December 14, 2023

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

Re: K233648
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: November 14, 2023
Received: November 14, 2023

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 (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.

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,

Naira Muradyan -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233648

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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510(k) Summary K233648

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:	December12th, 2023

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:	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
Manufacturer:	Perfuze Ltd.
510(k) Number:	K231802

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, 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 subject Millipede 088 Access Catheter is identical to the predicate device.

Comparison to the Predicate Device

The intended use of the subject device is identical to the predicate device. The subject and predicate devices have similar technological characteristics as shown in the following table.

Attribute	**Predicate Device** Millipede 088 Access Catheter (K231802)	**Subject Device** Millipede 088 Access Catheter (K233648)
Regulation Number	21 CFR 870.1250	Same
Regulation Name	Percutaneous catheter	Same
Classification	Class II	Same
Product Code	QJP	Same
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.	Same
Prescription/Over-the-Counter Use	Prescription	Same
Device Description	Single-use, variable stiffness, wire-reinforced catheter with a single lumen. The catheter is 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 neurovasculature.	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.	Proximal end of catheter: Same patient-contacting materials. Distal end of catheter: Same metal reinforcement with additional polymer materials in distal tip. Accessories and packaging: Same
Distal Tip	Soft, flexible.	Same
Catheter Wall Construction	Coil and braid reinforced, with ribbed surface at distal section.	Same
Coating	Hydrophilic coating	Same
Catheter Profile	8 Fr	Same
Inner Diameter	Distal: 0.088” Proximal: 0.088’’	Same
Outer Diameter	Distal: 0.104” Proximal: 0.108”	Same
Working Length	119 cm	120 cm

Attribute	Predicate Device Millipede 088 Access Catheter (K231802)	Subject Device Millipede 088 Access Catheter (K233648)
Packaged Accessories	RHV and Valve Crossing Tool	Same
Condition Supplied	Sterile and single use	Same
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 and valve crossing tool onto a cardboard packaging card, placed into a pouch, sealed, and labeled. The sealed pouch and Instructions for Use are placed in a labeled shelf carton box.	Same
Labelled Shelf Life	8 months	12 months

Performance Testing (Bench)

The successful completion of the performance testing listed in the table below demonstrates that the subject Millipede 088 Access Catheter meets the defined design specifications and is suitable for its intended use.

Test	Test Method	Conclusions
Dimensional Inspection	The device dimensions were measured to confirm conformance to the specifications.	The device met established specifications.
Visual Inspection	Device surface characteristics were assessed to confirm freedom from defects that could affect clinical use.	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 sizes and counts generated during simulated use of the test article.	The particulate generation was similar to control devices.
Kink Resistance	Test specimen segments were formed into a defined bend diameter to evaluate kink resistance.	The device met established specifications.
Tip Stiffness	The bending stiffness of the catheter tip was measured to confirm conformance to the specification derived from comparator devices.	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 as per ISO 10555-1:2013 Annex C.	The device integrity is suitable for its intended use.
Static Burst	Tested as per ISO 10555-1 Annex F.	The device integrity is suitable for its intended use.
Catheter Joint Tensile Testing	The tensile strength was evaluated for the bonds between sections of the catheter.	The device met established specifications.
Torque Strength	The test specimens were rotated with the distal end constrained from movement to evaluate integrity after rotation.	The device met established specifications.

Test	Test Method	Conclusions
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.

Biocompatibility

The subject device includes some material differences compared to the predicate device. To ensure that all new materials were assessed, relevant biocompatibility endpoints were addressed through biocompatibility testing of the subject Millipede 088 Access Catheter. The testing was completed in accordance with ISO 10993-1:2018. The table below summarizes the biocompatibility testing completed.

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 article had similar thromboresistance characteristics as the control device.

Shelf Life and Packaging

The subject device has a labeled shelf life of 12 months, compared to 8 months for the predicate device. Device performance was verified by functional and performance testing after 12-month accelerated aging according to ASTM F1980.

Packaging validation for the predicate device included testing on units subjected to accelerated aging to simulate a 12-month shelf life as per ASTM F1980.This was used to support the labelled 8-month shelf life for the predicate device. The packaging is identical for the subject and predicate devices. Therefore, the original packaging testing for the predicate device remains valid and supports the subject device's 12-month shelf life. No further packaging testing is required for the subject device.

Sterilization

The sterilization method is identical for the subject and predicate devices. Confirmatory EO residual testing was repeated on the subject Millipede 088 Access Catheter to confirm that the design differences did not impact residual EO levels of the device. The testing confirmed that EO residuals were within the limits specified in ISO 10993-7.

Animal Study

No animal study was deemed necessary to demonstrate substantial equivalence between the subject and predicate devices.

Clinical Data

The non-clinical performance data presented were determined to be sufficient to support the substantial equivalence of the subject and predicate devices. Therefore, no clinical study was conducted.

Conclusion

The indications for use of the Millipede 088 Access Catheter are identical to the predicate device. The subject Millipede 088 Access Catheter and the predicate device use the same operating principles and have a similar design. The differences identified in this submission do not raise different or new questions of safety or effectiveness. The successful completion of performance and biocompatibility testing demonstrates that the subject Millipede 088 Access Catheter is substantially equivalent to the predicate device.