May 2, 2025

PFM Medical, Inc
Jessica Jho
Director, Regulatory Affairs
1916 Palomar Oaks Way
Carlsbad, California 92008

Re: K242763
Trade/Device Name: JetCan® Pro Safety Huber Needle
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: April 1, 2025
Received: April 1, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Porsche Bennett
For David Wolloscheck, Ph.D
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242763

Device Name
JetCan® Pro Safety Huber Needle

Indications for Use *(Describe)*
The JetCan® Pro Safety Huber Needle is indicated for use in the delivery of fluids and drugs, as well as blood sampling through surgically implanted vascular access ports for up to 24 hours. It is compatible with power injection ports and associated power injection procedures up to 325 psi.

The JetCan® Pro Safety Huber Needle incorporates a passive safety mechanism, activated upon the withdrawal from a port catheter to aid in the prevention of accidental needle sticks and minimize exposure to hazardous fluids.

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.

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K242763 - 510(k) Summary

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

I. SUBMITTER

PFM Medical, Inc
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Carlsbad, CA 92008, USA

Contact Person: Jessica Jho
Director, Regulatory Affairs
PFM Medical, Inc
JJho@pfmmedicalusa.com
760.758.8749

Date Summary Prepared: May 2, 2025

II. DEVICE

Trade or Proprietary Name	JetCan® Pro Safety Huber Needle
Common Name	Set, administration, intravascular
Regulation Name	Intravascular Administration Set
Device Class	Class II
Regulation Number	21 CFR §880.5440
FDA Product Code	FPA

III. LEGALLY MARGETED PREDICATE DEVICE

Predicate Device		
510(k)	**Product Name**	**Clearance Date**
K071846	EZ Huber Safety Infusion Set	August 8, 2007

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IV. DEVICE DESCRIPTION

The JetCan® Pro Safety Huber Needle is a non-coring Huber needle used to access the septum of a surgically implanted vascular access port for the delivery of intravenous fluids, blood sampling and power injection of contrast media, up to 5 mL/s at 325 psi.
The JetCan® Pro Safety Huber Needle is a single use, external communicating device, with direct blood contact and a duration of use of less than or equal to 24 hours. The JetCan® Pro Safety Huber Needle consists of the following components:

Component	Material
Needle	Stainless Steel
Needle Housing	Polycarbonate
Comfort Pad	Closed cell polyethylene foam, Medical Foam Tape
Rack Housing	Polycarbonate Acrylated urethane, Pellethane, Stainless Steel
Tape	Photo Film Splicing Tape
Pull Up Wing	Polypropylene
Extension tubing	Thermoplastic Polyurethane
Pinch Clamp (s)	Polypropylene
Y-Site Luer	Rigid polyvinyl chloride (PVC)
Female Luer	Copolyester
Dust cap(s)	MABS polymer

Below is a table listing the configurations for the JetCan® Pro Safety Huber Needle:

Size	Extension	Flow Rate	Priming Volume
19 G × 15 mm	Straight	5 mL/s	0.2 mL
19 G × 19 mm	Straight	5 mL/s	0.2 mL
19 G × 25 mm	Straight	5 mL/s	0.2 mL
19 G × 38 mm	Straight	5 mL/s	0.2 mL
20 G × 15 mm	Straight	5 mL/s	0.2 mL
20 G × 19 mm	Straight	5 mL/s	0.2 mL
20 G × 25 mm	Straight	5 mL/s	0.2 mL
20 G × 38 mm	Straight	5 mL/s	0.2 mL
22 G × 15 mm	Straight	2 mL/s	0.2 mL
22 G × 19 mm	Straight	2 mL/s	0.2 mL
22 G × 25 mm	Straight	2 mL/s	0.2 mL

Size	Extension	Flow Rate	Priming Volume
22 G × 38 mm	Straight	2 mL/s	0.2 mL
19 G × 19 mm	Y-site	5 mL/s	0.3 mL
19 G × 25 mm	Y-site	5 mL/s	0.3 mL
19 G × 38 mm	Y-site	5 mL/s	0.3 mL
20 G × 19 mm	Y-site	5 mL/s	0.3 mL
20 G × 25 mm	Y-site	5 mL/s	0.3 mL
20 G × 38 mm	Y-site	5 mL/s	0.3 mL
22 G × 19 mm	Y-site	2 mL/s	0.3 mL
22 G × 25 mm	Y-site	2 mL/s	0.3 mL
22 G × 38 mm	Y-site	2 mL/s	0.3 mL
19 G x 19 mm	Straight	5 mL/s	0.2 mL
19 G x 25 mm	Straight	5 mL/s	0.2 mL
19 G x 38 mm	Straight	5 mL/s	0.2 mL
20 G x 19 mm	Straight	5 mL/s	0.2 mL
20 G x 25 mm	Straight	5 mL/s	0.2 mL

V. INDICATIONS FOR USE

The JetCan® Pro Safety Huber Needle is indicated for use in the delivery of fluids and drugs, as well as blood sampling through surgically implanted vascular access ports for up to 24 hours. It is compatible with power injection ports and associated power injection procedures up to 325 psi.

The JetCan® Pro Safety Huber Needle incorporates a passive safety mechanism, activated upon the withdrawal from a port catheter to aid in the prevention of accidental needle sticks and minimize exposure to hazardous fluids.

