March 16, 2026

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

Re: K253590
Trade/Device Name: Millipede System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: February 10, 2026
Received: February 10, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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, 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253590

Device Name
Millipede System

Indications for Use *(Describe)*

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.

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 – K253590

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:	11th March 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:	Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set
Common/Usual Name:	Percutaneous Catheter
Classification Name:	Catheter, Thrombus Retriever
Regulatory Class:	II
Regulation:	21 CFR 870.1250
Product Code:	NRY
Manufacturer:	Route 92 Medical, Inc.
510(k) Number:	K243601

Reference Devices

The following table lists the reference devices that were used to support the substantial equivalence determination in this submission.

510(k) Number	Product Code	Device Name	Manufacturer
K252392	NRY	Millipede70 Aspiration Catheter; Perfuze Aspiration Tube Set	Perfuze Ltd.
K242504	QJP	Millipede 088 Access Catheter	Perfuze Ltd.
K233648	QJP	Millipede 088 Access Catheter	Perfuze Ltd.

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. Both have a hydrophilic coating on their outer surface at the distal end (distal 350 mm of the Millipede88 Aspiration Catheter and distal 500 mm of the Millipede70 Aspiration Catheter) 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 Catheter to a compatible aspiration pump.

Comparison to the Predicate Device

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

Attribute	**Predicate Device** Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set (K243601)	**Subject Device** Millipede System (K253590)
Regulation Number	21 CFR 870.1250	Same
Regulation Name	Percutaneous Catheter	Same
Classification	Class II	Same
Product Code	NRY	Same

Attribute	**Predicate Device** Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set (K243601)	**Subject Device** Millipede System (K253590)
Indications for Use	The Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set, when used with a compatible vacuum 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 thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.	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.
Device Description	The Aspiration Catheter is a variable stiffness catheter with a distal polymer shaft section connected to a proximal control wire. A Delivery Catheter to facilitate delivery of the Aspiration Catheter is provided. The HiPoint Reperfusion System is used with the Route 92 Medical Aspiration Tubing Set	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.

Attribute	**Predicate Device** Route 92 Medical HiPoint Reperfusion System and Aspiration Tubing Set (K243601)	**Subject Device** Millipede System (K253590)
	and the Route 92 Medical Base Camp Sheath System.	
User	Physicians trained in neurovascular interventional techniques.	Same
Principle of Operation	Designed to remove thrombus from the neurovasculature using direct aspiration.	Same
Materials	Polymers and metals commonly used in the manufacture of medical devices.	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”	88 Aspiration Catheter: 0.088” 70 Aspiration Catheter: 0.070” distal/ 0.069” proximal
Outer Diameter	88 Aspiration Catheter: 0.101” distal / 0.105” proximal 70 Aspiration Catheter: 0.082” distal / 0.087” proximal	88 Aspiration Catheter: 0.104” distal / 0.108” proximal 70 Aspiration Catheter: 0.0837” distal/ 0.0865” proximal
Length	88 Aspiration Catheter: 143 cm 70 Aspiration Catheter: 142 cm	88 Aspiration Catheter: 120 cm 70 Aspiration Catheter: 136 cm
Delivery Catheter		
Inner Diameter	0.019”	Delivery catheter not included as part of the subject device.
Outer Diameter	88 Delivery Catheter: 0.080” distal/ 0.062” proximal 70 Aspiration Catheter: 0.062”	Delivery catheter not included as part of the subject device.
Length	151 cm	Delivery catheter not included as part of the subject device.
Aspiration Tubing		
Inner Diameter	0.110”	0.110”
Outer Diameter	0.188”	0.187”
Length	112”	100”

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.

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 shelf life and packaging configuration remain unchanged compared to the following reference devices: Millipede70 Aspiration Catheter and Perfuze Aspiration Tube Set (K252392); Millipede 088 Access Catheter (K242504 and K233648). Therefore, no additional shelf-life validation or packaging testing was required.

Biocompatibility

The patient-contacting materials of the Millipede88 Aspiration Catheter, Millipede70 Aspiration Catheter and Perfuze Aspiration Tube Set are unchanged compared to the reference devices described in K242504. Therefore, no additional biocompatibility testing was required.

