking Atherectomy System to the Proposed 2.2mm X 130cm Phoenix Deflecting Atherectomy System		
Technological Characteristic	Predicate Phoenix Atherectomy System (K140944), 6F (FG1984) Phoenix Catheters	Modified Phoenix Atherectomy System (Subject Device), 6F (FG3061)
<i>Rotational Speed</i>	10,000-12,000 RPM	Identical
<i>Guidewire Exchange</i>	Over-the-wire	Identical
<i>Guidewire Compatibility</i>	0.014"	Identical
<i>Sheath Compatibility</i>	6F	Identical
<i>Catheter Working Length</i>	130 cm	Identical
<i>Catheter Torque Shaft</i>	Multi-Strand Stainless Steel (SS)	Identical
<i>Catheter Outer Shaft</i>	Stainless Steel Outer Shaft and Teflon sheath	Identical
<i>Catheter Shaft Diameter</i>	1.7mm	Identical
<i>Distal Cutter Flute Maximum Diameter</i>	2.2 mm (FG1984)	Identical
<i>Tip Diameter and Crossing Profile</i>	2.2 mm (FG1984)	Identical
<i>Cutting Tip Port</i>	Single exit port conveys excised debris from the inner guidewire lumen into the Distal Cutting Flute channel	Identical
<i>Second Stage Maceration within Housing</i>	Yes	Yes
<i>Cutter Housing</i>	No Coating	Identical
<i>Distal Tip Assembly Coating</i>	Coated	Identical
<i>Minimum Vessel Size for Device Use</i>	3.0 mm (FG1984)	Identical
<i>Tip Configuration</i>	Straight	Shaped
<i>Deflection Span (Side to Side)</i>	N/A	3.0-4.0mm
<i>Steering (Directional) Mechanism</i>	Rotation of Knob steers distal tip and cutter by torqueing Catheter Shaft	Identical
<i>Debris Collection & Removal</i>	Continuous collection and removal of excised debris by mechanical conveyance	Identical
<i>Catheter Coating</i>	No	Identical
<i>Sterilization</i>	Ethylene Oxide	Identical
<i>Single-use only</i>	Yes	Identical