August 12, 2026

Perfuze Ltd.
Jeanine O'Donnell
Principal Regulatory Affairs Specialist
Unit 6, Galway Business Park,
Dangan,
Galway, H91 W7CP,
Ireland

Re: K262399
Trade/Device Name: Millipede System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: July 13, 2026
Received: July 14, 2026

Dear Jeanine O'Donnell:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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, PhD
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262399

Please provide the device trade name(s).

Millipede System

Please provide your Indications for Use below.

Millipede88 Aspiration Catheter
As part of the Millipede System, the Millipede88 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 artery and middle cerebral artery M1 segment 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.

Millipede70 Aspiration Catheter
As part of the Millipede System, the Millipede70 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
As part of the Millipede System, the Perfuze Aspiration Tube Set is indicated to connect the Millipede88 or Millipede70 Aspiration Catheter to a compatible aspiration pump.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary – K262399

Submitter Information

Submitter's Name:	Perfuze Ltd.
Address:	Unit 6, Galway Business Park, Dangan, Galway, H91 W7CP, Ireland
Contact Person:	Jeanine O'Donnell
Telephone:	+353 91 428083
Date Prepared:	13th July 2026

Subject Device

Proprietary Name:	Millipede System
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 System
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:	K253590

Reference Device

Proprietary Name:	Millipede88 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:	K253901

Device Description

The Millipede System is comprised of the Millipede88 Aspiration Catheter, the Millipede70 Aspiration Catheter and the Perfuze Aspiration Tube Set.

The Millipede88 and Millipede70 Aspiration Catheters are single-lumen, reinforced, variable stiffness catheters. The distal 500mm of each catheter has a hydrophilic coating on its outer surface to enhance tracking through the vasculature. A radiopaque marker provides the user with visual confirmation of the distal tip location under fluoroscopy. Both catheters are supplied with a rotating hemostasis valve (RHV). The RHV is designed to be attached to the proximal hub of the catheter and is used to maintain hemostasis during infusion of saline and contrast agent and insertion of devices into the catheter.

The Millipede88 Aspiration Catheter is also supplied with a valve crossing tool. The valve crossing tool is included to facilitate insertion of the Millipede88 Aspiration Catheter through an access sheath with a cross-cut valve. The valve crossing tool is not required if the access sheath has an RHV.

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 the Millipede88 or Millipede70 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 Millipede88 and Millipede70 Aspiration Catheters are used in conjunction with a compatible aspiration pump with prespecified performance parameters along with a legally marketed canister and accessories kit. The aspiration pump is connected to the aspiration catheter using the Perfuze Aspiration Tube Set.

Indications for Use

Millipede88 Aspiration Catheter:

As part of the Millipede System, the Millipede88 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 artery and middle cerebral artery M1 segment 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.

Millipede70 Aspiration Catheter:
As part of the Millipede System, the Millipede70 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:
As part of the Millipede System, the Perfuze Aspiration Tube Set is indicated to connect the Millipede88 or Millipede70 Aspiration Catheters to a compatible aspiration pump.

Comparison to the Predicate Device

The method of action, design, and materials of the subject Millipede System are substantially equivalent to the predicate device, as outlined in the table below.

Attribute	**Predicate Device** Millipede System (K253590)	**Subject Device** Millipede System (K262399)
Regulation Number	21 CFR 870.1250	Same
Regulation Name	Percutaneous catheter	Same
Classification	Class II	Same
Product Code	NRY	Same

Attribute	**Predicate Device** Millipede System (K253590)	**Subject Device** Millipede System (K262399)
Indications for Use	Millipede88 Aspiration Catheter: As part of the Millipede System, the Millipede88 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 artery and middle cerebral artery M1 segment 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. Millipede70 Aspiration Catheter: As part of the Millipede System, the Millipede70 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: As part of the Millipede System, the Perfuze Aspiration Tube Set is indicated to connect the Millipede88 or Millipede70 Aspiration Catheters to a compatible aspiration pump.	Same
Device Description	The Aspiration Catheter is a single lumen catheter with a semi-rigid proximal section that transitions to a flexible distal tip. The Millipede Aspiration Catheter is used with the Perfuze Aspiration Tube Set.	Same
User	Physicians trained in neurovascular interventional techniques.	Same

