December 17, 2018

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

Re: K181877
Trade/Device Name: Phoenix 2.4mm Atherectomy Plus System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: November 15, 2018
Received: November 16, 2018

Dear Ms. 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,

For Eleni Whatley
Date: 2018.12.17 13:25:35 -05'00'

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K181877

Device Name
Phoenix 2.4 Atherectomy Plus 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, pulmonary, or renal vasculature.

Phoenix Atherectomy Plus System:
When used with the Phoenix Aspiration Pump as the vacuum source, the Phoenix 2.4 Deflecting Atherectomy System is indicated for the removal of thrombus from vessels of the peripheral arterial 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 - K181877

Submitter Information:

Date of 510(k) Summary Preparation:	November 29, 2018
Name and Address of Manufacturer:	Volcano AtheroMed, Inc. 1530 O'Brien Dr. Menlo Park, CA 94025
Contact Person:	Jean Chang Senior Director, Operations Phone: (650) 352 5255

Subject Device:

Device Trade Name:	Phoenix® 2.4mm Atherectomy *Plus* System
Common Name:	Atherectomy System
Regulation Description:	Intraluminal Artery Stripper
Regulation Number:	21 CFR 870.4875
Product Code:	MCW
Device Class:	Class II
Classification Panel:	Cardiovascular

Predicate Devices:

Primary Predicate:	Jetstream Atherectomy System (K130637)
Reference Devices:	The Phoenix® Atherectomy System (K172386) & the Penumbra INDIGO™ Aspiration System (K161523) serve as additional reference devices

Device Description:

The Phoenix 2.4mm Atherectomy *Plus* System comprises the currently cleared Phoenix 2.4mm Deflecting Atherectomy System (K172386) and a new Phoenix Aspiration Pump, which when used in conjunction with each other are designed for removal of thrombus from vessels of the peripheral arterial vasculature.

The Phoenix 2.4mm Deflecting Atherectomy System and the Phoenix Aspiration Pump are sterile, single-use devices that are sterilized using Ethylene Oxide (EO). The Phoenix 2.4mm Deflecting Atherectomy System comprises the Phoenix 2.4mm Deflecting Atherectomy Catheter and the Phoenix Atherectomy Handle with Wire Support Clip.

The Phoenix Catheter is an over-the-wire (OTW), multi-lumen Catheter with a cutter at the distal tip that continuously captures and clears debulked (excised) material 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, and 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 Phoenix 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. The Phoenix Catheter is compatible with commercially available 0.014" exchange length (260 cm or greater) guidewires.

For the purpose of this 510(k), the design of the Phoenix 2.4mm Deflecting Atherectomy System remains unchanged.

The Phoenix Aspiration Pump connects to the disposal outlet of the Phoenix Catheter via the pump's aspiration tubing. The exit end of the aspiration tubing is connected to a waste disposal bag to collect aspirated material. A 60 ml syringe is provided as part of the Aspiration Pump Assembly to assist in priming the pump aspiration tubing and purging the aspiration system of air. The Aspiration Pump is battery-operated and is operated by an ON/OFF switch. It serves as a vacuum source for the Aspiration System for aspirating the thrombus from the target vessel out of the Phoenix Catheter via the pump aspiration tubing and into the disposal bag. The Aspiration Pump is non-patient contacting.

Indications for Use:

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, pulmonary, or renal vasculature.

Phoenix Atherectomy *Plus* System:
When used with the Phoenix Aspiration Pump as the vacuum source, the Phoenix 2.4mm Deflecting Atherectomy System is indicated for the removal of thrombus from vessels of the peripheral arterial vasculature.

Comparison with Predicate:

The Phoenix 2.4mm Atherectomy *Plus* System is the subject of this submission for removal of thrombus from peripheral arterial vasculature. The Phoenix 2.4mm Atherectomy *Plus* System has been assessed for substantial equivalence relative to the currently marketed Boston Scientific Jetstream Atherectomy System as the predicate device, along with consideration of two additional reference devices, the Phoenix 2.4mm Deflecting Atherectomy System and the Penumbra INDIGO Aspiration System. The Phoenix 2.4mm Atherectomy *Plus* System has the same design, materials, technological characteristics and principle of operation of the reference Phoenix 2.4mm Deflecting Catheter and Handle. There is no change to the currently marketed 2.4mm Deflecting Atherectomy Catheter and Handle with Wire Support Clip. The Phoenix Aspiration Pump that is used as part of the Phoenix Atherectomy *Plus* System is comparable to the Penumbra INDIGO Aspiration System and shares a similar mechanism of action. The proposed indications for use to add aspiration for thrombus removal for the Phoenix Atherectomy *Plus* System are similar to those of the predicate Boston Scientific Jetstream Atherectomy System, with respect to a combined atherectomy and thrombectomy indication, as well as the reference Penumbra INDIGO System with thrombus removal using vacuum aspiration. Any differences between the subject and predicate device were evaluated through technological comparison (also taking into account the noted reference devices) and design verification and validation testing, which demonstrated no new questions of safety and effectiveness.

