September 20, 2022

Perfuze Ltd.
Anne-Marie Gannon
Director of Regulatory Affairs
Unit 6, Galway Business Park, Dangan
Galway, H91 W7CP
Ireland

Re: K214048
Trade/Device Name: Millipede 088 Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: August 18, 2022
Received: August 22, 2022

Dear Anne-Marie Gannon:

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,

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214048

Device Name
Millipede 088 Access Catheter

Indications for Use *(Describe)*
The Millipede 088 Access Catheter is indicated for use in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovasculature.

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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K214048 - 510(k) Summary

Submitter Information

Submitter's Name:	Perfuze Ltd.
Address:	Unit 6, Galway Business Park, Dangan, Galway, H91 W7CP, Ireland
Contact Person:	Anne-Marie Gannon
Telephone:	+353 91 428083
Date Prepared:	September 20, 2022

Subject Device

Proprietary Name:	Millipede 088 Access Catheter
Common/Usual Name:	Guide Catheter
Classification Name:	Catheter, Percutaneous, Neurovasculature
Regulatory Class:	II
Regulation:	21 CFR 870.1250
Product Code:	QJP

Predicate Device

Proprietary Name:	TracStar™ Large Distal Platform Zoom™ 88 Large Distal Platform Zoom™ 88-T Large Distal Platform
Common/Usual Name:	Guide Catheter
Classification Name:	Catheter, Percutaneous, Neurovasculature
Regulatory Class:	II
Regulation:	21 CFR 870.1250
Product Code:	QJP DQY
Manufacturer:	Imperative Care
510(k) Number:	K203764

Reference Devices

The following table lists the reference devices that were used to support the substantial equivalence determination in this submission.

510(k) Number	Product Code	Name of Device	Device Manufacturer
K190010	NRY	Penumbra System Reperfusion Catheter JET 7	Penumbra Inc.
K161152	DQY	Navien Intracranial Support Catheter	Micro Therapeutics Inc. d/b/a ev3 Neurovascular
K152541	NRY	Penumbra System ACE 64 Reperfusion Catheter	Penumbra Inc.
K193034	DQY	AXS Infinity LS Plus Long Sheath	Stryker Neurovascular
K203840	QJP, DQY	BOSS 8F Balloon Guide Catheter	Marblehead Medical LLC
K182097	DQY	React 71 Catheter	Micro Therapeutics Inc. d/b/a ev3 Neurovascular

510(k) Number	Product Code	Name of Device	Device Manufacturer
K183464	NRY	AXS Catalyst 7 Distal Access Catheter	Stryker Neurovascular
K133177	DQY, DQO	Modified HD Guide Catheter	Concentric Medical Inc.
K090752	NRY	Penumbra Reperfusion Catheter 054	Penumbra Inc.

Device Description

The Millipede 088 Access Catheter consists of the catheter, a rotating hemostasis valve (RHV) and a valve crossing tool. The catheter, RHV and valve crossing tool are provided sterile. They are sterilized by ethylene oxide (EO).

The Millipede 088 Access Catheter is a single lumen, coil-reinforced, variable stiffness catheter. The distal segment has a hydrophilic coating for navigation through the vasculature. The catheter has a radiopaque marker located at its distal end for visualization under fluoroscopy. The valve crossing tool is used to open the valve of the access sheath and to facilitate insertion of the Millipede 088 Access Catheter through the access sheath without damage. The RHV is assembled onto the hub of the Millipede 088 Access Catheter and is used to maintain hemostasis during infusion of saline and contrast agent and insertion of other devices through the Millipede 088 Access Catheter.

Indications for Use

The Millipede 088 Access Catheter is indicated for use in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovasculature.

The Indications for Use statement for the Millipede 088 Access Catheter is not identical to the predicate device. However, both the Millipede 088 Access Catheter and the predicate device can be used to facilitate insertion and guidance of microcatheters into the neurovasculature. The differences in the Indications for Use statement do not raise new questions of safety and effectiveness for the Millipede 088 Access Catheter relative to the predicate device.