VI. TECHNICAL COMPARISON TO PREDICATE

The technological design features of the subject device, such as intended use, indications for use, overall design, function, and technology, were compared to the predicate device and are described below:

	Subject Device: **JetCan® Pro Safety Huber Needle**	**Predicate Device:** **EZ Huber Safety Infusion Set**	**Comparison Discussion**
Indications for Use	The JetCan Pro Safety Huber Needle is indicated for use in the delivery of fluids and drugs, as well as blood sampling through surgically implanted vascular access ports for up to 24 hours. It is compatible with power injection ports and associated power injection procedures up to 325 psi. The JetCan Pro Safety Huber Needle incorporates a passive safety mechanism, activated upon the withdrawal from a port catheter to aid in the prevention of accidental needle sticks and minimize exposure to hazardous fluids.	The EZ Huber Safety Infusion Set is a device used to administer fluids from a container to a patient's vascular system through an implanted port. The EZ Huber Safety Infusion Set incorporates an active safety feature that aids in the prevention of accidental needle sticks. The EZ Huber Safety Infusion Set is a safety needle designed with an anti-coring needle tip configuration. The primary use for Huber needles is to deliver solutions to implanted ports. The safety feature is designed to protect the practitioner from accidental needle sticks.	The subject and predicate devices have similar indications for use although the wording of the statements is different. Both are intended to be used to access surgically implanted vascular access ports. The clerical differences do not indicate differences in intended use.
FDA Product Code	FPA (Intravascular administration set), 21 CFR 880.5440	FPA (Intravascular administration set), 21 CFR 880.5440	The subject device has the identical FDA Product Code as the predicate.
Placement	Utilized to access the septum of surgically implanted vascular access port catheters.	Utilized to access the septum of surgically implanted vascular access port catheters.	The subject device has the identical placement location as the predicate.

	Subject Device: JetCan® Pro Safety Huber Needle	Predicate Device: EZ Huber Safety Infusion Set	Comparison Discussion
Patient Population	The device is utilized in long term intravenous access pediatric or adult patients with a surgically implanted port catheter. The trained user determines the appropriate device configuration for each individual patient after considering the contraindications, the health condition of the patient and personal clinical experience	The device is utilized in long term intravenous access pediatric or adult patients with a surgically implanted port catheter. The trained user determines the appropriate device configuration for each individual patient after considering the contraindications, the health condition of the patient and personal clinical experience	The subject device is utilized in the same patient population as the predicate device.
Design	JetCan® Pro Safety Huber Needle is comprised of the following parts: needle, safety mechanism, extension tube, female Y site (optional) and a female luer. The extension tube(s) contains a thumb clamp	EZ Huber Safety Infusion Set is comprised of the following parts: needle, safety mechanism, extension tube, female Y site (optional) and a female luer. The extension tube(s) contains a thumb clamp	The design of the subject device is identical to the predicate device.
Device Base Materials	Stainless steel needle Polycarbonate needle housing Foam pad Polyurethane Extension tubing Copolyester or PVC-DEHP Free luers	Stainless steel needle. Polycarbonate needle housing Foam pad Polyurethane Extension tubing Copolyester or PVC-DEHP Free luers	The base materials of the known critical components of the subject and predicate devices are identical.
Device Sizes	Needle Sizes: 19, 20, 22 gauge Needle Length: 0.50”, 0.75”, 1”, 1.5”	Needle Sizes: 19, 20, 22 gauge Needle Length: 0.50”, 0.75”, 1”, 1.5”	The device sizes of the predicate and subject are identical.
Flow Rate	2 or 5 mL/s at 325 psi	300 psi	The subject device has been qualified and demonstrated through design verification testing to withstand pressures during injection of 325 psi. This difference does not impact the safety profile of the device as compared to the predicate as the hazards are identical.

	Subject Device: JetCan® Pro Safety Huber Needle	Predicate Device: EZ Huber Safety Infusion Set	Comparison Discussion
Safety Mechanism	The JetCan Pro Safety Huber Needle incorporates a passive safety mechanism, activated upon the withdrawal from a port catheter to aid in the prevention of accidental needle sticks and minimize exposure to hazardous fluids.	The EZ Huber Safety Infusion Set incorporates a passive safety mechanism, activated upon the withdrawal from a port catheter to aid in the prevention of accidental needle sticks and minimize exposure to hazardous fluids.	Both the subject and predicate devices incorporate a passive safety mechanism. The safety mechanisms are not identical, however the method of activation for the subject devices is not novel and its use has been validated through simulated use testing.

VII. PERFORMANCE DATA

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.

The following testing was conducted:

- Peak Tensile Force
- Positive Pressure Leakage
- Negative Pressure Leakage
- Luer Testing
- Burst Pressure
- Power Injection Flowrate
- Gravity Flowrate
- Priming Volume
- Particulate Evaluation
- Needle Surface
- Non-Coring
- Needle Safety
- Surface Lubrication
- Mechanical Hemolysis
- MRI Compatibility
- Corrosion Resistance
- Biocompatibility Per ISO 10993-1

The subject device conforms to the applicable sections of the following FDA Recognized Standards:

- ISO 8536-4, 2019: Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed
- ISO 6009, 2016: Hypodermic needles for single use – Colour coding for identification
- ISO 9626, 2016: Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ISO 10555-1, 2023: Intravascular catheters - Sterile and single-use intravascular catheters - Part 1: General requirements
- ISO 7864, 2016: Sterile hypodermic needles for single use - Requirements and test methods
- ISO 80369-7, 2021: 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
- ISO 10993-1, 2018: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 23908, 2011: Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
- ISO 10993-7, 2008: Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- 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 [Including: Amendment 1 (2018)]

- ANSI/AAMI IEC 62366-1, 2020: Medical devices - Part 1: Application of usability engineering to medical devices
- ISO 11607, 2019: Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including Amendment 1 (2023)]

VIII. CLINICAL TESTING

Clinical data was not required to support a substantial equivalence determination.

IX. CONCLUSION

Based on the information provided, the differences between the subject and predicate device do not raise new or different questions of safety and effectiveness. Therefore, it has been determined that the subject device is substantially equivalent to the legally marketed predicate device, K071846.