



Food and Drug Administration
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November 13, 2015

Cathera, Inc.
Victor Ham
Chief Regulatory & Quality Officer
627 National Ave.
Mountain View, California 94043

Re: K151638

Trade/Device Name: Phenom™ Catheters
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: October 9, 2015
Received: October 13, 2015

Dear Mr. Ham:

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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style and is positioned above the typed name.

for

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

Enclosure

Indications for Use

510(k) Number (if known)

K151638

Device Name

Phenom™ Catheter

Indications for Use (Describe)

The Phenom™ Catheters are intended for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the neuro, peripheral, and coronary vasculatures.

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

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Submitted by:

Cathera, Inc.
627 National Ave.
Mountain View, CA 94043
Tel.: (650) 388-5088
Fax: (650) 390-0107

Contact Person: Victor Ham

Date summary prepared: May 29, 2015

Trade Name: Phenom™ Catheter

Common Name: Catheter

Classification Name & Product Codes: Continuous Flush Catheter
(21 CFR 870.1210, Product Code KRA)

Predicate Devices: Prowler® 14 Infusion Catheter (510K # K021591)
Prowler® Plus Infusion Catheter (510K # K993266)
Marksman™ Catheter (510K # K091559)
Tracker® Infusion Catheter (510k # K862117)

Device Description:

The Phenom™ Catheters are variable stiffness, single lumen catheters designed to access small, tortuous vasculature. They are available in a variety of lengths, stiffness and inner and outer diameters. The outer surface of the catheter is coated to enhance navigation in the vessel. The catheter also incorporates a liner to facilitate movement of introduction devices passing through its lumen. The distal tip has radiopaque marker(s) to aid visualization and positioning under fluoroscopy.

Indications for Use:

The Phenom™ Catheters are intended for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the neuro, peripheral, and coronary vasculatures.

Performance Data:

The following bench testing was performed in support of the Phenom™ Catheter and to establish substantial equivalence to the predicate devices:

- Dimensional Inspection (OD, ID, Length, Distal Tip Configuration)
- Material Verification
- Accessibility/ Trackability
- Device Compatibility (with Guide Catheter, Guide Wire, RHV)
- Shaft Stiffness
- Chemical Compatibility (Saline, Contrast Medium)
- Tip Shapeability
- Kink Resistance
- Conical Fitting for Hub
- Dead Space Volume
- Corrosion Resistance
- Tensile Strength of Catheter (Body & Hub Attachment)
- Liquid Leakage at Air Leakage During Aspiration Hub
- Burst Pressure
- Particulate Testing
- Outer Surface Coating Lubricity and Durability
- Catheter Flow Rate
- Flexural Fatigue
- Torque strength
- Tip Mark Radiopacity testing
- Biocompatibility Testing
- Shelf-life Testing

Substantial Equivalence Determination

The information presented in the 510k shows that the Phenom™ Catheters are substantially equivalent to predicate endovascular catheters in regards to the following aspects:

- Design:** The subject and predicate devices are substantially equivalent with respect to design characteristics. The slight variations in flexibility, length of coated segments and lubricity are what differentiate these catheters. Each manufacturer optimizes these design variations towards a more specific application (e.g. infusion of diagnostic and therapeutic agents) or for the introduction of a specific devices such as embolic agents, coils and stents.
- Function:** The subject and predicate devices are substantially equivalent with respect to functional characteristics.
- Manufacturing:** The subject and predicate devices are similar with respect to technological manufacturing processes.
- Materials:** The subject and predicate devices are composed of similar materials, all of which have an extensive clinical history of safe use in medical devices.
- Indications:** The subject and predicate devices maintain similar indications.
- Packaging:** The subject and predicate devices utilize similar packaging configurations.
- Sterilization:** The subject and predicate devices are both sterilized utilizing an Ethylene Oxide sterilization cycle validated in accordance with ISO 11135 - *Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization*.
- Labeling:** Both the subject and predicate devices have similar labeling.

Testing was conducted to show that no new risks were identified and that the performance profile is similar to well-established predicate devices cleared for the market. Evaluation was performed in the more complex and higher risk neurovascular anatomy, which is the worst case representation of the cardiac and peripheral vascular anatomies.