Comparison to the Predicate Device

The subject and predicate devices have similar technological characteristics as shown in the following table.

Attribute	**Predicate Device** TracStar™ Large Distal Platform Zoom™ 88 Large Distal Platform Zoom™ 88-T Large Distal Platform (K203764)	**Subject Device** Millipede 088 Access Catheter
Regulation Number	21 CFR 870.1250	Same
Regulation Name	Percutaneous catheter	Same
Classification	Class II	Same
Product Code	QJP, DQY	QJP

Attribute	**Predicate Device** TracStar™ Large Distal Platform Zoom™ 88 Large Distal Platform Zoom™ 88-T Large Distal Platform (K203764)	**Subject Device** Millipede 088 Access Catheter
Indications for use	The TracStar Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature. The ZOOM 88 and ZOOM 88-T Large Distal Platform are indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The Millipede 088 Access Catheter is indicated for use in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovasculature.
Prescription/over-the-counter use	Prescription	Same
Device Description	Single-use, variable stiffness, wire-reinforced catheters with a single lumen. The catheters are comprised of a hollow cylindrical tube bonded at the proximal end to a standard luer fitting. The wall of the tube is constructed using metals and polymers. A radiopaque marker provides visual confirmation of the distal tip location under fluoroscopy.	Same
Principle of Operation	May be used with support catheters to assist in accessing the target vasculature.	Same
Techniques for Use	Standard percutaneous interventional techniques, including access site preparation, introduction of the catheter into the access vessel, advancing the catheter under fluoroscopy, withdrawing the catheter, and closing the access site.	Same
Materials	Polymers and metals commonly used in the manufacture of medical devices.	Same
Distal Tip	Beveled edge, soft, flexible, and atraumatic	Square edge, soft, flexible, and atraumatic
Catheter Wall Construction	Coil-reinforced	Coil-reinforced with ribbed surface at distal section
Coating	Hydrophilic Coating	Same
Catheter Profile	8 Fr	Same
Inner Diameter	Distal: 0.088” Proximal: 0.088’’	Distal: 0.088” Proximal: 0.087’’
Outer Diameter	Distal: 0.106” Proximal: 0.108”	Distal: 0.104” Proximal: 0.108”
Effective Length	80cm -110cm	115cm
Packaged Accessories	RHV	RHV and Valve Crossing Tool
Condition Supplied	Sterile and Single Use	Same

Attribute	Predicate Device TracStar™ Large Distal Platform Zoom™ 88 Large Distal Platform Zoom™ 88-T Large Distal Platform (K203764)	Subject Device Millipede 088 Access Catheter
Sterilization Method	Ethylene Oxide (EO), Sterility Assurance Level 10^{-6}	Same
Packaging Configuration	The catheters are placed in a protective polyethylene tube, mounted with accessory RHV onto a polyethylene packaging card, placed into a pouch, sealed, and labeled. The sealed pouch and IFU are placed in a labeled shelf carton box.	The catheters are placed in a protective polyethylene tube, mounted with accessory RHV and valve crossing tool onto a cardboard packaging card, placed into a pouch, sealed, and labeled. The sealed pouch and IFU are placed in a labeled shelf carton box.

Biocompatibility Testing

The Millipede 088 Access Catheter is constructed using materials that are commonly used in the medical device industry. All patient contacting components have been evaluated for biocompatibility in accordance with ISO 10993-1, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process." The Millipede 088 Access Catheter is classified per ISO 10993-1 as an externally communicating device that contacts circulating blood for a limited (< 24 hours) duration. A summary of the biocompatibility testing is outlined below.

