

JAN 17 2014

5 510(k) Summary

Submitter Information:

Date of 510(k) Summary Preparation: January 15, 2014

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

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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 Devices:

(1) Device Trade Name: ev3 SilverHawk™ Peripheral Plaque Excision System

510(k) Numbers: Multiple 510(k)s for the SilverHawk System family of devices, including K024243, K043553, K053460, K061063 and K061188

(2) Device Trade Name: Pathway Medical Jetstream System

510(k) Numbers: Multiple 510(k)s for the Jetstream System family of devices, including K081328, K093918, K101334, K111229 and K120242

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.

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 Phoenix Atherectomy System to the selected predicate devices, 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
- Proximal Catheter Shaft Assembly Tensile Test – Deflection Catheter
- 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
- Radiopacity
- Catheter Trackability in Below-the-Knee Anatomy
- Handle and Wire Support Clip Visual and Functional Testing
- Handle Life Testing
- Minimum Debulking Diameter for Deflection Catheter
- Sterilization Validation
- Packaging and Shelf Life
- Electrical Safety Testing in accordance with IEC 60601-1, Edition 3.0: Medical Electrical Equipment - Part 1: General Requirements for Safety
- Electromagnetic Compatibility (EMC) in accordance with IEC 60601-1-2, Edition 3.0: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- Usability in accordance with IEC 60601-1-6, Edition 3.0: Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability and IEC 62366:2007, Application of Usability Engineering to Medical Devices
- Biocompatibility
 - Cytotoxicity (L929 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 – LAL (Kinetic Turbidimetric Assay Pyrogen Test)
- Preclinical Animal Testing
 - Porcine study with acute, 3-day, and 28-day assessments and in vivo performance comparison to a predicate device
 - Acute porcine study of largest (2.4mm) Phoenix Catheter size
 - Acute porcine study of smallest (1.8mm) Phoenix Catheter size

The results from this testing demonstrate that the performance and technological characteristics of the Phoenix Atherectomy System meet defined design requirements and that the Phoenix Atherectomy System performs in a manner equivalent to the predicate devices currently on the market with the same intended atherectomy use.

Table 1 on the following page presents a summary of technological characteristics of the Phoenix Atherectomy System, as compared to the predicate devices.

Clinical Summary:

The EASE clinical study was a prospective, multi-center, non-randomized, single-arm study to evaluate the safety, effectiveness, and performance of the Phoenix Atherectomy System in the percutaneous atherectomy treatment of de novo and restenotic atherosclerotic lesions of infra-inguinal lower extremity arteries. 128 total patients were enrolled across 16 centers for treatment. 105 subjects (with 123 treated lesions) comprising the Per-Protocol group were enrolled in accordance with the vessel sizing and anatomic location requirements corresponding to each Phoenix Catheter device size. The primary safety endpoint was freedom from major adverse events (MAE) at 30 days, as assessed by an independent physician adjudicator. The primary effectiveness endpoint was acute technical success, defined as the ability to achieve a residual diameter stenosis $\leq 50\%$ as assessed by the study investigator at the time of treatment with the Phoenix Atherectomy System (prior to any adjunctive therapy) using quantitative angiography or visual estimate. Patients were monitored for 6 months following baseline atherectomy treatment.

The 30-day freedom from MAE rate was 94.3% (99/105) and technical success was achieved in 95.1% (117/123) of the lesions treated in the per protocol group. Both primary endpoints met the predefined IDE study success criteria.

Following treatment of the first 36 subjects enrolled in the EASE Study, a higher than anticipated complication was observed. Of the first 36 subjects treated, there were 19 serious procedure or

device related adverse events and 6 adverse events met the definition of major adverse events (MAE). Specific to the MAE, there have been 5 dissections/perforations and one vessel occlusion requiring treatment. AtheroMed initiated a review of available data to assess the underlying causes. The analysis of these early results led to additional sizes of the Phoenix Atherectomy Catheter being added to the EASE Study protocol, as well as updated recommendations regarding minimum vessel diameters and anatomical locations for device use.

Table 1. Summary of Technological Characteristics for the Phoenix Atherectomy System and Predicate Devices

Technological Characteristic	AtheroMed Phoenix Atherectomy System	Predicate FoxHollow/ev3 SilverHawk	Predicate Pathway Medical Jetstream System
<i>Rotational Speed</i>	10,000-12,000 RPM	~8,000 RPM	~70,000 RPM
<i>Guidewire Exchange</i>	Over-the-wire	Monorail	Over-the-wire
<i>Guidewire Compatibility</i>	0.014"	0.014"	0.014"
<i>Sheath Compatibility</i>	5F - 7F	6F - 8F	7F
<i>Catheter Working Length(s)</i>	130cm	107cm - 136cm	120cm - 145cm
<i>Tip Diameter or Crossing Profile</i>	1.8mm - 2.4mm (tip diameter and crossing diameter)	1.9mm - 2.7mm (crossing profile)	1.6mm - 2.4mm ("blades down" range, tip diameter) 3.0mm - 3.4mm ("blades up" range, tip diameter)
<i>Minimum Vessel Size for Device Use</i>	2.5mm - 4.5mm	1.5mm - 7.0mm	2.5mm - 4.5mm
<i>Debris Collection & Removal</i>	Continuous collection and removal of excised debris by mechanical conveyance.	Debris collection in distal nosecone during use, with emptying of nosecone via catheter removal.	Continuous collection and removal of excised debris via vacuum aspiration.
<i>Deflection mechanism</i>	<u>Deflecting Catheters:</u> Advancing knob on handle causes distal tip to deflect, creating off-axis apposition of cutter to plaque. <u>Tracking Catheters:</u> Not applicable -- no deflection capability.	<u>All Catheters:</u> Advancing knob on handle causes nosecone to deflect, creating off axis apposition of cutter to plaque.	No deflection mechanism. However, certain Jetstream models allow for a larger diameter cutter ("blades up") by reversing rotational direction to deploy expandable blades.
<i>Steering (Directional) mechanism</i>	Rotation of knob on handle steers distal tip and cutter by torquing catheter shaft.	Rotation knob steers distal tip and cutter by torquing catheter shaft.	Not applicable.
<i>Catheter Coating</i>	No	Yes (hydrophilic coating)	No
<i>Sterilization</i>	Ethylene Oxide	Ethylene Oxide (catheter) Gamma (cutter driver)	Ethylene Oxide
<i>Single-use only</i>	Yes	Yes	Yes

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

January 17, 2014

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

Re: K132682
Trade/Device Name: Phoenix® Atherectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: II
Product Code: MCW
Dated: November 21, 2013
Received: November 29, 2013

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" (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 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

4 Indications for Use

510(k) Number: K132682

Device Name: Phoenix® Atherectomy System

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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

Please do not write below this line - continue on another page if needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kenneth J. Cavanaugh -S