February 26, 2025

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

Re: K250012
Trade/Device Name: Millipede 070 Aspiration Catheter; Perfuze Aspiration Tube Set
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: January 30, 2025
Received: January 30, 2025

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)*
K250012

Device Name
Millipede 070 Aspiration Catheter;
Perfuze Aspiration Tube Set

Indications for Use *(Describe)*

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 thrombolytic drug therapy or who have not responded to thrombolytic drug 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K250012

Submitter Information

Submitter's Name:	Perfuze Ltd.
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Contact Person:	Anne-Marie Gannon
Telephone:	+353 91 428083
Date Prepared:	17th February 2025

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:	K242504

Device Description

The Millipede 070 Aspiration Catheter is a sterile single-use device. It consists of the catheter and a rotating hemostasis valve (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. The aspiration pump is

connected using the Perfuze Aspiration Tube Set along with a legally marketed canister and accessories kit.

Indications for Use

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 thrombolytic drug therapy or who have not responded to thrombolytic drug 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 Device

Attribute	**Predicate Device** **Millipede 070 Aspiration Catheter; Perfuze Aspiration Tube Set (K242504)**	**Subject Device** **Millipede 070 Aspiration Catheter; Perfuze Aspiration Tube Set (K250012)**
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.	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 thrombolytic drug therapy or who have not responded to thrombolytic drug therapy are candidates for treatment. The Perfuze Aspiration Tube Set is indicated to connect the Millipede 070 Aspiration Catheter to a compatible aspiration pump.
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	Same

Attribute	Predicate Device Millipede 070 Aspiration Catheter; Perfuze Aspiration Tube Set (K242504)	Subject Device Millipede 070 Aspiration Catheter; Perfuze Aspiration Tube Set (K250012)
	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 for the proximal end.	
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.	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	Ethylene Oxide (EO)	Same
Packaging Configuration	Polyethylene terephthalate Tyvek® pouch, polyethylene tube, paperboard packaging card, cardboard carton.	Same
Perfuze Aspiration Tubing	100 in length Tubing ID = 0.110 in Pinch clamp valve for vacuum control	Same

Non-Clinical Testing

Performance Testing (Bench)

The subject and predicate devices have the same indications for use, operating principle, and design. There are no changes to technological characteristics. Therefore, non-clinical bench testing was not required for the subject Millipede 070 Aspiration Catheter and Perfuze Aspiration Tube Set.

Biocompatibility

The materials, formulation, and suppliers of the materials used in the Millipede 070 Aspiration Catheter and Perfuze Aspiration Tube Set are identical in the subject and predicate devices. The product-contacting packaging materials in the subject and predicate devices are also identical. Therefore, no biocompatibility testing was required for the subject Millipede 070 Aspiration Catheter and Perfuze Aspiration Tube Set.

Sterilization

The Millipede 070 Aspiration Catheter and Perfuze Aspiration Tube Set are sterilized using a validated EO process with a sterility assurance level of $1x10^{-6}$. There is no change to the sterilization method used for the subject Millipede 070 Aspiration Catheter compared to the predicate device. Therefore, no additional sterilization validation data was required for the subject Millipede 070 Aspiration Catheter.

A different sterilization cycle will be used for the subject Perfuze Aspiration Tube Set compared to the predicate device. A validation was conducted for this cycle 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

The subject and predicate devices have an identical shelf life and packaging configuration. To ensure that the new sterilization cycle for the Perfuze Aspiration Tube Set does not impact integrity of the sterile barrier, packaging testing was conducted following sterilization with the new process. The device packaging met established specifications.

Animal Study

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

Clinical Data

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

Conclusion

The subject and predicate devices have the same indications for use, operating principle, and design. The different sterilization cycle used for the Perfuze Aspiration Tube Set does not raise different questions of safety or effectiveness. The successful completion of sterilization and packaging validation demonstrates that the subject device is substantially equivalent to the predicate device.