Test	Results
Cytotoxicity – ISO MEM Elution	The test article is non-cytotoxic.
Sensitization – ISO Guinea Pig Maximization Sensitization Test	The test article did not elicit a sensitization response.
Irritation – ISO Intracutaneous Reactivity	Requirements of the ISO intracutaneous reactivity test were met for the test article.
Acute Systemic Toxicity – ISO Acute Systemic Injection	Requirements of the ISO acute systemic injection test were met for the test article.
Material-Mediated Pyrogenicity	The test article is non-pyrogenic.
Hemocompatibility – Complement Activation (SC5b-9)	The test article is not considered to be a potential activator of the complement system.
Hemocompatibility – Partial Thromboplastin Time	The test article is not considered to be an activator of the intrinsic coagulation pathway.
Hemocompatibility – ASTM Hemolysis	The test article is considered non-hemolytic.
Hemocompatibility – Thromboresistance	The test articles have similar thromboresistance characteristics as the control devices.

Performance Testing

The successful completion of the performance testing listed in the following table demonstrates that the Millipede 088 Access Catheter is suitable for its intended use.

Test	Test Method	Conclusions
Dimensional Inspection	Device dimensions were measured to confirm conformance to the specifications.	The device met established specifications.
Tip Stiffness	Test specimens were tested for tip flexibility and compared to predicate and reference devices.	The device met established specifications.

Test	Test Method	Conclusions
Visual Inspection	Device surface characteristics were assessed to confirm freedom from defects.	The device surface characteristics are suitable for its intended use.
Simulated Use Testing	Deliverability and compatibility with accessory devices were evaluated in a neurovascular model.	The device performs as intended under simulated use conditions.
Hydrophilic Coating Integrity	The integrity of the hydrophilic coating was evaluated after multiple insertion and withdrawal cycles.	The hydrophilic coating integrity is suitable for its intended use.
Particulate Recovery	The purpose of this test was to quantify the particulate size and count generated by simulated use of the test article.	The particulate size and count were similar to control devices.
Tensile Strength	The tensile strength was evaluated for the bonds between sections of the catheter.	The device met established specifications.
Air Leakage	Tested per ISO 10555-1:2013 Annex D.	The device integrity is suitable for its intended use.
Liquid Leakage	Tested per ISO 10555-1:2013 Annex C.	The device integrity is suitable for its intended use.
Static Burst	Tested per ISO 10555-1:2013 Annex F.	The device integrity is suitable for its intended use.
Luer Integrity	The luers were evaluated for compliance to relevant standards.	The luers on the device are suitable for their intended use.
Kink Resistance	Test specimen segments were formed into a defined bend diameter to evaluate kink resistance.	The device met established specifications.
Torque Strength	The test specimens were rotated in a simulated use model to evaluate integrity after rotation.	The device met established specifications.
Flow Rate Characterization	The flow rate of saline and a contrast-saline solution was characterized when injected through the catheter.	The flow rate was characterized.
Radiopacity	Radiopacity of the device was evaluated in an animal model under fluoroscopy.	The radiopacity of the Millipede 088 Access Catheter was similar to a control device.

Animal Testing

The *in vivo* performance and safety of the device was assessed in two studies in a porcine model at 3-day and 30-day time points. Studies were conducted under Good Laboratory Practices. Usability, radiopacity, thromboresistance, and vessel injury were assessed. The results for the subject device were comparable to a control device, demonstrating acceptable results.

Sterilization

The Millipede 088 Access Catheter is sterilized using a validated EO process with a sterility assurance level of $1x10^{-6}$. The validation was conducted using the overkill method according to ISO 11135, “Sterilization of Health-Care Products - Ethylene Oxide - Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices”.

Shelf Life and Packaging

Accelerated aging testing based on ASTM F1980 was conducted to verify packaged device performance. A real time aging equivalent of 8 months was used to support an 8-month shelf-life claim. Device performance was verified by functional and performance testing.

Substantial Equivalence

The intended use of the Millipede 088 Access Catheter is similar to the intended use of the predicate device. The Millipede 088 Access Catheter and the predicate device use the same operating principles and have a similar design. The minor technological differences identified do not raise different questions of safety or effectiveness for the two devices. The successful completion of biocompatibility testing and performance testing demonstrates that the Millipede 088 Access Catheter is substantially equivalent to the predicate device.