February 13, 2026

Puracath Medical, Inc.
Julia Rasooly
Chief Executive Officer
37600 Central Court
Suite 210
Newark, California 94560

Re: K251375
Trade/Device Name: PuraCath Firefly Needleless Connector IT (9005)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA

Dear Julia Rasooly:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on February 12, 2026. Specifically, FDA is updating this substantial equivalence (SE) letter as an administrative correction to include the correct version of the SE letter, 510(k) Summary, and IFU for K251375.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact David Wolloscheck, OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices, 301-796-1480, david.wolloscheck@fda.hhs.gov.

Sincerely,

DAVID WOLLOSCHECK -S

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

February 12, 2026

Puracath Medical, Inc.
Julia Rasooly
Chief Executive Officer
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Re: K251375
Trade/Device Name: PuraCath Firefly Needleless Connector IT (9005)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA
Dated: December 29, 2025
Received: December 29, 2025

Dear Julia Rasooly:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

DAVID WOLLOSCHECK -S

David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
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General Hospital, and Urology Devices
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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)*
K251375

Device Name
PuraCath Firefly Needleless Connector IT (9005)

Indications for Use *(Describe)*
The PuraCath™ Firefly™ Needleless Connector IT is a sterile single patient use connector for needleless access to the IV line and/or IV catheter during IV therapy and can be used for direct injection, intermittent infusion, continuous infusion or aspiration.

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.

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PRAStaff@fda.hhs.gov

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1 General Company Information

Company Name:	PuraCath Medical, Inc.
Company Address:	37600 Central Court, Suite 210 Newark, CA 94560 USA
Company Telephone:	415.305.4134
Official Contact	Julia Rasooly 415.305.4134 julia@puracath.com
Date Prepared:	February 12, 2026

2 Device Identification

Classification Name:	IV Administration Set,
Common Name:	Needleless Connector, Closed Access
Trade Name:	Firefly Needleless Connector IT
Classification:	Class II, 21 CFR 880.5440, Product code: FPA
Predicate Device:	PuraCath Firefly Needleless Connector (K203796)

3 Device Description

3.1 Subject Device Overview

The PuraCath™ Firefly™ Needleless Connector IT is a sterile single patient use connector for needleless access to the IV line and/or IV catheter during IV therapy and can be used for direct injection, intermittent infusion, continuous infusion or aspiration.

PuraCath Medical received clearance for the predicate Firefly Needleless Connector (9001) under K203796. PuraCath would like to inform the FDA that two minor changes have been made to the predicate Firefly Needless Connector. Although most of the components and processes are identical for the two designs, minor modifications involve a slightly shorter and lighter design, resulting in the subject Firefly Needleless Connector IT. The Model Numbers for the Predicate and Subject Devices are listed in **Table 17-02.1**

Table 1 Model Number for Subject and Predicate Devices

Model Number	Model Name	Device Type
9001	Firefly Needleless Connector	Predicate Device
9005	Firefly Needleless Connector IT	Subject Device

4 PuraCath Firefly Needleless Connector IT

The PuraCath Firefly Needleless Connector IT is a neutral displacement needleless connector intended for connection to the female luer port(s) of a vascular access catheter. The Firefly Needleless Connector IT is for single patient use, including pediatrics and immunocompromised patients, for direct injection, intermittent infusion, continuous infusion or aspiration of drugs, blood and fluids when using a vascular access device. The Firefly Needleless Connector IT is a closed, luer activated device. This means that when the Firefly Needleless Connector IT is attached to the female luer of the vascular access catheter, the valve remains closed until the ISO male luer of the accessing syringe, extension set, or standard administration set activates the flow of fluid through the needleless connector. The PuraCath Firefly Needleless Connector IT does not require a specific clamping sequence or technique in order to be used safely. The clear housing and open, fluid filled design enhances flushing practice. There is no interstitial or dead space internal to the connector. Refer to **Figure 17-02.1** for a visual representation of the device.

Figure 1 PuraCath Firefly Needleless Connector IT

5 Indications for Use

The PuraCath™ Firefly™ Needleless Connector IT is a sterile single patient use connector for needleless access to the IV line and/or IV catheter during IV therapy and can be used for direct injection, intermittent infusion, continuous infusion or aspiration.

6 Firefly Needleless Connector IT Technological Comparison with Predicate Device

Table 2 provides the key technological characteristics of the subject Firefly Needleless Connector IT compared to the predicate PuraCath Firefly Needleless Connector.

