September 7, 2021

Applied Medical Resources Corporation
Jessica Piovarcsik
Director, Regulatory Affairs
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K202049
Trade/Device Name: Python Catheter/Over-the-Wire Latis Graft Cleaning Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: DXE, KRA
Dated: August 6, 2021
Received: August 9, 2021

Dear Jessica Piovarcsik:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or post marketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202049

Device Name
Python Catheter

Indications for Use *(Describe)*
Python catheters are indicated for removal of thromboemboli from the peripheral arterial system, and for occlusion and infusion of fluids into a vessel.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202049

Device Name
Over-the-Wire Latis Graft Cleaning Catheter

Indications for Use *(Describe)*
The Over-the-Wire Latis Graft Cleaning Catheter is indicated for the removal of thromboemboli from vascular grafts, and for occlusion and infusion of fluids into a graft.

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 – K202049

510(k) Submitter: Applied Medical Resources Corporation
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Rancho Santa Margarita, CA 92688
(949) 713 – 8000

Contact Person: Jessica Piovarcsik
Director, Regulatory Affairs
Applied Medical Resources Corporation
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Email: jessica.piovarcsik@appliedmedical.com

Preparation Date: September 7, 2021

Trade Name: Python® Embolectomy Catheter & Over-the-Wire Latis® Graft Cleaning Catheter

Common Name: Embolectomy Catheter

Device Classification: Product codes
DXE - Catheter, Embolectomy (21 CFR 870.5150)
KRA – Catheter, Continuous Flush (21 CFR 870.1210)
Device Class: Class II

Predicate Devices: Python Catheter
510(k)#: K970762
Product Code: DXE

Over-the-Wire Latis Graft Cleaning Catheter
510(k)#: K973465
Produce Code: DXE

Model Numbers:

A4E01	CE0340DR	A4GW6
A4E02	CE0380DR	
A4E03	CE0440DR	
A4E04	CE0480DR	
A4E05	CE0540DR	
A4E06	CE0580DR	
A4E07	CE0680DR	
A4E08		
A4E09		

Sterilization Method: Ethylene Oxide

Device Descriptions: The Python Embolectomy Catheter & Over-the-Wire Latis Graft Cleaning Catheters are sterile, single use vascular balloon catheters intended for use in the

	removal of thromboemboli, occlusion of vessels, and the infusion of fluids. The devices are intended for use in arterial vessels and artificial vascular grafts respectively. The body of the catheters utilize a dual lumen design with one inflation lumen used to inflate the balloon, and one through lumen allowing for insertion over a guide wire or infusion of fluids. The outer diameter of the body is designed to accommodate use with a standard percutaneous access sheath. The Over-the-wire Latis Graft Cleaning Catheter includes a braided mesh which surrounds the balloon and is designed to increase engagement with wall of artificial vascular graft.
General type of material used:	Polymers, metal
Indications for Use:	Python catheters are indicated for removal of thromboemboli from the peripheral arterial system and for occlusion and infusion of fluids into a vessel. The Over-the-Wire Latis Graft Cleaning catheter is indicated for the removal of thromboemboli from vascular grafts and for occlusion and infusion of fluids into a graft.
Environment of use:	Operating rooms
Duration and type of contact:	External communicating device in contact with circulating blood for less than 24 hours.

Summary of Technological Characteristics between Subject and Predicate Devices:

The subject and predicated devices are single use, vascular balloon catheters designed for the removal of thromboemboli from the arterial system and artificial vascular grafts. The devices are offered at in range of sizes varying with respect to lengths and inflated balloon diameter sizes to accommodate use in the vessels within their respective indications for use.

Modifications have been made to the design & materials of the subject devices, however, the underlying dual lumen design remains the same as their respective predicate device.

Differences in the indications for use statements:

Minor edits were made to the indications for use statements; however, these were simply for clarification and do not alter the meaning of the indications or the intended use of the devices.

The intended use of the subject Over-the-Wire Latis Graft Cleaning catheter has not changed. However, the indications for use statement was clarified to align with the terminology commonly utilized in the clinical environment by updating the term “thrombus” to “thromboemboli”. The terms “thrombus” and “thromboembli” are used interchangeably within the clinical setting. Therefore, the change is not considered an expansion of the indications for use.

The intended use of the Python catheter, has not changed. However, the indications for use were modified slightly to:

- Further clarify the devices should be used to remove thomboemboli from the *peripheral* arterial system; and
- Remove the term "temporary" from the intended use of occluding the vessel.

Peripheral arterial thromboembolisms are encompassed within the arterial thromboemboli stated in the indications for use of the predicate device. Therefore, the modification was only made to provide further clarity and is not considered an expansion of the intended use of the device.

The term "temporary" was the term is subjective and the duration of use of the device in occluding the vessel is intuitive to the user. Applied Medical has not changed the classification of the patient contact duration with respect to biocompatibility (i.e. in contact with blood < 24 hrs)

Discussion of Performance Testing:

The FDA recognized consensus standard International Standard Organization (ISO) 10555-1:ed2:2017 *Intravascular catheters – Sterile and single -use catheters – Part 1: General Requirements* was considered when evaluating the performance of the subject devices. The following test endpoints were utilized to demonstrate substantial equivalence to their respective predicate devices.

Engineering/Bench Testing

- Balloon Pull Force (ISO 10555-1, Annex B)
- Inflation & Guidewire Hub Pull Force (ISO 10555-1, Annex B)
- Catheter Body Tensile Strength
- Catheter Balloon Cycling Test
- Balloon Burst Pressure Test
- Inflated Balloon Diameter Inspection
- Guidewire & Inflation Hub Leak Test (ISO 10555-1, Annex C)
- Simulated Use Bend Test
- Torsion Test
- Kink Test (EN 13868, Annex B)

Biocompatibility Testing:

- Cytotoxicity
- Intracutaneous Irritation
- Sensitization
- Acute Systemic Toxicity
- Hemolysis
- Materials Mediated Pyrogenicity
- Platelet and Leukocyte Counts
- Partial Thromboplastin Time
- Complement Activation
- Thrombogenicity

Conclusion:

Both the subject Python Catheters and subject Over-the-wire Latis Graft Cleaning Catheters, with modified materials, are substantially equivalent in performance and intended use to the predicate Dual Lumen Embolectomy Catheters and Dual Lumen Graft Cleaning Catheter, respectively.