June 11, 2018

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

Re: K180959
Trade/Device Name: Phenom 27 Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, KRA
Dated: May 30, 2018
Received: May 31, 2018

Dear Victor 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.

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,

Xiaolin Zheng -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K180959

Device Name
Phenom 27 Catheter

Indications for Use *(Describe)*

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.

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510(k) Summary – K180959

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

Submitted by:
Cathera, Inc.
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Tel.: (650) 388-5088
Fax: (650) 390-0107

Contact Person: Victor Ham

Date summary prepared: April 22, 2018

Trade Name: Phenom® 27 Catheter

Common Name: Catheter

Classification Name & Product Codes:

Percutaneous Catheter (21 CFR 870.1250, Product Code DQY)

Continuous Flush Catheter (21 CFR 870.1210, Product Code KRA)

Predicate Devices: Phenom® 27 Catheter (510K # K151638)

Device Description:

The Phenom® 27 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 aid in 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:

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

Device Comparison of Technological Characteristics

Table A provides a comparison of the technological characteristics of the Phenom® 27 Catheter and the modified Phenom® 27 Catheter with additional effective length.

Table A-Summary of Technological Characteristics, Components and Materials

Technological Characteristic	Phenom® 27, predicate (510k # K151638)	Phenom® 27, modified (510k # K180959)	Rationale for Difference (if present)
Indication for Use	Phenom® Catheters are intended for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the neuro, peripheral, and coronary vasculatures.	Identical	N/A-No difference
Composite Shaft	PTFE composite polymeric catheter	Identical	N/A-No difference
Composite Shaft support	Stainless Steel Reinforcement	Identical	N/A-No difference
Hub	Polyamide	Identical	N/A-No difference
Stain Relief	Thermoplastic elastomer	Identical	N/A-No difference
Marker(s)	Platinum/Iridium Alloy	Identical	N/A-No difference
Coating	Polymeric hydrophilic coating	Identical	N/A-No difference
Proximal OD	3.1F (1.02mm)	Identical	N/A-No difference
Distal OD	2.8F (0.91mm)	Identical	N/A-No difference
Proximal ID	0.027 inches (0.69 mm)	Identical	N/A-No difference
Distal ID	0.027 inches (0.69 mm)	Identical	N/A-No difference
Effective Length Range (cm)	75 to 150	75 to 160	Increasing the length of the proximal shaft provide the physicians extra length for set-up. Working (distal) shaft of catheter is the same therefore equivalent.
Tip Configurations	Steam shapeable straight tip	Identical	N/A-No difference
Accessories			
Steam shaping mandrel	Stainless Steel	Identical	N/A-No difference
Packaging & Sterilization			
Packaging materials and configuration	Catheter package inside dispensing coil; inside Tyvek® pouch; inside cardboard box	Identical	N/A-No difference
Sterilization	Ethylene Oxide	Identical	N/A-No difference

Conclusion- Based on the comparison shown in **Table A** (above), the technological characteristic of the modified Phenom® 27 and the predicate Phenom® 27 are equivalent. The only design modification was to increase the effective length from 150 cm to 160 cm. This provides the user with additional length during the set-up procedure which does not alter the intended use or the fundamental scientific technology of the device as originally cleared for the predicate device and therefore substantially equivalent.

Performance Testing – Bench

As identified in the risk analysis, the increased length would require testing of the flow rate and dead space volume. Testing was conducted according to the same method used for the original predicate device. Accessibility and tractability testing was performed to verify that modified catheter can reach M1 region of tortuous neurovascular model. The modification to add extra length to the proximal shaft of the catheter did not affect the design or function of the distal shaft of the catheter that enters the body. All other tests performed on the predicate device apply to the modified version. A summary of the pre-clinical bench testing performed for the Phenom® 27 Catheter and the modified Phenom® 27 Catheter is presented in the **Table B** below:

Table B- Summary of Pre-Clinical Bench Testing

Test Description	Test Method Summary	Results
Catheter Flow Rate	The purpose of the testing is to provide the user with a flow rate reference when using various contrast media and pressure conditions. Similar to the predicate device, 2 pressure conditions and 3 commonly used contrast media are used for the testing. High pressure vessel and tank, timer and scale are used to determine flow rate.	Flow rate data was collected for the modified (160cm) device and the predicate device (150cm). As expected, the new geometry result in slightly different fluid dynamics (i.e., lower flow rates). The results are within the expected range and therefore are equivalent.
Flow rate for each lumen, according to ISO 10555-1	Test method is to verify compliance to catheter standard BS EN ISO 10555-1: 2013. Conditions, method and equipment as prescribed in the standard.	Flow rate data was collected for the modified (160 cm) device and the predicate device (150 cm). As expected, the new geometry result in slightly different fluid dynamics (i.e., lower flow rates). The passing results are within the expected range and therefore are equivalent.
Dead Space Volume	The purpose of the testing is to provide the user with the dead space volume (fill volume) of the catheters.	Data was collected for the modified (160 cm) device and the predicate device (150 cm). As expected, the new geometry result in slightly larger dead space volume. The passing results within the expected range and therefore are equivalent.

Test Description	Test Method Summary	Results
Accessibility/ Tractability Test	The purpose is to verify that the modified Catheter can reach M1 region of tortuous neurovascular model. Test were conducted at body temperature, using the appropriate guidewires, guide catheters, RHV and continuous flushing conditions to mimic actual use.	Data was collected for the modified (160 cm) device and the predicate device (150 cm). Similar to the predicate device, all tested articles were able to reach M1 region of model neurovasculature. All samples passed. This confirms functional equivalence between the predicate and the modified device. The added length to the proximal shaft does not affect the working (distal) shaft of the catheter.
Dimensional Verification	Purpose is to verify that all dimensional requirements will meet the specified attributes. Performed visual and dimensional inspection on pre- and post-sterile.	Test samples were inspected and passed the specified attributes as specified. All test articles met the visual and dimensional specifications pre-sterilization and post-sterilization. Modified and predicate device meet the same equivalent requirements.
Material verification	The purpose is to verify that all materials are as specified in raw material, final assembly, subassembly specifications and vendor certifications.	The results verified that all materials are as specified and confirms that all material of the modified device and the predicate are identical therefore equivalent.
Catheter/ Guide Catheter Compatibility	The purpose is to verify that the catheter can track through a guiding catheter with an I.D. ≥ 0.0445".	The added length to the proximal shaft does not affect the working (distal) shaft of the catheter that goes through the guide catheter. The passing test results of the predicate device apply to the modified device and therefore equivalent. Results are also confirmed with Accessibility/Tractability Test (above).
Catheter/Guide Wire Compatibility	Catheter is able to track over the guide wire that is ≤ 0.025" in diameter.	The added length to the proximal shaft does not affect the working (distal) shaft of the catheter that goes through the guide catheter. The passing test results of the predicate device apply to the modified device and therefore equivalent. Results are also confirmed with Accessibility/Tractability Test (above).
Catheter/ RHV Compatibility and Leakage Verification	Catheter is compatible with rotating hemostasis value (RHV) in dimension and RHV will not leak during use.	The added length to the catheter shaft does not affect the RHV connection. It is the identical RHV. The passing test results of the predicate device apply to the modified device and therefore equivalent.

Test Description	Test Method Summary	Results
Shaft Stiffness	Catheter shaft to meet specification on stiffness.	The added length to the proximal shaft does not affect the shaft stiffness of the working (distal) shaft of the catheter that goes into the body. The passing test results of the predicate device apply to the modified device and therefore equivalent. Results are also confirmed with Accessibility/ Tractability Test (above).
Chemical Compatibility	Catheter should show no damage when exposed to saline and contrast medium.	Materials are all identical. The passing test results of the predicate device apply to the modified device and therefore equivalent.
Shaping Mandrel compatibility & shapeability	The purpose is to verify that the steam shaping mandrel fits the distal lumen of the catheter; the tip meets retention specification and dimensional shrinkage OD and ID requirements.	The added length to the proximal shaft does not affect the working (distal) shaft of the catheter is subjected to tip shaping. The passing test results of the predicate device apply to the modified device and therefore equivalent.
Kink Resistance	The purpose of the test is to verify that the catheter distal shaft will not kink when tested in accordance with BS EN 13868:2002 Annex A; and lumen integrity when catheter is looped to predetermine diameter. Method, equipment and conditions as prescribed in standard.	The added length to the proximal shaft does not affect the working (distal) shaft of the catheter is subjected to kinking. The passing test results of the predicate device apply to the modified device and therefore equivalent.
Conical Fitting for Hub	The purpose of the test is to verify that the catheter hub will meet the testing requirements as specified in BS EN 1707:1997. Method, equipment and conditions as prescribed in standard.	The added length to the catheter proximal shaft does not affect the hub connection. It is the identical hub. The passing test results of the predicate device apply to the modified device and therefore equivalent.
Corrosion Resistance	Catheter shall show no sign of corrosion per ISO10555-1:2013 Annex A. (material characterization only)	Materials are all identical. The passing test results of the predicate device apply to the modified device and therefore equivalent.