Performance Testing (Bench)

The Millipede70 Aspiration Catheter and Perfuze Aspiration Tube Set have an identical design to the reference device described in K252392. No additional bench testing was required for the Millipede70 Aspiration Catheter and Perfuze Aspiration Tube Set.

The Millipede88 Aspiration Catheter has an identical design to the reference device described in K242504. Previous testing for the reference devices, as described in K242504 and K233648, 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.
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.
Clot Retrieval Testing	Clot retrieval performance was evaluated in a neurovascular model.	The device performs as intended under simulated use conditions.

Animal Testing

The safety and effectiveness of the Millipede System 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 Study

Summary

The Millipede AspiRation for Revascularization in Stroke (MARRS) Study was a prospective, multi-center, interventional, open-label, single-arm clinical investigation designed to assess the safety and effectiveness of the Millipede System for revascularization of subjects with acute ischemic stroke secondary to intracranial large vessel occlusions. The study was conducted at 22 sites in the United States, France, and Spain.

Patient Population

Inclusion Criteria

1. Subjects aged ≥ 18 and ≤ 85 years.
2. Pre-stroke modified Rankin Scale (mRS) score of ≤ 1.
3. Baseline National Institutes of Health Stroke Scale (NIHSS) score of ≥ 6.
4. A new focal disabling neurologic deficit consistent with acute cerebral ischemia.
5. Evidence of a large vessel occlusion of the intracranial ICA (internal carotid artery, including T or L occlusions), the M1 or M2 segments of the MCA (middle cerebral artery), the intracranial vertebral artery, or the basilar artery on magnetic resonance angiography (MRA) or computed tomography angiography (CTA).
6. Subject belongs to one of the following subgroups:
    a. Subject is ineligible for thrombolytic therapy, OR
    b. Subject is eligible for thrombolytic therapy and thrombolytic therapy was administered without delay and per current practice guidelines.
7. For strokes in the anterior circulation, the following imaging criteria should be met:
    a. Magnetic Resonance Imaging (MRI) criterion: volume of diffusion restriction visually assessed as ≤ 50 mL, or Alberta Stroke Program Early CT Score (ASPECTS) 6-10; OR
    b. Computed Tomography (CT) criterion: ASPECTS 6-10 on baseline CT or CTA-source images, or volume of significantly lowered relative Cerebral Blood Flow (rCBF) <30% (volume of ≤ 50 mL if CT perfusion is performed).
8. For strokes in the posterior circulation, the following imaging criterion should be met: pcASPECTS score 8 to 10 on baseline CT, CTA-source images, or Diffusion-Weighted Imaging (DWI) MRI.
9. The interventionalist estimates that arterial puncture can be completed within 8 hours of onset/last known well.
10. Informed consent obtained in accordance with the applicable country-specific regulations and as approved by the Institutional Review Board (IRB) / Research Ethics Committee (REC).
11. Angiographic confirmation of a single large vessel occlusion (modified thrombolysis in cerebral infarction (mTICI) of 0-1) of the intracranial ICA (including T or L occlusions), the M1 or M2 segments of the MCA, the intracranial vertebral artery, or the basilar artery that is accessible to the Millipede System.

Exclusion Criteria

1. Known previous stroke within the past 3 months.
2. Females who are known to be pregnant or breastfeeding.
3. In the Investigator's opinion, any known comorbidity (including COVID-19) that may complicate treatment or prevent improvement or follow-up.
4. Subject currently participating in or has previously participated in another trial involving an investigational device or drug within 30 days of enrollment.
5. Known history of severe contrast allergy.
6. Pre-existing neurological or psychiatric disease that would confound the neurological or functional evaluation.
7. Life expectancy of less than 6 months prior to stroke onset.
8. Known cocaine, methamphetamine, or heroin use at time of treatment.

