



Food and Drug Administration  
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May 26, 2015

Volcano AtheroMed, Inc.  
c/o Ms. Jean Chang  
Vice President, Operations  
1455 Adams Drive, Suite 1120  
Menlo Park, CA 94025

Re: K151145

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: April 28, 2015  
Received: April 29, 2015

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Kenneth J. Cavanaugh -S**

for

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

## Indications for Use

510(k) Number (if known)

**K151145**

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.

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## **510(k) Summary**

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### **Submitter Information:**

Date of 510(k) Summary Preparation: April 28, 2015

Name and Address of Manufacturer: Volcano AtheroMed, Inc.  
1455 Adams Dr.  
Menlo Park, CA 94025

Contact Person: Jean Chang  
Vice President, Operations  
Phone: (650) 473-6846  
Fax: (650) 473-9927

### **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) Number: K132682 & K140944

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. An accessory, the Phoenix Wire Support Clip, is also supplied and can be used to clip a guidewire torque device in a fixed position relative to the Phoenix Handle. The Catheter, Handle, and Wire Support Clip are each packaged separately as sterile, single-use components of the Phoenix Atherectomy System.

There are multiple models of the Phoenix Catheter. The smaller 1.8mm and 2.2mm Phoenix Catheter models are compatible with 5F and 6F sheaths, respectively, and track directly over the guidewire with no tip deflection capability. The larger 2.4mm Phoenix Catheter is 7F with the tip having deflection capability. All Phoenix Catheter models use the same Phoenix Handle and are compatible with specific commercially available 0.014" exchange length (260 cm or greater) guidewires listed in the product's instructions for use.

This 510(k) includes modifications to the 2.4mm tip diameter Phoenix Deflecting Catheter distal cutter assembly, as well as the Catheter and proximal chassis design to optimize the ease of use, tip deflection capabilities and manufacturability of the device. Table 9-1 summarizes 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 2.4mm Deflecting Phoenix Atherectomy System to the predicate 2.4mm Deflecting Phoenix Atherectomy System, the performance and technological characteristics were evaluated by completion of the following testing:

- Dimensional and Visual Inspection
- Catheter Sweep & Deflection Span Verification
- Simulated Use

- Comparative Predicate Testing in Simulated Lesion
- Cutter Torque Chain Torque-to-Failure Test
- Functional Outer Shaft Torque Test
- Outer Shaft Torque Test, Deflecting Catheter
- Thrust Bearing Tensile Test
- Outer Shaft to Slider Tensile Test
- Catheter Drive Train Stress Test
- Cutter Stall Test
- Temperature Rise of Catheter During Simulated Use
- Kink Bend Radius Test
- Guidewire Compatibility
- Sheath Compatibility
- Sheath Flow Rate
- Corrosion Resistance
- Large Vessel Debulking Diameter for Deflecting Catheter
- Packaging and Shelf Life

The results from this testing demonstrate that the performance and technological characteristics of the modified Phoenix 2.4mm Deflecting Atherectomy System meet defined design requirements and that the modified device performs in a manner equivalent to the predicate Phoenix 2.4mm Deflecting Atherectomy System with the identical intended use.

<b>Table 9-1: Summary of Technological Characteristics for the Modified Phoenix Atherectomy System</b>		
<b>Technological Characteristic</b>	<b>Predicate Phoenix Atherectomy System (K132682), 7F Phoenix Catheters (FG1179)</b>	<b>Modified Phoenix Atherectomy System, (Subject Device), 7F Phoenix Catheters (FG1728)</b>
<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>	7F	Identical
<i>Catheter Working Length</i>	130 cm	127 cm Straight 117 cm Deflected
<i>Catheter Torque Shaft</i>	Multi-Strand Stainless Steel (SS)	Multi-Strand Stainless Steel (SS)
<i>Catheter Inner Shaft</i>	Stainless Steel Outer Shaft and Teflon Sheath	Stainless Steel Outer Shaft and Thicker Teflon sheath
<i>Catheter Outer Shaft</i>	Stainless Steel Outer Shaft and Teflon sheath	Identical
<i>Catheter Shaft Diameter</i>	2.2mm	Identical
<i>Distal Cutter Flute Maximum Diameter</i>	2.3mm	2.4mm
<i>Tip Diameter and Crossing Profile</i>	2.4mm	Identical
<i>Cutting Tip Port</i>	None	Single exit port conveys excised debris from the inner guidewire lumen into the Distal Cutting Flute channel
<i>Second Stage Maceration within Housing</i>	Yes	Identical
<i>Cutter Housing</i>	Coating	No Coating
<i>Distal Tip Assembly Coating</i>	Yes	Yes
<i>Minimum Vessel Size for Device Use</i>	3.0mm	Identical
<i>Deflection span (Side-to-side)</i>	≥ 5.5mm	≥ 6.0mm
<i>Deflection Mechanism</i>	Knob Advances/Retracts Inner Shaft to straighten or buckle inner Nitinol tube for deflection	Slider Advances/Retracts the Outer Shaft with the pre-shaped Nitinol section at the distal end to deflect or straighten the tip of the Inner Shaft housing the cutter assembly
<i>Debris Collection &amp; Removal</i>	Continuous collection and removal of excised debris by mechanical conveyance	Identical
<i>Steering (Directional) mechanism</i>	Rotation of knob steers distal tip and cutter by torquing Catheter Inner Shaft	Identical Mechanism: Rotation of knob steers distal tip and cutter by torquing Catheter Outer Shaft
<i>Catheter Coating</i>	No	Identical
<i>Sterilization</i>	Ethylene Oxide	Identical
<i>Single-use only</i>	Yes	Identical