October 28, 2019

PFM Medical, Inc.
Mina Jiang
Associate Regulatory Affairs Specialist
1916 Palomar Oaks Way, Suite 150
Carlsbad, California 92008

Re: K192802
Trade/Device Name: primeMidline™ Catheters
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: PND
Dated: September 27, 2019
Received: September 30, 2019

Dear Mina Jiang:

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 Geeta Pamidimukkala
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192802

Device Name

4F Dual Lumen primeMidline™ Catheter

Indications for Use *(Describe)*

The primeMIDLINE™ Catheters are indicated for short term access to the peripheral venous system for selected intravenous therapies, blood sampling and power injection of contrast media. These catheters are indicated for patients older than 28 days and that weigh more than 10 kg, with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The primeMIDLINE™ Catheters are suitable for use with power injectors.

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 section 807.92

General Information	
510(k) Owner:	PFM Medical, Inc.
Submitter Address:	1916 Palomar Oaks Way, Suite 150 Carlsbad, CA 92008
Contact Person:	Mina Jiang
Telephone Number:	760.758.8749
Fax Number:	760.758.1167
Date of Preparation:	October 25, 2019
Subject Device Information	
Trade Name:	4F Dual Lumen *prime*MIDLINE™ Catheter
Premarket Notification:	K192802
Common Name:	Midline Catheter
Classification Name:	Intravascular Catheter
Product Code:	PND
Regulation Number:	21 CFR §880.5200
Predicate Device Information	
Trade Name:	*prime*MIDLINE™ Catheters
Premarket Notification:	K173114
Classification:	PND, 21 CFR §880.5200
Manufacturer:	PFM Medical, Inc.

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Device Description
The 4F DL *prime*MIDLINE™ Catheter is a peripherally placed midline catheter designed to provide access to the vascular system. The catheter lumen is an open-ended design comprised of radiopaque polyurethane. The 4F DL *prime*MIDLINE ™ Catheter is packaged sterile in a tray with the accessories necessary to establish short-term (less than 30 days) vascular access. The 4F DL *prime*MIDLINE Catheter is suitable for use with power injectors.
Indications for Use
The primeMIDLINE™ Catheters are indicated for short term access to the peripheral venous system for selected intravenous therapies, blood sampling and power injection of contrast media. These catheters are indicated for patients older than 28 days and that weigh more than 10 kg, with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The primeMIDLINE™ Catheters are suitable for use with power injectors.
Technological Characteristics
The proposed 4F Dual Lumen primeMIDLINE™ Catheter is substantially equivalent to the primeMidline Catheters previously reviewed and cleared under K173114. When compared to the predicate, the proposed 4F Dual Lumen primeMIDLINE™ Catheter has identical intended use, materials, overall design, components, technological characteristics and Indications for Use. The minor differences between the subject 4F DL primeMIDLINE™ catheter and the predicate device do not change the intended use of the device and they do not raise different questions of safety and effectiveness. The following is a summary of the technological characteristics of the 4F Dual Lumen primeMIDLINE™ catheter as compared to the predicate and reference devices:

	Subject Device: 4F Dual Lumen primeMIDLINE Catheter	**Predicate Device: primeMIDLINE Catheters**	**Comparison Discussion**
Manufacturer	PFM Medical, Inc.	PFM Medical, Inc.	This attribute is identical between the subject and predicate device.
510(k) Number	K192802	K173114	N/A
FDA Product Code	PND	PND	This attribute is identical between the subject and predicate device.
Intended Use	The primeMIDLINE™ Catheters are intended to access the vascular system for administration of fluids intravenously, blood sampling, and power injection of contrast media.	The primeMIDLINE™ Catheters are intended to access the vascular system for administration of fluids intravenously, blood sampling, and power injection of contrast media.	This attribute is identical between the subject and predicate device.

Indications for Use	The primeMIDLINE™ Catheters are indicated for short term access to the peripheral venous system for selected intravenous therapies, blood sampling and power injection of contrast media. These catheters are indicated for patients older than 28 days and that weigh more than 10 kg, with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The primeMIDLINE™ Catheters are suitable for use with power injectors.	The primeMIDLINE™ Catheters are indicated for short term access to the peripheral venous system for selected intravenous therapies, blood sampling and power injection of contrast media. These catheters are indicated for patients older than 28 days and that weigh more than 10 kg, with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The primeMIDLINE™ Catheters are suitable for use with power injectors.	This attribute is identical between the subject and predicate device.
Duration of Use	Short term (<30 days)	Short term (<30 days)	This attribute is identical between the subject and predicate device.
Duration of Use	Short term (<30 days)	Short term (<30 days)	This attribute is identical between the subject and predicate device.
Insertion Method	Percutaneous, using Modified Seldinger Technique and guidewire	Percutaneous, using Modified Seldinger Technique and guidewire	This attribute is identical between the subject and predicate device.
Tip Placement Location	Peripheral venous system, with catheter tip terminating prior to the axilla	Peripheral venous system, with catheter tip terminating prior to the axilla	This attribute is identical between the subject and predicate device.
Insertion Site	Peripheral	Peripheral	This attribute is identical between the subject and predicate device.
Catheter Base Materials	Shaft Tubing Polyurethane Catheter Junction Polyurethane Extension Legs Polyurethane Luer Hubs Polyurethane Extension Leg Clamps Acetal Resin	Shaft Tubing Polyurethane Catheter Junction Polyurethane Extension Leg(s) Polyurethane Luer Hub(s) Polyurethane Extension Leg Clamp(s) Acetal Resin	This attribute is identical between the subject and predicate device.
Catheter Proximal Configuration	Luer Connection	Luer Connection	This attribute is identical between the subject and predicate device.