9. Known history of coagulation factor deficiency or oral anti-coagulant therapy with an International Normalized Ratio (INR) of more than 3.0.
10. Known history of treatment with heparin within 48 hours with a Partial Thromboplastin Time (PTT) more than two times the laboratory normal.
11. Known history of treatment with a direct thrombin inhibitor within 48 hours with a PTT more than 1.5 times the laboratory normal.
12. Known glucose level< 50 mg/dl (2.78 mmol/L) or > 400 mg/dl (22.20 mmol/L).
13. Known platelet count <50,000/μL.
14. Clinical history, past imaging or clinical judgement suggest that the intracranial occlusion is chronic.
15. For all patients, severe sustained hypertension with systolic blood pressure (SBP) >220 mmHg and/or diastolic blood pressure (DBP) >120 mmHg; for patients treated with thrombolytic therapy, sustained hypertension despite treatment with SBP >185 mmHg and/or DBP > 110 mmHg.
16. Renal failure with serum creatinine ≥3 mg/dL or Glomerular Filtration Rate (GFR) <30 mL/min.
17. Ongoing seizure due to stroke.
18. Initially treated with intra-arterial thrombolytics or a different neurothrombectomy device before use of the Millipede System.
19. Clinical symptoms of bilateral stroke or stroke in multiple territories.
20. Known history of cerebral vasculitis.
21. Evidence of active systemic infection (e.g., septicemia). Exceptions: common cold, hepatitis B virus (HBV), hepatitis C virus (HCV).
22. Any known hemorrhagic or coagulation deficiency.
23. Evidence of current intracranial hemorrhage on imaging.
24. Significant mass effect with midline shift.
25. Known arterial condition in a proximal vessel that requires treatment or prevents access to the site of occlusion or safe recovery of the investigational device (for example, severe stenosis, complete occlusion in the cervical ICA, tandem occlusion).
26. Suspicion or evidence of aortic dissection, septic embolus, or bacterial endocarditis.
27. Evidence of dissection in the extracranial or intracranial cerebral arteries.
28. Excessive arterial tortuosity that may preclude device placement as determined by CTA/ MRA and/or conventional angiography.
29. Evidence of multiple vascular occlusions (e.g., bilateral anterior circulation, anterior/posterior circulation, concurrent occlusions in the anterior cerebral artery (ACA) and MCA, other concurrent ipsilateral occlusions in the same or different territories).
30. CT or MRI showing mass effect or intracranial tumor (apart from small meningioma, ≤ 2 cm in diameter).
31. Known cancer with metastases.
32. Known aneurysm at or near the target treatment segment.
33. Angiographic evidence of known or suspected underlying intracranial vasculopathy or atherosclerotic lesions responsible for the target occlusion.

Analysis Populations

Of the 235 subjects that were consented and enrolled, 55 did not meet the eligibility criteria during pre-screening (n=13) or the baseline digital subtraction angiography (n=42). The remaining 180 subjects underwent the study procedure and were included in the Intent-to-Treat (ITT) Analysis Set, defined as all enrolled subjects for whom the Millipede System was inserted into the access sheath. The main study analyses were based on this ITT Analysis Set.

A supplementary analysis was also conducted on a Per Protocol Analysis Set, which excluded an additional 38 subjects that had later identified protocol deviations against any of the eligibility criteria for the study. The reasons for exclusion from the Per Protocol Analysis Set were baseline mTICI >1 (n=8), baseline ASPECTS <6 (n=6), multiple occlusions (n=5), underlying vasculopathy/lesion responsible for target occlusion (n=5), time from symptom onset > 8 hours (n=5), extracranial occlusion/stenosis that prevents access to the target occlusion (n=4), renal failure (n=2), mRS >1 (n=2), previous stroke within 7 days (n=1), age >85 years (n=1), cancer with metastases (n=1),

intracranial hemorrhage at baseline (n=1), aneurysm at/near the target treatment segment (n=1) and comorbidity that may complicate treatment or prevent improvement/follow-up (n=1). Note: three subjects had deviations against two or more eligibility criteria.

Subject Follow-Up

Subjects were assessed at 24 hours and 90 days post-procedure. As outlined below, the 24-hour assessment was completed in 178/180 (98.9%) subjects. Non-completion of the 24-hour assessment was due to death in both cases. The 90-day assessment was completed in 154/180 (85.6%) subjects. Non-completion of the 90-day assessment was due to death in 25/180 (13.9%) subjects, and one subject was lost to follow-up.

