June 14, 2021

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

Re: K211518
Trade/Device Name: 1.5mm X 149cm Phoenix Atherectomy System, 2.4mm X 130cm Phoenix Deflecting Atherectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: May 13, 2021
Received: May 17, 2021

Dear 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/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)*

Device Name
2.4mm X 130cm Phoenix Deflecting Atherectomy System
1.5mm X 149cm Phoenix Atherectomy System

Indications for Use *(Describe)*

The Phoenix Atherectomy System is intended for use in atherectomy of the peripheral vasculature. The system is not intended for use in the 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
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

Submitter Information:

Date of 510(k) Summary Preparation:	May 13, 2021
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:	2.4mm X 130cm Phoenix® Deflecting Atherectomy System, 1.5mm X 149cm 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:	K182972 and K172386 Volcano
Manufacturer:	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 the 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 Phoenix Tracking Catheter models track directly over the guidewire with no tip deflection capability. The currently marketed models available for clinical use are 1.8mm, 2.2mm, and 2.4mm tip diameter sizes. The controls for 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.

The subject 510(k) submission is proposed to introduce the following modifications:

(i) the predicate 2.2 mm X 130cm Phoenix Deflecting Catheter is being modified to add a new model with a 2.4mm distal cutter assembly to enable debulking to a larger lumen diameter. The 2.4 mm distal cutter assembly is equivalent in design to the currently marketed 2.4mm X 127cm Phoenix Deflecting Catheter.

(ii) the predicate 1.8 mm X 149cm Phoenix Tracking Catheter is being modified to add a 1.5mm tip diameter X 149cm Phoenix Tracking Catheter model to the Phoenix Catheter product family.

Tables 9-1 and 9-2 summarize the subject modifications relative to the predicate devices.

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 modified Phoenix Atherectomy System to the predicate Phoenix Atherectomy System, the performance and technological characteristics were evaluated by completion of the following testing:

- Dimensional and Visual Inspection
- Simulated Use
- Cutter Torque Chain Torque-to-Failure Test
- Functional Outer Shaft Torque Test
- Knob to Shaft Testing
- Catheter Drive Train Stress Test
- Cutter Stall Test
- Embolic Profile Test
- Temperature Rise of Catheter During Simulated Use
- Kink Bend Radius Test
- Catheter Trackability in Below-the-Knee Anatomy
- Large Vessel Debulking Diameter (2.4mm X 130cm Deflecting)
- Packaging and Shelf Life

The results from this testing demonstrate that the performance and technological characteristics of the modified Phoenix Atherectomy System meet pre-defined acceptance criteria for the 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.