October 18, 2023

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

Re: K232524
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: August 18, 2023
Received: August 18, 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
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232524

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 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 – K232524

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:	12th October 2023

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:	SOFIA Plus Aspiration Catheter
Common/Usual Name:	Percutaneous Catheter
Classification Name:	Catheter, Thrombus Retriever
Regulatory Class:	II
Regulation:	21 CFR 870.1250
Product Code:	NRY
Manufacturer:	MicroVention, Inc.
510(k) Number:	K173200

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 that 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 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 Device

Attribute	**Predicate Device** SOFIA Plus Aspiration Catheter (K173200)	**Subject Device** Millipede 070 Aspiration Catheter; Perfuze Aspiration Tube Set (K232524)
Regulation Number	21 CFR 870.1250	Same
Regulation Name	Percutaneous Catheter	Same
Classification	Class II	Same
Product Code	NRY	Same
Indications for Use	The SOFIA Plus Aspiration Catheter with the Gomco 405 Aspiration Pump and MicroVention Tubing Kit is intended 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 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.
Prescription/over-the-counter use	Prescription	Same

Attribute	**Predicate Device** SOFIA Plus Aspiration Catheter (K173200)	**Subject Device** Millipede 070 Aspiration Catheter; Perfuze Aspiration Tube Set (K232524)
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.	Same
Distal Tip	Straight - steam shapeable by user.	Tapered, soft, flexible.
Catheter Wall Construction	Braid and coil reinforcement.	Braid and coil reinforcement, with ribbed internal surface at distal end.
Coating	Hydrophilic coating	Same
Catheter Profile	6 Fr	Same
Inner Diameter	0.070 in	Distal: 0.070 in Proximal: 0.069 in
Outer Diameter	Distal: 0.082 in Proximal: 0.083 in	Distal: 0.0835 in Proximal: 0.0865 in
Effective Length / Working Length	125 – 131 cm	136 cm
Packaged Accessories	Introducer sheath and shaping mandrel	Rotating Hemostasis Valve
Condition Supplied	Sterile and single use	Same
Sterilization Method	Ethylene Oxide (EO)	Same
Packaging Configuration	Polyester/polyethylene/Tyvek® pouch, polyethylene tube, polyethylene card, paperboard carton.	Polyethylene terephthalate Tyvek® pouch, polyethylene tube, paperboard packaging card, cardboard carton.
Aspiration Tubing	112 in length Tubing ID = 0.110 in Integrated valve for vacuum control	100 in length Tubing ID = 0.110 in Pinch clamp valve for vacuum control

Biocompatibility Testing

Millipede 070 Aspiration Catheter

The Millipede 070 Aspiration 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 070 Aspiration 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 MTS Cytotoxicity Test	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.

Perfuze Aspiration Tube Set

The Perfuze Aspiration Tube Set is categorized according to ISO 10993-1 as a surface-contacting medical device that contacts intact skin surfaces for a limited (< 24 hours) duration. A summary of the biocompatibility testing is outlined below.

Test	Results
Cytotoxicity – ISO Elution Method	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.

Performance Testing

The successful completion of the performance testing listed in the following tables demonstrates that the Millipede 070 Aspiration Catheter and the Perfuze Aspiration Tube Set meet their design specifications and are suitable for their intended use.

Millipede 070 Aspiration Catheter

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.	The device met established specifications.

Test	Test Method	Conclusions
Visual Inspection	Device surface characteristics were assessed to confirm freedom from defects that could cause injury.	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.
Stent-retriever Compatibility	Durability of the catheter was evaluated after a stent-retriever was deployed and retrieved through it such that the stent-retriever engages the catheter tip.	The device met established specifications.
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.
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 with the distal end constrained from movement 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 aspiration flow rate of saline through the catheter was also characterized.	The flow rate was characterized.
Radiopacity	Radiopacity of the device was evaluated in an animal model under fluoroscopy.	The radiopacity was similar to a control device.
Clot Retrieval Testing	Clot retrieval performance was evaluated in a neurovascular model.	The device met established specifications.

Perfuze Aspiration Tube Set

Test	Test Method	Conclusions
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.
Dimensional Inspection	Device dimensions were measured to confirm conformance to the specifications.	The device met established specifications.
Luer and Suction Connector Compatibility	Compatibility of device connectors to Millipede 070 Aspiration Catheter hub and aspiration pump canister was assessed.	The device met established specifications.
Luer Integrity	The luer was evaluated for compliance to relevant standards.	The luer on the device is suitable for its intended use.
Kink Resistance and Collapse under Aspiration	Device was inspected for kinks or visible collapse after application of vacuum pressure.	The device met established specifications.
Vacuum Decay	Device was assessed for air leakage when under vacuum.	The device met established specifications.
Pinch Clamp Functionality	Ability to enable and disable suction using the pinch clamp was assessed.	The device met established specifications.
Tensile Testing	Tensile strength was evaluated for the bonds between tube and connectors.	The device met established specifications.

Animal Study

The safety and effectiveness of the subject device was evaluated in two comparative animal studies conducted under Good Laboratory Practices in a porcine model against two controls (Penumbra System with JET 7 Reperfusion Catheter and AXS Vecta Aspiration System with Vecta 71 Aspiration Catheter). Assessments included aspiration of experimental soft and firm clots and application of maximum vacuum with the device in a wedged position against the vessel wall. Both the subject and control devices were evaluated at subacute (3 day) and chronic (30 day) time points. Wedge assessment and clot aspiration assessment results were comparable between the test and control systems. Angiographic and histological evaluations concluded the devices were comparable at all time points.

Clinical Data

The non-clinical performance data presented were determined to be sufficient to support the substantial equivalence of the Millipede 070 Aspiration Catheter and Perfuze Aspiration Tube Set. Therefore, no clinical study was conducted.

Sterilization

The Millipede 070 Aspiration Catheter and Perfuze Aspiration Tube Set are sterilized using a validated EO process with a sterility assurance level of $1x10^{-6}$. 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

The Millipede 070 Aspiration Catheter has a 12-month shelf life, and the Perfuze Aspiration Tube Set has a 24-month shelf life. Accelerated aging testing based on ASTM F1980 was conducted to verify packaged device performance. Device performance was also verified by functional and performance testing on devices conditioned by accelerated aging.

Conclusion

The intended use of the Millipede 070 Aspiration Catheter and Perfuze Aspiration Tube Set is the same as the predicate device. The Millipede 070 Aspiration Catheter and Perfuze Aspiration Tube Set and the predicate device use the same operating principles and have a similar design. The technological differences identified do not raise different questions of safety or effectiveness for the two devices. The successful completion of biocompatibility and performance testing demonstrates that the Millipede 070 Aspiration Catheter and Perfuze Aspiration Tube Set are substantially equivalent to the predicate device.