The similarities and differences between the subject device and the predicate and reference devices are outlined in the table below:

Table 1-1: Comparison Table				
Design/ Technological Characteristic	**Subject Phoenix Atherectomy *Plus* System**	**Predicate Boston Scientific (Pathway Medical) Jetstream System K130637**	**Reference Phoenix Atherectomy System K172386**	**Reference Penumbra Indigo Aspiration System K161523**
Indications / Intended Use	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, pulmonary, or renal vasculature. Phoenix Atherectomy *Plus* System: When used with the Phoenix Aspiration Pump as the vacuum source, the Phoenix 2.4mm Deflecting Atherectomy System is indicated for the removal of thrombus from vessels of the peripheral arterial vasculature.	The Jetstream System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, iliac or renal vasculature.	Intended for use in atherectomy of the peripheral vasculature. It is not intended for use in coronary, carotid, iliac or renal vasculature.	INDIGO Aspiration Catheters and Separators: As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems. INDIGO Aspiration Tubing: As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheter to the Penumbra Aspiration Pump. Penumbra Aspiration Pump: The Penumbra Aspiration Pump is indicated as a vacuum source for the Penumbra Aspiration Systems.

Table 1-1: Comparison Table				
Design/ Technological Characteristic	**Subject Phoenix Atherectomy *Plus* System**	**Predicate Boston Scientific (Pathway Medical) Jetstream System K130637**	**Reference Phoenix Atherectomy System K172386**	**Reference Penumbra Indigo Aspiration System K161523**
General Technological Design	Phoenix Catheter with distal rotating cutter head cuts through target lesion, where the cutter geometry (helical flutes) draws shaved material proximally within the catheter housing as it cuts. The excised material is removed continuously from the patient by mechanical conveyance along with vacuum assist from the Aspiration Pump and deposited in a collection bag outside the patient. Catheter deflection allows the catheter to cut directionally to a diameter larger than the catheter. Aspiration Pump - handheld battery powered pump capable of providing a vacuum source of ≥ 25inch Mercury (Hg) to aspirate blood and thrombus related materials.	Atherectomy via rotating distal tip advanced longitudinally through target lesion. The distal tip ("blades down") has cutting flutes to remove lesion material when rotating at the minimum diameter. Simultaneous irrigation/infusion and continuous aspiration during device activation remove excised debris to a collection bag outside the patient. In certain Jetstream models, rotational direction is reversed to deploy expandable blades ("blades up") to achieve an increased diameter for further lesion treatment.	Phoenix Catheter with distal rotating cutter cuts through target lesion. The cutter geometry (helical flutes) draws shaved plaque proximally within the catheter housing as it cuts. Excised debris is removed continuously from the patient by mechanical conveyance and deposited in a collection bag outside the patient. Catheter deflection allows the catheter to cut directionally to a diameter larger than the catheter.	The Penumbra Aspiration System is designed to remove thrombus from vasculature by aspirating the proximal side of the thrombus using continuous aspiration through the Aspiration Catheter from the pump directly to the thrombus. For the aspiration source, the Aspiration Catheter is used in conjunction with the Aspiration Pump, which is connected using the Aspiration Tubing and the Pump Canister/Tubing. The Aspiration Catheter is used with the Aspiration Pump to aspirate thrombus from an occluded vessel. As needed, the Separator may be deployed from the Aspiration Catheter to assist with thrombus removal. The Separator is advanced and retracted through the Aspiration Catheter at the proximal margin of the primary occlusion to facilitate clearing of the thrombus from the Aspiration Catheter tip.

Table 1-1: Comparison Table				
Design/ Technological Characteristic	**Subject Phoenix Atherectomy *Plus* System**	**Predicate Boston Scientific (Pathway Medical) Jetstream System K130637**	**Reference Phoenix Atherectomy System K172386**	**Reference Penumbra Indigo Aspiration System K161523**
Debulking Mechanism	Front Cutting Rotational Device	Front Cutting Rotational Device	Front Cutting Rotational Device	Vacuum aspiration only
Debris Collection & Removal	Active aspiration Continuous collection and removal of thrombus by mechanical conveyance of Catheter and vacuum provided by aspiration pump	Active aspiration Continuous collection and removal of excised debris via vacuum aspiration.	Continuous collection and removal of excised debris by mechanical conveyance of Catheter.	Continuous aspiration and removal of thrombus via vacuum aspiration with the catheter targeting aspiration from the pump to the thrombus.
Catheter Rotational Speed	10,000-12,000 RPM	~70,000 RPM (atherectomy) ~24,000 RPM (guidewire removal)	10,000-12,000 RPM	Not applicable
Vacuum Aspiration	≥ 25 inch Hg Vacuum (battery powered, diaphragm pump)	> 20 inch Hg Vacuum (electrical, peristaltic pump)	Not applicable	Up to 29 inch Hg Vacuum (electrical, piston vacuum pump)
Power Source	6V DC Battery for Phoenix Handle 12V DC Battery for Aspiration Pump	110/220 V AC, 50/60 Hz AC power supply from wall socket	6V DC Battery for Phoenix Handle Not applicable for aspiration	100-115 V AC/ 230 V AC, 50/60 Hz AC power supply from wall socket for Penumbra Max Pump
Guidewire Exchange	Over-the-wire	Over-the-wire	Over-the-wire	Over-the-wire
Guidewire Compatibility	0.014"	0.014”	0.014"	0.014”- 0.035”
Sheath Compatibility	7F	7F	7F	6F-8F
Catheter Working Length(s)	125 - 127 cm	120cm – 145cm	125 - 127 cm	85cm – 120 cm