Catheter Distal Configuration	Open Ended	Open Ended	This attribute is identical between the subject and predicate device.
Catheter Dimensions	4F Dual Lumen x 20cm length	3F Single Lumen x 20cm length 4F Single Lumen x 20cm length 5F Single Lumen x 20cm length 5F Dual Lumen x 20cm length	The French size of the catheter is reduced as compared to the 5F DL primeMidline configuration covered under K173114. The reduction in the French size does not raise new questions of safety and effectiveness. The fundamental operating principals, materials and overall design remain the same between the subject and predicate devices. The 4F DL primeMidline does not increase the current risk profile of or introduce new risks to the primeMidline family of catheters.
Number, Shape of Lumens	Dual Lumen = Double D	Single Lumen = Round Dual Lumen = Double D	Identical to 5F Dual Lumen configuration.
Depth Markings	Number every 5 cm and depth mark every cm	Number every 5 cm and depth mark every cm	This attribute is identical between the subject and predicate device.
Stylet Configuration	Pre-Inserted Stiffening Stylet	Pre-Inserted Stiffening Stylet	This attribute is identical between the subject and predicate device.

Power Injection Maximum Flow Rate	4F DL: 4mL/sec	3F SL: 6mL/sec 4F SL: 7mL/sec 5F SL: 7mL/sec 5F DL: 7mL/sec	The subject device has a different flowrate as compared to the predicate devices. This difference does not raise new questions of safety and effectiveness. Clinicians will determine which catheter size, lumen configuration and performance capabilities are appropriate based on patient size and need. The 4F DL primeMidline catheter represents one size and performance option in the family of primeMidline catheters. The differences in flowrate do not increase the current risk profile of or introduce new risks to the primeMidline family of catheters.
Sterility	100% Ethylene Oxide, SAL of 10^{-6}	100% Ethylene Oxide, SAL of 10^{-6}	This attribute is identical between the subject and predicate device.

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Performance Testing

PFM Medical, Inc. conducted a risk analysis per ISO 14971: *Medical devices – Application of risk management of medical devices* to assess the risk profile of the 4F DL primeMIDLINE™ catheter. Control mechanisms, including design verification testing, were defined to mitigate the identified risks and to demonstrate that the devices perform as intended. Below is a listing of non-clinical testing that was conducted on the subject device:

Visual Inspection	Tensile Strength
Dimensional Characteristics	Catheter Elongation
Radiopacity	Lifecycle Performance
Catheter Collapse	Static Burst Pressure
Leak	Suture Wing Integrity
Priming Volume	Luer Testing
Gravity Flowrate	Power Injection Flowrate

The following standards and FDA guidance documents were utilized in the testing listed above:

- ISO 10555-1:2013, Intravascular Catheters – Sterile and Single-Use Catheters
- ASTM F640-12 – Standard Test Methods for Determining Radiopacity for Medical Use
- ISO 80369-7:2016, Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications
- FDA Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters
- PFM Medical Internal Standards

Additionally, the primeMIDLINE™ catheters 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:

Cytotoxicity	Sensitization
Irritation or Intracutaneous Reactivity	Acute Systemic Toxicity
Material Mediated Pyrogenicity	Subacute/Subchronic Toxicity
Genotoxicity	Carcinogenicity
Chronic Toxicity	Hemocompatibility
Implantation	Particulate
Complement Activation Assay	

The subject device met all predetermined acceptance criteria as defined in the referenced Standards, FDA Guidance Document or PFM Medical, Inc. Internal Standards.

Conclusion

Based on detailed comparison of intended use, technological characteristics and performance testing of the subject and predicate device, the 4F DL primeMidline Catheter is substantially equivalent to the predicate primeMidline Catheters. Risk identification and verification and validation activities ensure that the risk acceptability criteria have been met, and the risks have been mitigated.