DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 22, 2014

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

Re: K140944
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: July 24, 2014
Received: July 25, 2014

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 Industry and Consumer Education 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" (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 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 Industry and Consumer Education 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,

Fernando Aguel -S

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

Enclosure

Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K140944

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

9 510(k) Summary

Submitter Information:

Date of 510(k) Summary Preparation:	July 24, 2014
Name and Address of Manufacturer:	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
Manufacturer:	AtheroMed, Inc.

Device Description:

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

There are three different models of the Phoenix Catheter. Two Phoenix Catheter models track directly over the guidewire with no tip deflection capability. These models are available in 1.8mm and 2.2mm tip diameter sizes. A third, 2.4mm tip diameter model has a Catheter tip design that can be deflected and rotated by the user so that the cutter can eccentrically debulk to a larger diameter than the Catheter's 2.4mm distal cutter. The controls for deflection and rotation are housed in the Phoenix Handle when the Catheter is inserted into the Handle. All three Phoenix Catheter models are compatible with commercially available 0.014" exchange length (260cm or greater) guidewires, and all use the same Phoenix Handle.

This 510(k) includes modifications to the cutter and distal assembly of the 1.8mm and 2.2mm tip diameter Phoenix Catheter models, as well as modifications to the Catheter and proximal chassis design, to further optimize the device design and manufacturability of the device. Table 9-1 summarizes the subject modifications relative to the predicate device. Additionally, the Phoenix Guidewire has been added as a compatible guidewire in the product labeling.

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
- Comparative Predicate Testing in Simulated Lesion
- 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
- Corrosion Test
- Kink Bend Radius Test
- Guidewire Compatibility
- Sheath Compatibility

- Sheath Flow Rate
- Catheter Trackability in Below-the-Knee Anatomy
- Shelf Life
- Biocompatibility
    - Cytotoxicity (L-929 MEM Test)
    - Sensitization (Kligman Maximization Test, 2 extracts - saline and SO)
    - Intracutaneous Reactivity (Injection Test, 2 extracts - saline and SO)
    - Acute Systemic Toxicity (2 extracts - saline and SO)
    - Hemolysis (Human Blood - indirect contact)
    - Hemolysis (Human Blood - direct contact)
    - Prothrombin Time Assay (ISO direct contact)
    - Partial Thromboplastin Time Assay (ISO direct contact)
    - In Vitro Platelet Aggregation Assay (ISO direct contact)
    - Complement Activation (C3a and SC5a-9 direct contact)
    - Pyrogenicity (Material Mediated)
    - Pyrogenicity – Bacterial Endotoxin/LAL (Kinetic Turbidimetric Assay Pyrogen Test)

The results from this testing demonstrate that the performance and technological characteristics of the modified Phoenix Atherectomy System meet 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: Summary of Technological Characteristics for the Modified Phoenix Atherectomy System		
Technological Characteristic	**Predicate Phoenix Atherectomy System (K132682), 5F (FG1105) and 6F (FG1493) Phoenix Catheters**	**Modified Phoenix Atherectomy System (Subject Device), 5F (FG1847) and 6F (FG1984) Phoenix Catheters**
Rotational Speed	10,000-12,000 RPM	Identical
Guidewire Exchange	Over-the-wire	Identical
Guidewire Compatibility	0.014"	Identical
Sheath Compatibility	5F - 6F	Identical
Catheter Working Length	130 cm	Identical
Catheter Torque Shaft	Multi-Strand Stainless Steel (SS)	Multi-Strand Stainless Steel (SS)
Catheter Outer Shaft	Stainless Steel Outer Shaft and Teflon sheath	Stainless Steel Outer Shaft and thicker Teflon sheath
Catheter Shaft Diameter	1.7mm	Identical
Distal Cutter Flute Maximum Diameter	1.6mm (FG1105) 2.0mm (FG1493)	1.8mm (FG1847) 2.2mm (FG1984) (Modified Distal Cutter Flute is flush with Cutter Housing)
Tip Diameter and Crossing Profile	1.8mm (FG1105) 2.2mm (FG1493)	Identical (FG1847) Identical (FG1984)
Cutting Tip Port	None	Single exit port added to convey excised debris from the inner guidewire lumen into the Distal Cutting Flute channel
Second Stage Maceration within Housing	Yes	Yes, with increased capacity/volume
Cutter Housing	Coated	No Coating
Distal Tip Assembly Coating	Coated	Coated
Catheter Chassis Material Changes	Bearing Lubricant - Aerospace Grade Silicone O-Ring	Bearing Lubricant - Food Grade Silicone O-Ring - Medical Grade
Minimum Vessel Size for Device Use	2.5mm (FG1105) 3.0mm (FG1493)	Identical (FG1847) Identical (FG1984)
Debris Collection & Removal	Continuous collection and removal of excised debris by mechanical conveyance	Identical
Steering (Directional) mechanism	Rotation of knob on handle steers distal tip and cutter by torqueing catheter shaft	Identical
Catheter Coating	No	Identical
Sterilization	Ethylene Oxide	Identical
Single-use only	Yes	Identical