Table 1-1: Comparison Table				
Design/ Technological Characteristic	**Subject Phoenix Atherectomy *Plus* System**	**Predicate Boston Scientific (Pathway Medical) Jetstream System K130637**	**Reference Phoenix Atherectomy System K172386**	**Reference Penumbra Indigo Aspiration System K161523**
Tip Diameter or Crossing Profile	2.4mm (tip diameter and crossing diameter)	1.6mm – 2.4mm ("blades down" range, tip diameter) 3.0mm – 3.4mm ("blades up" range, tip diameter)	2.4mm (tip diameter and crossing diameter)	2.2mm – 3.0mm
Minimum Vessel Size for Device Use	≥ 3.0mm	≥2.5mm (XC) ≥ 3.0mm (SC)	≥ 3.0mm	≥ 4.0mm
Deflection mechanism	Deflecting Catheter: Advancing slider forward on catheter chassis causes distal tip to deflect	No deflection mechanism. However, certain Jetstream models allow for a larger diameter cutter ("blades up") by reversing rotational direction to deploy expandable blades.	Deflecting Catheter: Advancing slider forward on catheter chassis causes distal tip to deflect	Not applicable 8F device with Angled tip
Steering (Directional) mechanism	Rotation of knob on handle steers distal tip and cutter by torqueing catheter shaft	Not applicable	Rotation of knob on handle steers distal tip and cutter by torqueing catheter shaft	Not applicable 8F Catheter with Angled Tip
Catheter Coating	No	No	No	Yes
Biocompatibility	per ISO 10993-1	per ISO 10993-1	per ISO 10993-1	per ISO 10993-1
Cutting Tip Material	DLC coated Stainless Steel	Stainless Steel	DLC coated Stainless Steel	Not applicable
Sterilization	Ethylene Oxide	Ethylene Oxide –(Catheter/Pod Component)	Ethylene Oxide	Ethylene Oxide
Single-use only	Catheter and Handle: Yes Aspiration Pump: Yes	Catheter and Pod- Yes Console – Reusable/electrical	Catheter and Handle: Yes	Catheter: Yes Aspiration Pump: Reusable/electrical

Testing Summary:

Since there is no change to the currently marketed Phoenix 2.4 mm Deflecting Atherectomy Catheter and Handle with Wire Support Clip (K172386 and K151145) that is used as part of the subject Phoenix Atherectomy *Plus* System, previous testing for biocompatibility, bench performance, sterilization, packaging and shelf-life, electrical safety and EMC, remain applicable and was not repeated.

To demonstrate the substantial equivalence of the subject Phoenix Atherectomy *Plus* System to the selected predicate device, the performance and technological characteristics were evaluated by completion of the following tests:

- Visual Inspection
- Vacuum and Leak Test
- Flow Rate Test
- System Simulated Use Test
- Life Cycle Test
- Tubing Tensile Test
- System Comparative Testing in Simulated Lesion
- Pump Comparative Test
- Sterilization Validation
- Packaging and Shelf Life
- Electrical Safety and EMC
- Preclinical Animal Testing

Conclusion

The subject Phoenix Atherectomy *Plus* System shares the same intended use, technological characteristics, and principles of operation with the currently marketed predicate and reference devices. Additionally, the design of the 2.4mm Phoenix Deflecting Catheter and Handle components are identical to that of the currently marketed reference Phoenix Atherectomy System. The Phoenix Aspiration Pump component of the subject Phoenix Atherectomy *Plus* System has similar indications for use and technological characteristics as those of the reference Penumbra INDIGO Aspiration System. Any differences between the subject and predicate device were evaluated through design verification and validation testing which demonstrated no new questions of safety and effectiveness.

Based on the information submitted in this 510(k) premarket notification, the subject Phoenix 2.4mm Atherectomy *Plus* System is substantially equivalent to the currently marketed predicate device.