Attribute	**Predicate Device** Millipede System (K253590)	**Subject Device** Millipede System (K262399)
Principle of Operation	Designed to remove thrombus from the neurovasculature using direct aspiration.	Same
Condition Supplied	Sterile and Single Use	Same
Sterilization Method	Ethylene Oxide (EO)	Same
Aspiration Catheter		
Inner Diameter	88 Aspiration Catheter: 0.088” 70 Aspiration Catheter: 0.070” distal/ 0.069” proximal	Same Same
Outer Diameter	88 Aspiration Catheter: 0.104” distal / 0.108” proximal 70 Aspiration Catheter: 0.0837” distal/ 0.0865” proximal	Same Same
Length	88 Aspiration Catheter: 120 cm 70 Aspiration Catheter: 136 cm	Same Same
Materials	88 Aspiration Catheter: Polymers and metals commonly used in the manufacture of medical devices 70 Aspiration Catheter: Polymers and metals commonly used in the manufacture of medical devices	88 Aspiration Catheter: Proximal end - same Distal end - same polymers and metal reinforcement with changes to the color additives used and the addition of stabilizers 70 Aspiration Catheter: Same
Coating	88 Aspiration Catheter: Hydrophilic coating on distal 350mm of the catheter 70 Aspiration Catheter: Hydrophilic coating on distal 500mm of the catheter	88 Aspiration Catheter: Same hydrophilic coating on distal 500mm of the catheter 70 Aspiration Catheter: Same
Packaged Accessories	88 Aspiration Catheter: RHV and Valve Crossing Tool 70 Aspiration Catheter: RHV and Valve Crossing Tool	88 Aspiration Catheter: Identical RHV; Valve Crossing Tool with same fundamental design but changes to the materials to incorporate different color additives and the addition of stabilizers 70 Aspiration Catheter: Same

Attribute	Predicate Device Millipede System (K253590)	Subject Device Millipede System (K262399)
Packaging Configuration	The catheters are placed in a protective polyethylene tube, mounted with accessories onto a cardboard packaging card, placed into a pouch, sealed and labelled. The sealed pouch and Instructions for Use are placed in a labelled shelf carton box.	The catheters are placed in a protective polyethylene tube, mounted with accessories onto a packaging card, placed into a pouch, sealed and labelled. The sealed pouch and Instructions for Use are placed in a labelled shelf carton box.
Aspiration Tubing		
Inner Diameter	0.110”	Same
Outer Diameter	0.187”	Same
Length	100”	Same

Non-Clinical Performance Testing

Sterilization and Shelf Life

The Millipede88 Aspiration Catheter, Millipede70 Aspiration Catheter and Perfuze Aspiration Tube Set are sterilized using a validated EO process with a sterility assurance level of $1x10^{-6}$ in accordance with ISO 11135.

There is no change to the shelf life for any of the Millipede System components. The Millipede88 and Millipede70 Aspiration Catheters have a 12-month shelf life, and the Perfuze Aspiration Tube Set has a 24-month shelf life.

The packaging configuration of the Millipede70 Aspiration Catheter and Perfuze Aspiration Tube Set remains unchanged compared to the predicate device (K253590). The packaging configuration for the Millipede88 Aspiration Catheter is identical to that of the reference device (Millipede88 Access Catheter; K253901). Therefore, no additional shelf-life validation or packaging testing was required.

Biocompatibility

The patient-contacting materials of the Millipede70 Aspiration Catheter and Perfuze Aspiration Tube Set are unchanged compared to the predicate device. The patient-contacting materials of the Millipede88 Aspiration Catheter are identical to the reference device (Millipede88 Access Catheter; K253901). Therefore, no additional biocompatibility testing was required.

Performance Testing (Bench)

The Millipede70 Aspiration Catheter and Perfuze Aspiration Tube Set are identical to the predicate device. No additional bench testing was required to assess these device components.

The Millipede88 Aspiration Catheter has an identical design to the reference device (Millipede88 Access Catheter; K253901). Previous testing for the reference device, as described in K253901, is used to support substantial equivalence to the predicate device. In addition, the following non-clinical testing was conducted to demonstrate that the Millipede88 Aspiration Catheter is suitable for its intended use.

Test	Test Method	Conclusions
Simulated Use Testing	Deliverability, compatibility and durability for use with ancillary devices, ability to apply vacuum through the catheter, and resistance to lumen collapse were evaluated in a neurovascular model.	The device performs as intended under simulated use conditions.

Test	Test Method	Conclusions
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 integrity was maintained.
Flow Rate Characterization	The aspiration flow rate of saline through the catheter was characterized.	The flow rate was characterized.

Animal Testing

No animal testing was required to demonstrate substantial equivalence between the subject and predicate devices.

Clinical Study

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 System are identical to the predicate device. The subject and predicate devices use the same operating principles.

The Millipede70 Aspiration Catheter and Perfuze Aspiration Tube Set included in the subject Millipede System are identical to that of the predicate Millipede System. The subject Millipede88 Aspiration Catheter and the predicate device 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 non-clinical performance testing demonstrates that the Millipede System with the modified Millipede88 Aspiration Catheter is substantially equivalent to the predicate device.