October 6, 2022

PFM Medical, Inc.
Jessica Jho
Regulatory Affairs Consultant
1916 Palomar Oaks Way Suite 150
Carlsbad, California 92008

Re: K213666
Trade/Device Name: NuCath Wedge Pressure Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: November 18, 2021
Received: November 22, 2021

Dear Jessica Jho:

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 postmarketing 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

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
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)*

K213666

Device Name

NuCath™ Wedge Pressure Catheter

Indications for Use *(Describe)*

The NuCath™ Wedge Pressure Catheter is indicated for measuring pressure in the right heart (including central venous pressure, right ventricle pressure, pulmonary artery pressure, and pulmonary artery wedge pressure).

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
As required by 21 CFR §807.92

I. SUBMITTER:

PFM Medical, Inc
1916 Palomar Oaks Way, Suite 150
Carlsbad, CA 92008

Contact Person: Jessica Jho
Regulatory Affairs
PFM Medical
JJho@pfmmedicalusa.com

Date Summary Prepared: November 18, 2021

II. DEVICE

Trade or Proprietary Name:	NuCath™ Wedge Pressure Catheter
Classification Name:	Catheter, Intravascular, Diagnostic
Device Class:	II
Regulation Number:	21 CFR §870.1200
Product Code:	DQO

III. LEGALLY MARKETED PREDICATE DEVICE

Predicate Device		
510(K)	**Product Name**	**Clearance Date**
K864943	NuMed Balloon Wedge Pressure Catheter	February 20, 1987

Reference Device		
510(K)	**Product Name**	**Clearance Date**
K960479	Arrow Bipolar Pacing/Balloon Wedge Pressure Catheter	October 19, 1996

IV. DEVICE DESCRIPTION

The NuCath Wedge Pressure Catheter is an intravascular catheter with a balloon at the distal tip intended to measure pressure in the right heart.

V. INDICATIONS FOR USE

The NuCath Wedge Pressure Catheter is indicated for measuring pressure in the right heart (including central venous pressure, right ventricle pressure, pulmonary artery pressure, and pulmonary artery wedge pressure).

VI. TECHNOLOGICAL COMPARISON TO PREDICATE

The technological features of the subject device, such as intended use, indications for use, design, function and technology, were compared to the predicate device and it was demonstrated that they are substantially equivalent. The following is a summary of the technological characteristics of the subject, predicate and reference devices:

	Subject Device: NuCath Wedge Pressure Catheter	Predicate Device: NuMed Balloon Wedge Pressure Catheter	Reference Device: Arrow Bipolar Pacing/Balloon Wedge Pressure Catheter	Comparison Discussion
Manufacturer	PFM Medical, Inc.	NuMed, Inc.	Arrow/Teleflex	Not Applicable
510(k) Number	Subject of this Review	K864943	K960479	Not Applicable
Indications for Use	The NuCath Balloon Wedge Catheter is indicated for measuring pressure in the right heart (including central venous pressure, right ventricle pressure, pulmonary artery pressure, and pulmonary artery wedge pressure).	Sampling blood for oxygen levels and measuring pressures in the right heart	For use in sampling blood for oxygen levels and measuring pressure in the right heart (including central venous pressure, right ventricle pressure, pulmonary artery pressure, and pulmonary artery wedge pressure). The second pressure lumen allows infusion of a solution with simultaneous measurement of pressure. The catheter is intended for temporary use in electrophysiology studies for intracardiac simulation and/or ECG recording only.	The subject device has the identical indication as the predicate device with the exception of the details specific to "right heart". The information in the parenthesis of the subject device is identical to the reference device and does not add a new intended use as compared to the predicate.
FDA Product Code	DQO (Catheter, Intravascular, Diagnostic) 21 CFR 870.1200	DQO (Catheter, Intravascular, Diagnostic) 21 CFR 870.1200	LDF (Electrode, Pacemaker, Temporary) 21 CFR 870.3680	The subject device is identical to the predicate.
Balloon Material	Pebax + TiO_2	Natural Latex	Unknown	Updated materials have successfully passed all required biocompatibility testing and do not add new or increased risk as compared to the predicate device.

	Subject Device: NuCath Wedge Pressure Catheter	Predicate Device: NuMed Balloon Wedge Pressure Catheter	Reference Device: Arrow Bipolar Pacing/Balloon Wedge Pressure Catheter	Comparison Discussion
Catheter Base Materials	Pebax, Bismouth Subcarbonate, TiO_2, Nylon	Tecoflex polyurethane w/ 20% Barium Sulfate	Unknown	Updated materials have successfully passed all required biocompatibility testing and do not add new or increased risk as compared to the predicate device.
Catheter Size (French)	4F, 5F, 6F	4F, 5F, 6F, 7F	4F, 5F, 6F, 8F	The French size of the subject devices are identical to the subject device except for the 7F, which is not part of the subject NuCath portfolio. The subject device does not add a worst case configuration as compared to the predicate device.
Max Inflation Vol. (cc/mL)	4F = 1.5 5F = 1.5 6F = 2.5	4F = .60 5F = .75 6F = 1 7F = 1.25	4F = .60 5F = .75 6F = 1 8F = 1.25	The subject device 6F catheter has a balloon diameter of 10mm, which has been qualified to 2.5cc/mL max inflation volume. The technological difference does not add a new or increased risk to the subject device as compared to the predicate device.
Sterility	100% Ethylene Oxide, SAL, 10^{-6}	100% Ethylene Oxide, SAL, 10^{-6}	Unknown	The subject device is identical to the predicate.
Single Use	Yes	Yes	Yes	The subject device is identical to the predicate.

VII. PERFORMANCE TESTING

A risk analysis per *ISO 14971: Medical devices – Application of risk management of medical devices* was conducted to assess the risk profile of the subject device. Control mechanisms, including design verification testing, were defined to mitigate the identified risks, to demonstrate that the subject device performs as intended and to evaluate substantial equivalence. Below is a list of non-clinical testing that is included in the submission:

Visual Inspection	Tip Pulling and Torquing
Balloon Preparation	Minimum Burst Strength
Diameter and Profile	Repeated Balloon Inflation (Balloon Fatigue)
Radio-detectability	Balloon Inflation and Deflation
Catheter Body Maximum Pressure	Balloon Deflatability
Hubs/Luers	Balloon Distensibility (Compliance)
Bond Strength (Peak Tensile Force)	

The following standards were referenced in the testing listed above:

- ISO 10555-1:2013, Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements [including Amendment 1 (2017)]
- ISO 10555-4: 2013, Intravascular Catheters – Sterile and single-use catheters – Part 4: Balloon dilation catheters
- ASTM F640-12, Standard Test Methods for Determining Radiopacity for Medical Use
- ISO 80369-1: 2018, Small-bore connectors for liquids and gases in healthcare applications – Part 1: General requirements
- ISO 80369-7: 2016, Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for Intravascular or hypodermic applications
- ISO 80369-20: 2015, Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods

Additionally, the NuCath Wedge Pressure Catheter were subjected to applicable biocompatibility testing as required per ISO 10993-1: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

The subject device met all predetermined acceptance criteria as defined in the referenced and internal standards.

VIII. CONCLUSION

Based on the information provided in this 510(k) submission, including the indications for use, technological characterizes, and performance testing result, the subject NuCath Wedge Pressure Catheter is substantially equivalent to the predicate device.