July 30, 2021

PuraCath Medical, Inc
Julia Rasooly
CEO
37600 Central Court, Suite 210
Newark, California 94560

Re: K203796
Trade/Device Name: Firefly Needleless Connector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: July 26, 2021
Received: July 28, 2021

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 (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,

CAPT Alan M. Stevens
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)*
K203796

Device Name
Firefly Needleless Connector

Indications for Use *(Describe)*
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.

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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5. 510(k) Summary K203796

5.1. 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
Telephone:	415.305.4134
email:	julia@puracath.com

Date Prepared:	July 26, 2021

5.2. Device Information

Common Name:	IV Administration Set, Needleless Connector, Closed Access
Trade Name:	Firefly Needleless Connector
Classification:	Class II, 21 CFR 880.5440 Product Code: FPA
Predicate Device:	CareFusion, MaxZero Needleless Connector, MZ1000 (K132413)

5.3. Device Description

5.3.1. Subject Device Overview

The PuraCath Firefly Needleless Connector, Model 9001, is listed in Table 1

Table 1 Model Numbers for System Components

Model Number	Model Name
9001	Firefly Needleless Connector

5.4. PuraCath Firefly Needleless Connector

The PuraCath Firefly Needleless Connector is a neutral displacement needleless connector intended 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 PuraCath Firefly Needleless Connector is a closed, luer activated device that eliminates the risk of needlestick injuries. The PuraCath Firefly Needleless Connector 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. The Firefly Needleless Connector may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10 mL per second. The Firefly Needleless Connector can be used for seven (7) days and 200 activations. The PuraCath Firefly Needleless Connector is designed to be disinfected using standard of care alcohol wipe down.

5.5. Indications For Use:

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.

5.6. Technological Comparison

Table 5.6.1 provides the key technological characteristics of the Firefly Needleless Connector compared to the Predicate Device (CareFusion, MaxZero Needleless Connector).

Table 5.6.1 Technology Characteristics

Characteristic	Subject Device	Predicate Device	Same or Different
Device name	Firefly Needleless Connector	MaxZero (MZ1000) Needleless Connector (K132413)	N/A
Common Name	IV Administration Set	IV Administration Set	Same
Classification	Class II, IV Administration Set, Needle Connector, Closed Access	Class II, IV Administration Set, Needleless Connector, Closed Access	Same
Indications for use	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.	The MZ1000 Is a sterile single patient use connector for needleless access to the IV line and/or IV catheter during IV therapy. The MZ1000 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

Characteristic	Subject Device	Predicate Device	Same or Different
Proximal Configuration	Female Luer Lock with Luer Actuated Valve	Female Luer Lock with Luer Actuated Valve	Same
Distal Configuration	Male Luer Lock	Male Luer Lock	Same
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 ≥ 100ml/minute	Different
Connector Fluid Displacement	<9 µL	16 µL	Different
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
Method of Disinfection	70% IPA	70% IPA	Same
Electronic Chip	Yes	No	Different
Sterilization Method	Ethylene Oxide	Gamma Irradiation	Different
Sterile Barrier Packaging	Tyvek polyethylene; heat-sealed	Tyvek polyethylene; heat-sealed	Same
Packaged Quantity	Single Unit per Package	Single Unit per Package	Same

Technological Characteristics and Substantial Equivalence

The indications for use of the Firefly Needless Connector are identical to the predicate MaxZero (MZ1000) Needleless Connector (K132413) in that they are both indicated as sterile single patient use connectors 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 Firefly Needless Connector is identical to the predicate device with respect to material composition and device characteristics. The Firefly Needless Connector device and the predicate device are the identical in general system design and configuration in that they are both External Flow with a male luer lock and a female Luer Lock with Luer Actuated Valve Normally Closed Elastomeric Valve, Luer Activated same device and identical in materials and design. Both devices are very similar in technological characteristics however there are minor differences in the Firefly Needleless Connector compared to the previously cleared MaxZero MZ 1000 Needleless Connector predicate device that were highlighted in "Table 11.5.1 – Subject Device to Predicate Comparison Table".

- The gravity flow rate of the two connectors is different. The MaxZero has a flow rate of 100ml/min whereas the Firefly Needleless connector has a flow rate of 67 ml/min. The flow rate through a 20G catheter is 60 ml/min and, according to authoritative references, is used for most infusions, rapid fluid replacement, and routine blood transfusion. Other commercially available needleless connectors have flow rates from 24 ml/min to 533 ml/min[1].

- Both the Firefly Needless Connector and the predicate MaxZero (MZ1000) Needleless connectors incorporate the same mechanism of action where the valve opens when a male luer is connected and closes when the luer is removed. Both are external flow. However, one minor difference is the connector fluid displacement for the predicate MaxZero device is slightly greater (16 µL) than for the subject, Firefly (<9 µL) connector.

- The Firefly Connector is ethylene oxide gas sterilized compared to the predicate MaxZero (MZ1000) Needleless connector device which is sterilized by radiation. Both methods of sterilization are widely used in the medical device industry and utilize FDA recognized standards for sterilization validation. Both devices were functionally evaluated after all manufacturing processes including exposure to sterilization conditions which demonstrates no issues of safety or effectiveness.

- The device contains an electronic chip in its design for future functionalities that are not yet approved. The performance data demonstrate the chip does not impact the safety and effectiveness of the current device.

These minor differences in technological characteristics between the Firefly Needleless Connector and the predicate MaxZero (MZ1000) Needleless connector device do not raise new issues of safety or effectiveness. The Firefly Needleless Connector has been evaluated in bench, laboratory, and clinician use tests with results that are equivalent in terms of functional and dimensional performance.

[1]http://hadawayassociates.com/uploads/3/5/4/4/35447364/needleless_connectors_for_iv_catheters_23.pdf

Therefore, this information demonstrates that there are no new issues of safety or effectiveness and provides evidence of substantial equivalence of the Firefly Needless Connector to the MaxZero (MZ1000) Needleless connector subject of K132413.

5.7. Performance Testing

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

Biocompatibility

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, Jun 16, 2016 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 5.7.1 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 following nonclinical bench testing was conducted on the Firefly Needleless Connector to determine the proposed device is substantially equivalent to the predicate device.

Table 5.7.2 Performance Testing

TEST	STANDARD	RESULT
Particulate Matter	USP <788> Particulate Matter in Injections	**Pass**
Sterility	ISO 11135:2014, Ethylene oxide — Requirements for development, v ISO 10993-7:2008 ISO 10993-7:2008, Biological evaluation of medical devices — Part 7 - Ethylene oxide sterilization residuals validation and routine control	**Pass**
6 Month Shelf Life	ASTM F1980-16: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices 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	FDA Guidance: Intravascular Administration Sets Premarket Notification Submission [510(k)]: 2008	**Pass**

Valve pressure test Tensile strength Flexural strength		
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**

5.8. Conclusion Statement

The conclusions drawn from the nonclinical tests above demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device predicate