March 7, 2018

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

Re: K173114
Trade/Device Name: primeMidline™ Catheters
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: PND
Dated: February 1, 2018
Received: February 5, 2018

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. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K173114

Device Name

primeMidline™ Catheters

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 10kg, 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 K173114
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:	Jessica Jho, RAC
Telephone Number:	760.758.8749
Fax Number:	760.758.1167
Date of Preparation:	March 6, 2018
Subject Device Information	
Trade Name:	*prime*MIDLINE™ Catheters
Common Name:	Midline Catheter
Classification Name:	Intravascular Catheter
Product Code:	PND
Regulation Number:	21 CFR §880.5200
Predicate Device Information	
Trade Name:	PowerMidline Catheter
Premarket Notification	K153393
Classification	PND, 21 CFR §880.5200
Manufacturer	Bard Access Systems
Reference Device Information	
Trade Name:	4F Single Lumen, 5F Single Lumen and 5F Dual Lumen *prime*PICC Catheters
Premarket Notification	K083873
Classification:	L JS, 21 CFR §880.5970
Manufacturer:	PFM Medical, Inc.

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Device Description
The *prime*MIDLINE™ Catheters are a family of peripherally placed midline catheters designed to provide access to the vascular system. These catheters are offered in 3F, 4F and 5F Single Lumen and 5F Dual Lumen configurations with 20cm lengths. The catheter lumen is an open-ended design comprised of radiopaque polyurethane. Each *prime*MIDLINE™ Catheter is packaged sterile in a tray with the accessories necessary to establish short-term (less than 30 days) vascular access. The *prime*MIDLINE™ Catheters are suitable for use with power injectors.
Indications for Use
The *prime*MIDLINE™ 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 10kg, with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The *prime*MIDLINE™ Catheters are suitable for use with power injectors.
Technological Characteristics
The proposed *prime*MIDLINE™ Catheters are substantially equivalent to the Power Midline Catheters, previously reviewed and cleared under K153393. When compared to the predicate, the proposed *prime*MIDLINE™ Catheters have equivalent materials, design, components, technological characteristics and Indications for Use statements. The minor differences between the subject *prime*MIDLINE™ catheters 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 *prime*MIDLINE™ catheters as compared to the predicate and reference devices:

	Subject Device: *prime*MIDLINE™ Catheters	**Predicate Device: PowerMidline Catheters**	**Reference Device: 4F SL, 5F SL, 5F DL *prime*PICC Catheters**
Manufacturer	PFM Medical, Inc.	Bard Access Systems	PFM Medical, Inc.
510(k) Number	K173114	K153393	K083873
FDA Product Code	Identical to Predicate Devices	PND	L JS
Intended Use	Identical to Predicate/ Reference Devices	The PowerMidline catheter is intended to access the vascular system for administration of fluids intravenously, blood sampling, and power injection of contrast media.	The *pime*PICC catheters are intended to access the vascular system for administration of fluids intravenously, blood sampling, and power injection of contrast media.
Duration of Use	Identical to predicate PowerMidline Catheter	Short term (<30days)	Short term (<30days) or long term (>30 days)
Insertion Method	Identical to Predicate/ Reference Devices	Percutaneous, using Modified Seldinger Technique and guidewire	Percutaneous, using Modified Seldinger Technique and guidewire

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	Subject Device: *prime*MIDLINE™ Catheters	**Predicate Device: PowerMidline Catheters**	**Reference Device: 4F SL, 5F SL, 5F DL *prime*PICC Catheters**
Tip Placement Location	Identical to predicate PowerMidline Catheter	Peripheral venous system, with catheter tip terminating prior to the axilla	Central venous system, lower 1/3 of the Superior Vena Cava preferred
Insertion Site	Identical to Predicate/ Reference Devices	Peripheral	Peripheral
Catheter Base Materials	Identical to predicate PowerMidline Catheter	Shaft Tubing Polyurethane Catheter Junction Polyurethane Extension Leg Polyurethane Luer Hub Polyurethane Extension Leg Clamp Acetal Resin	Shaft Tubing Polyurethane Catheter Junction Polyurethane Extension Leg Polyurethane Luer Hub Polycarbonate Extension Leg Clamp Acetal Resin
Catheter Proximal Configuration	Identical to Predicate/ Reference Devices	Luer Connection	Luer Connection
Catheter Distal Configuration	Identical to Predicate/ Reference Devices	Open Ended	Open Ended
Catheter Dimensions	3F Single Lumen x 20cm length 4F Single Lumen x 20cm length 5F Single Lumen x 20cm length 5F Dual Lumen x 20cm length	3F SL x 20cm usable length 4F SL x 20cm useable length	4F Single Lumen x 50cm length 5F Single Lumen x 55cm length 5F Dual Lumen x 55cm length
Depth Markings	Identical to predicate/ reference devices	Number every 5 cm and depth mark every cm	Number every 5 cm and depth mark every cm
Stylet Configuration	Identical to predicate/ reference devices	Pre-Inserted Stiffening Stylet	Pre-Inserted Stiffening Stylet
Power Injection Maximum Flow Rate	3F SL: 5mL/sec 4F SL: 7mL/sec 5F SL: 7mL/sec 5F DL: 7mL/sec	3F SL = 3 mL/sec 4F SL = 7 mL/sec	5 mL/sec
Sterility	Identical to Predicate/ Reference Devices	100% Ethylene Oxide, SAL of 10^{-6}	100% Ethylene Oxide, SAL of 10^{-6}

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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 *prime*MIDLINE™ 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 is included in this submission:

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

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 F640-07 – Standard Test Methods for Determining Radiopacity for Medical Use
- ISO 594-1: 1986, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment- Part 1: General Requirements
- ISO 594-2: 1998, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment- Part 2: Lock Fittings
- FDA Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters
- PFM Medical Internal Standards

The *prime*MIDLINE™ catheters were subjected to the following 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	

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Performance Testing

The *prime*MIDLINE™ Catheters are sterilized by 100% Ethylene Oxide Gas with a Sterility Assurance level of 10^{-6}. The following sterilization qualification is applicable to the *prime*MIDLINE™ Catheters:

Sterilization Validation – Overkill Method	EO/ECH Residuals
Direct Product Sterility	Bioburden / Organism Characterization
Bacteriostasis Fungistasis Testing	Bacterial Endotoxins / Limulus Amebocyte Lysate

The sterilization testing listed above was conducted in accordance with the following standards:

- AAMI/ANSI/ISO 11135:2014, Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
- ANSI/AAMI/ISO 11737-1: 2006/(R)2011, Sterilization of health care products - Microbiological methods - Part 1: Determination of the population of microorganisms on product
- ANSI/AAMI/ISO 11737-2: 2009/(R)2014, Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- AAMI/ANSI/ISO 10993-7:2008, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals
- ANSI/AAMI ST72:2011/(R)2016, Bacterial Endotoxin–Test methods, routine monitoring, and alternatives to testing

The subject devices met all predetermined acceptance criteria as defined in the referenced Standards, FDA Guidance Documents 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 *prime*Midline Catheters are substantially equivalent to the predicate Power Midline Catheters.