Table 2 Key Technological Characteristics of the Firefly Needleless Connector IT

Characteristic	Subject Device	Predicate Device	Analysis of Differences
Device name	Firefly Needleless Connector IT	Firefly Needleless Connector K207396	**N/A**
Common Name	IV Administration Set	IV Administration Set	**Same**
Classification	Class II, IV Administration Set, Needleless Connector, Closed Access	Class II, IV Administration Set, Needleless Connector, Closed Access	**Same**
Indications for use	The PuraCath™ Firefly™ Needleless Connector IT is a sterile single patient use connector for needleless access to the IV line and/or IV catheter during IV therapy and can be used for direct injection, intermittent infusion, continuous infusion or aspiration.	The PuraCath™ Firefly™ Needleless Connector Is a sterile single patient use connector for needleless access to the IV line and/or IV catheter during IV therapy and can be used for direct Injection, Intermittent infusion, continuous infusion or aspiration	**Same**
General System Design (Mechanism of Action)	External Flow Normally Closed Elastomeric Valve, Luer Activated	External Flow Normally Closed Elastomeric Valve, Luer Activated	**Same**
Proximal Configuration	Female Luer Lock with Luer Actuated Valve	Female Luer Lock with Luer Actuated Valve	**Same**
Distal Configuration	Male Luer Lock, Locking Threads molded with Male Luer Taper	Male Luer Lock, Separate Locking Ring attached over Male Luer Taper	**Different**
Length	1.2 in	1.6 in	**Different**
Weight	2.4 g	3.2 g	**Different**
Priming Volume	0.16 ml	0.16 ml	**Same**
Hemolysis	Non-hemolytic	Non-hemolytic	**Same**
Connector Gravity Flow rate	Flow rate at gravity with 1 m head height > 67ml/minute	Flow rate at gravity with 1 m head height > 67ml/minute	**Same**
Connector Fluid Displacement	<9 µL	<9 µL	**Same**
Flush Volume	5 ml	5 ml	**Same**
Power Infusion Flow Rate	10ml/sec @325 PSI	10ml/sec @325 PSI	**Same**
Use	Single patient	Single patient	**Same**
Duration of Use	7 days	7 days	**Same**
Number of Activations	200	200	**Same**
Electronic Chip	Yes	Yes	**Same**
Sterilization Method	Ethylene Oxide	Ethylene Oxide	**Same**
Sterile Barrier Packaging	Tyvek polyethylene; heat-sealed	Tyvek polyethylene; heat-sealed	**Same**

Characteristic	Subject Device	Predicate Device	Analysis of Differences
Packaged Quantity	Single Unit per Package	Single Unit per Package	**Same**

6.1 Technological Characteristics and Substantial Equivalence

The subject Firefly™ Needleless Connector IT uses identical components and processes as the predicate Firefly™ Needleless Connector except that the Firefly™ Needleless Connector IT does not have a separately attached threaded collar and the Connector Bottom luer configuration is different in the two models. The devices are made from the same materials, and the same chemicals are used in the manufacturing of both (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents, etc.).

There are minor differences in technological characteristics of the subject Firefly Needleless Connector IT pertaining to dimensions and mass compared to the predicate/parent Firefly Needleless Connector. However, these differences do not raise new safety or effectiveness issues, as verified by performance testing.

Similarities:

General System Design: Both devices use a luer activated, external flow, normally closed elastomeric valve for needleless access to an IV line and/or IV catheter during IV therapy. Both devices have the same electronic chip for identification by accessory devices. Both devices have identical female luer lock with luer activated valve proximal configurations.

Performance Characteristics: Both devices have the same performance characteristics, including but not limited to: the same priming volume of 0.16 mL, non-hemolytic properties, a flow rate of ≥ 67 mL/minute at gravity with a 1m head height, a connector fluid displacement of < 9 uL, a flush volume of 5 mL, a power infusion flow rate of 10 mL/second at 325 psi, are single patient use needleless connectors, and can be used for up to seven (7) days or two hundred (200) activations.

Materials: Both devices use biocompatible materials for patient-contacting components

Sterilization and Packaging: Both devices are sterilized with ethylene oxide (EO) and packaged individually in Tyvek pouches.

Differences:

Distal Configuration:
Both systems have male luer connectors with locking threads. Molding the threads instead of attaching a separate collar simplifies the manufacturing process and facilitates a shorter and lighter needleless connector. The functionality is identical.

Predicate Device: Male Luer Lock, Separate Locking Ring attached over Male Luer Taper
Subject Device: Male Luer Lock, Locking Threads molded with Male Luer Taper

Length:
The overall length of the subject needleless connector is shorter. Shortening the connector results in a slightly lighter part. The functionality is identical.
Predicate Device: 1.6 in
Subject Device: 1.2 in

Weight:
The weight of the subject device is slightly lower than the predicate device. A slightly lighter connector results in less force pulling on attached catheters and may result in minimal decrease in discomfort to the user. The functionality is identical.
Predicate Device: 2.4 g
Subject Device: 3.2 g

7 Performance Testing

The following non-clinical data were provided in support of the substantial equivalence determination:

Biocompatibility

The subject PuraCath Firefly Needleless Connector IT is constructed using materials and processes that are the same as the predicate PuraCath Firefly Needleless Connector. The biocompatibility evaluation previously performed on the predicate PuraCath Firefly Needleless Connector demonstrates the biocompatibility of the subject PuraCath Firefly Needleless Connector IT. The results previously reported for the predicate PuraCath Firefly Needleless Connector have been included in this submission as well. Biocompatibility testing was conducted per Guidance Document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," Guidance for Industry and Food and Drug Administration Staff (September 8, 2023) and "Guidance for Industry and FDA Staff – Intravascular Administration Sets Premarket Notification Submissions [510(k)]" (July 11, 2008) as recognized by the FDA. Biocompatibility testing was conducted in accordance with the cited guidance and standards as required for an External Communicating Device, Blood Path Direct Contact (Infusion Only), Prolonged Duration.

Table 3 Biocompatibility Testing

TEST	STANDARD	RESULT
Cytotoxicity	ISO 10993-5: 2009, Biological Evaluation of Medical Devices Part 5: Tests for *in vitro* Cytotoxicity	**Pass**- No reactivity
Intracutaneous reactivity Irritation in Rabbits	ISO 10993-10: 2013 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization	**Pass** – Non-irritant
Sensitization	ISO 10993-10: 2013 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization	**Pass** – Non-sensitizing
Acute Systemic Toxicity	ISO 10993-1 1:2017 Biological evaluation of medical devices Part 11: Tests for systemic toxicity	**Pass** – Did not cause acute systemic toxicity
Hemolysis	ASTM F 756 – 17: Standard Practice for Assessment of Hemolytic Properties of Materials	**Pass** – Non-hemolytic
Pyrogenicity	USP Pyrogen Test Procedure, Section <151> (USP40)	**Pass** – Non-pyrogenic

The subject PuraCath Firefly Needleless Connector IT is constructed using materials and processes that are the same as the predicate PuraCath Firefly Needleless Connector. Nonclinical bench testing was performed on attributes that could be affected by the differences in the design and processing, where additional testing was not required, the non-clinical bench testing previously performed on the predicate PuraCath Firefly Needleless Connector demonstrates those attributes of the PuraCath Firefly Needleless Connector have been met. The results for attributes that did not require additional testing to support the subject design were previously reported for the predicate PuraCath Firefly Needleless Connector and have been included in this submission as well. The following nonclinical bench testing was conducted on the subject Firefly Needleless Connector IT to determine the proposed device is substantially equivalent to the predicate device. Where previous testing has been referenced has been indicated.

Table 4 Performance Testing

TEST	STANDARD	RESULT
Particulate Matter*	USP <788> Particulate Matter in Injections	**Pass**
Sterility*	ISO 11135:2014, Ethylene oxide – Requirements for development, ISO 10993-7:2008, Biological evaluation of medical devices – Part 7 - Ethylene oxide sterilization residuals validation and routine control	**Pass**
Sterilization Family Adoption	AAMI TIR28:2016 Product adoption and process equivalence for ethylene oxide sterilization	**Pass**
6 Month Shelf Life*	ISO 11607-1 Second Edition 2019-02: Packaging for terminally sterilized medical devices – Part 1. Requirements for materials, sterile barrier systems, and packaging systems	**Pass**
MR Compatibility*	FDA Guidance: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment: 2014	**Pass**
FDA Guidance Compliance: Microbial ingress* Fluid displacement Flow rate at gravity* Power infusion flow* Flush volume Priming volume Size and weight Valve actuation force* Valve recovery* Valve cycle test* Valve back pressure test Valve pressure test Tensile strength Flexural strength	FDA Guidance: Intravascular Administration Sets Premarket Notification Submission [510(k)]: 2008	**Pass**

ISO 8536-4 Compliance Particulate contamination* Leakage Tensile strength Male Conical fitting Reducing matter* Metal ions* Titration acidity or alkalinity* Residue on evaporation* UV absorption*	ISO 8536-4 Sixth edition 2019-09, Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed	**Pass**
ISO 80369-7 Compliance Dimensional requirements Positive pressure liquid leakage Sub-atmospheric pressure air leakage Stress cracking Resistance to separation from axial load Resistance to separation from unscrewing Resistance to overriding	ISO 80369-7 First edition 2016-10-15, Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic application	**Pass**

*Indicates testing was performed on the predicate PuraCath Firefly Needleless Connector and is applicable to the subject PuraCath Firefly Needleless Connector IT

8 Conclusion

PuraCath Medical, Inc. has provided the required detailed information, predicate equivalence analysis, test methods, test results, risk analysis and conclusions as required to conclude that the Subject PuraCath Firefly Needleless Connector IT Device is substantially equivalent to the Predicate Firefly Needleless Connector Device (K203796).