September 20, 2024

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

Re: K242504
Trade/Device Name: Millipede 088 Access Catheter; Millipede 070 Aspiration Catheter; Perfuze Aspiration Tube Set
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, NRY
Dated: August 22, 2024
Received: August 22, 2024

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.

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,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
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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)*
K242504

Device Name
Millipede 088 Access Catheter;
Millipede 070 Aspiration Catheter;
Perfuze Aspiration Tube Set

Indications for Use *(Describe)*

Millipede 088 Access Catheter
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.

Millipede 070 Aspiration Catheter
The Millipede 070 Aspiration Catheter, with the Perfuze Aspiration Tube Set and a compatible aspiration pump, is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Perfuze Aspiration Tube Set
The Perfuze Aspiration Tube Set is indicated to connect the Millipede 070 Aspiration Catheter to a compatible aspiration pump.

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 – K242504

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:	19th September, 2024

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:	K233648

Subject Device

Proprietary Name:	Millipede 070 Aspiration Catheter; Perfuze Aspiration Tube Set
Common/Usual Name:	Percutaneous Catheter
Classification Name:	Catheter, Thrombus Retriever
Regulatory Class:	II
Regulation:	21 CFR 870.1250
Product Code:	NRY

Predicate Device

Proprietary Name:	Millipede 070 Aspiration Catheter; Perfuze Aspiration Tube Set
Common/Usual Name:	Percutaneous Catheter
Classification Name:	Catheter, Thrombus Retriever
Regulatory Class:	II
Regulation:	21 CFR 870.1250
Product Code:	NRY
Manufacturer:	Perfuze Ltd.
510(k) Number:	K232524

Device Description

Millipede 088 Access Catheter

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.

Millipede 070 Aspiration Catheter; Perfuze Aspiration Tube Set

The Millipede 070 Aspiration Catheter is a sterile single-use device. It consists of the catheter and a RHV. The 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 RHV is assembled onto the hub of the catheter and is used to maintain hemostasis during infusion of saline and contrast agent and insertion of devices into the Millipede 070 Aspiration Catheter.

The Perfuze Aspiration Tube Set is a sterile, single-use device consisting of a single flexible braided tube. The tube has a rotating male luer-lock connector on the distal end and a suction connector on the proximal end. The rotating male luer-lock connector connects to the hub of a Millipede 070 Aspiration Catheter. The suction connector connects to the canister of an aspiration pump. A pinch clamp provides the user with the ability to apply vacuum to the catheter.

For the aspiration source, the Millipede 070 Aspiration Catheter is used in conjunction with a compatible aspiration pump with prespecified performance parameters that is connected using the Perfuze Aspiration Tube Set along with a legally marketed canister and accessories kit.

Indications for Use

Millipede 088 Access Catheter

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.

Millipede 070 Aspiration Catheter; Perfuze Aspiration Tube Set

Millipede 070 Aspiration Catheter
The Millipede 070 Aspiration Catheter, with the Perfuze Aspiration Tube Set and a compatible aspiration pump, is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Perfuze Aspiration Tube Set
The Perfuze Aspiration Tube Set is indicated to connect the Millipede 070 Aspiration Catheter to a compatible aspiration pump.

Comparison to the Predicate Devices

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

Millipede 088 Access Catheter

Attribute	**Predicate Device** Millipede 088 Access Catheter (K233648)	**Subject Device** Millipede 088 Access Catheter (K242504)
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 polymers and metal reinforcement with changes to the color additives used. Distal end of catheter: Same 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	120 cm	Same

Attribute	Predicate Device Millipede 088 Access Catheter (K233648)	Subject Device Millipede 088 Access Catheter (K242504)
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	12 months	Same

Millipede 070 Aspiration Catheter; Perfuze Aspiration Tube Set

Attribute	Predicate Device Millipede 070 Aspiration Catheter, Perfuze Aspiration Tube Set (K232524)	Subject Device Millipede 070 Aspiration Catheter, Perfuze Aspiration Tube Set (K242504)
Regulation Number	21 CFR 870.1250	Same
Regulation Name	Percutaneous catheter	Same
Classification	Class II	Same
Product Code	NRY	Same
Indications for Use	The Millipede 070 Aspiration Catheter, with the Perfuze Aspiration Tube Set and a compatible aspiration pump, is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. The Perfuze Aspiration Tube Set is indicated to connect the Millipede 070 Aspiration Catheter to a compatible aspiration pump.	Same
Prescription/Over-the-Counter Use	Prescription	Same