Test Description	Test Method Summary	Results
Tensile Strength of catheter body, hub attachment, distal attachment	The tip, distal, mid, proximal and hub junctions should meet the tensile strength requirement per EN ISO-10555-1: Annex B. Method, equipment and conditions as prescribed in standard.	The added length to the proximal shaft does not affect the various catheter segments, hub or distal attachments of the catheter. The passing test results of the predicate device apply to the modified device and therefore equivalent.
Liquid Leakage at Hub	No liquid leakage detected per BS EN ISO 10555-1:2013 Annex C. Method, equipment and conditions as prescribed in standard.	The added length modification does not affect the hub attachments to the catheter. The passing test results of the predicate device apply to the modified device and therefore equivalent.
Air Leakage During Aspiration	No leak detected when tested BS EN ISO 10555-1:2013 Annex D. Method, equipment and conditions as prescribed in standard.	The added length does not affect the various catheter segments and joints of the catheter. The passing test results of the predicate device apply to the modified device and therefore equivalent.
Rupture Pressure	Verify that the catheter can withstand predetermined static and dynamic rupture pressure testing.	The added length does not affect the various catheter segments, joints or methods of fabrication of the catheter. The passing test results of the predicate device apply to the modified device and therefore equivalent.
Particulate	Verify particulate levels catheter.	The added length does not affect the material, method and environment of fabrication of the catheter that affects particulates. The passing test results of the predicate device apply to the modified device and therefore equivalent.
Outer Surface Coating Lubricity and Durability	Test is to verify predetermine friction force of the coating.	The added length to the proximal shaft does not affect the working (distal) shaft of the catheter which is coated. The passing test results of the predicate device apply to the modified device and therefore equivalent.
Flexural Fatigue	The test method is to verify that the catheter structure will remain intact after predetermined number of cycles when used to accessing in a simulated torturous path model.	The added length does not affect the design of the shaft segments or joints of the catheter which affect flexural fatigue. The passing test results of the predicate device apply to the modified device and therefore equivalent.

Conclusion of the Pre-Clinical Bench Testing

Based on the non-clinical testing provided above in **Table B**, the proposed modified device is as safe, as effective, and performs as well or better than the legally marketed device. The additional length will assist the user in the set-up procedures without affecting the performance or safety of the device. The accessibility, trackability, high pressure flow rate testing show that the modified device is substantially equivalent to the predicate device.

Substantial Equivalence Determination

The information presented in the 510k shows that the modified Phenom® 27 Catheters are substantially equivalent to predicate Phenom® 27 catheters regarding the following aspects:

Design:	The subject and predicate devices are substantially equivalent with respect to design characteristics. The modified devices provide the user with additional effective length on the proximal shaft of the catheter which remain outside the patient. The working (distal) shaft of the catheter that enters the body is identical.
Function:	The subject and predicate devices are substantially equivalent with respect to functional characteristics. The modified devices provide the user with additional length on the proximal shaft of the catheter to assist in the procedural set-up. The working (distal) portion of the catheter that enters the body is identical. Trackability and accessibility testing was performed to verify that the modified catheter can reach the MI region of the neurovascular model.
Manufacturing:	The subject and predicate devices are the same with respect to technological manufacturing processes.
Materials:	The subject and predicate devices are composed of identical materials, all of which have an extensive clinical history of safe use in medical devices.
Indications:	The subject and predicate devices have identical indications.
Packaging:	The subject and predicate devices utilize same 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.

Conclusion for Substantial Equivalence Determination

Based on the comparison of the technological characteristics and the non-clinical testing provided in **Table A** & **Table B** (respectively, above), the proposed modified device is as safe, as effective, and performs as well or better than the legally marketed Phenom ® 27. The additional length of the proximal shaft will assist the user in the set-up procedures without affecting the safety performance of the device.

Testing was conducted to show that no new risks were identified, and that the performance and risk profile is the same as the predicate devices cleared for the market. Additional testing as identified in the risk analysis was performed to show that the modified Phenom® 27device is substantially equivalent to the predicate Phenom® 27 device.