Attribute	**Predicate Device** Millipede 070 Aspiration Catheter, Perfuze Aspiration Tube Set (K232524)	**Subject Device** Millipede 070 Aspiration Catheter, Perfuze Aspiration Tube Set (K242504)
Device Description	Single lumen catheter designed to be introduced over a steerable guidewire to access the neurovasculature. The semi-rigid proximal section transitions to a flexible distal tip to facilitate advancement through vessels. A single radiopaque marker at the distal end facilitates fluoroscopic visualization. The outer surface of the catheter is coated with a hydrophilic coating to reduce friction during navigation in the vasculature. A luer fitting on the catheter hub is used for the attachment of accessories. A strain relief at the hub provides kink resistance at the proximal end.	Same
Principle of Operation	Designed to remove thrombus from the neurovasculature using direct aspiration.	Same
Techniques for Use	Standard percutaneous, intravascular techniques.	Same
Materials	Polymers and metals commonly used in the manufacture of medical devices.	Proximal end of catheter: Same polymers and metal reinforcement with changes to the color additives used. Distal end of catheter: Same Accessories and packaging: Same
Distal Tip	Tapered, soft, flexible	Same
Catheter Wall Construction	Braid and coil reinforcement, with ribbed internal surface at distal end.	Same
Coating	Hydrophilic Coating	Same
Catheter Profile	6 Fr	Same
Inner Diameter	Distal: 0.070 in Proximal: 0.069 in	Same
Outer Diameter	Distal: 0.0835 in Proximal: 0.0865 in	Same
Working Length / Effective length	136 cm	Same
Packaged Accessories	Rotating Hemostasis Valve	Same
Condition Supplied	Sterile and Single Use	Same
Sterilization Method	EO	Same
Packaging Configuration	Polyethylene terephthalate Tyvek® pouch, polyethylene tube, paperboard packaging card, cardboard carton.	Same
Aspiration Tubing	100 in length Tubing ID = 0.110 inch Pinch clamp valve for vacuum control	Same

Biocompatibility

The subject Millipede 070 Aspiration Catheter and Millipede 088 Access Catheter include a change to the color additives used in the proximal shaft compared to the predicate devices. To ensure these new color additives were assessed, relevant biocompatibility endpoints were addressed through biocompatibility testing in accordance with ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process". The table below summarizes the biocompatibility testing completed.

Biocompatibility testing of the Millipede 070 Aspiration Catheter (listed below), which utilizes the same color additives, was used to also support the biocompatibility of the Millipede 088 Access Catheter.

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 Direct and Indirect (extract-based) Hemolysis	The test article is considered non-hemolytic in both direct and indirect hemolysis tests.
Hemocompatibility – Platelet and Leukocyte Count	The test article is not considered to have an effect on platelet and leukocyte concentrations.

Performance Testing

Non-clinical bench testing was performed to confirm that the change to the color additives used in the proximal shaft does not impact the visual characteristics or mechanical integrity of the devices.

The non-clinical bench testing of the Millipede 070 Aspiration Catheter (listed below) was used to also support the visual characteristics and mechanical integrity of the Millipede 088 Access Catheter.

Test	Test Method	Conclusions
Visual Inspection	Device surface characteristics were assessed to confirm conformance to the specifications.	The device met established specifications.
Tensile Strength	The tensile strength was evaluated for the bonds between sections of the catheter.	The device met established specifications.
Air Leakage	Resistance to air leak was assessed by pressurizing the catheter to 300kPa and monitoring for air leaks.	The device integrity is suitable for its intended use.

Shelf Life and Packaging

The subject devices' shelf life and packaging configuration remain identical to that of the predicate devices. Therefore, no shelf-life testing or packaging validation was required to demonstrate substantial equivalence between the subject and predicate devices.

Sterilization

The Millipede 088 Access Catheter, Millipede 070 Aspiration Catheter, and Perfuze Aspiration Tube Set are sterilized using a validated EO process with a sterility assurance level of $1x10^{-6}$. The sterilization method is identical for the subject and predicate devices.

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, Millipede 070 Aspiration Catheter, and Perfuze Aspiration Tube Set are identical to the predicate devices. The subject and the predicate devices use the same operating principles and have similar designs. The differences in color additives discussed in this submission do not raise different or new questions of safety or effectiveness. The successful completion of biocompatibility testing and performance testing demonstrates that the subject Millipede 088 Access Catheter and Millipede 070 Aspiration Catheter are substantially equivalent to the respective predicate devices.