Completed Follow-Up	**n/N (%)**
24 Hours Post-Procedure	178/180 (98.9%)
90 Days Post-Procedure	154/180 (85.6%)
Discontinued from the Study	**n/N (%)**
Subject death	25/180 (13.9%)
Lost to follow-up	1/180 (0.6%)

Baseline Demographics

Baseline Demographics and Clinical Characteristics	**N=180**	
Sex	**n**	**%**
Female	88	48.9
Male	92	51.1
Ethnicity	**n**	**% (N=100*)**
Hispanic or Latino	10	10.0
Not Hispanic or Latino	90	90.0
Missing	80	--
*Ethnicity data not collected for 77 EU subjects, as ethnicity data is not permitted to be collected in Europe. Missing ethnicity data for 3 subjects in US.		
Race	**n**	**% (N=97**)**
Asian	2	2.1
Black or African American	28	28.9
Other Pacific Islander	2	2.1
White	65	67.0
Missing	83	--
**Race data not collected for 77 EU subjects, as race data is not permitted to be collected in Europe. Missing race data for 6 subjects in US.		
Height, Weight, Body Mass Index (BMI) and Blood Pressure	**n**	**Mean (SD)**
Height (cm)	146	169.8 (9.9)
Weight (kg)	153	83.1 (20.5)
BMI (kg/m^2)	144	29.0 (6.6)
Systolic BP (mm/Hg)	179	144.3 (22.7)
Diastolic BP (mm/Hg)	179	81.8 (13.1)
Age	**n**	**Value**
Mean (SD)	180	67.2 (12.8)
Median (Min, Max)	180	69.0 (24,87)
Pre-Stroke mRS	**n**	**%**
0-1	178	98.9
2-3	2	1.1

Location of Occlusion	n	%
Left	79	43.9
Midline	5	2.8
Right	96	53.3
Location of Proximal End of Occlusion	**n**	**%**
Basilar Artery	5	2.8
Intracranial ICA - All	44	24.4
ICA - Carotid I	8	4.4
ICA - Carotid L	10	5.6
ICA - Carotid T	26	14.4
M1	112	62.2
M2	16	8.9
Other - Extracranial ICA	3	1.7
Pre-Treatment mTICI Score	**n**	**%**
0	161	89.4
1	12	6.7
≥ 2a	7	3.9
Baseline ASPECTS	**n**	**Value**
Mean (SD)	171	8.6 (1.7)
Median (Min, Max)	171	9.0 (2,10)
Baseline ASPECTS could not be determined by the Core Lab for 9 subjects due to inadequate image quality or missing imaging.		
Baseline NIHSS Score	**n**	**Value**
Mean (SD)	180	17.0 (5.9)
Median (Min, Max)	180	17.0 (6,42)
Stroke Onset to Groin Puncture	**n**	**Value**
Mean (SD)	180	262.4 (163.1)
Median (Min, Max)	180	224.0 (65,1483)

Catheters Used

Either the Millipede88 or Millipede70 Aspiration Catheter was used for direct aspiration during the first pass in all subjects: Millipede88 in 115/180 (63.9%) subjects and Millipede70 in 65/180 (36.1%) subjects. The Millipede catheter was used alone for the first pass in all except one subject. In this one case, a combined aspiration stent-retriever technique using the Millipede70 Aspiration Catheter was used. Seventy-nine (79) subjects were treated with Millipede88 only, and 29 subjects were treated with Millipede70 only.

Procedural Characteristics

Additional Therapy*	n/N (%)
Use of Any Additional Therapy During Procedure	47/180 (26.1%)
Other Aspiration Catheter	24/180 (13.3%)
Stent Retriever	28/180 (15.6%)
Other Therapy Type**	7/180 (3.9%)
* Includes additional therapy usage at and remote from the site of occlusion ** Other Therapy Type captures all instances of intra-arterial thrombolytic usage and intracranial stenting/angioplasty	
Procedural Time (Time from Groin Puncture to Groin Closure), Minutes	**N=180**
Mean (SD)	48.4 (29.8)
Median	41
Min, Max	11, 194
Time from Groin Puncture to Final Angiography, Minutes	**N=180**
Mean (SD)	40.3 (27.5)
Median	32

Min, Max	8, 164
Number of Revascularization Attempts	**N=180**
Mean (SD)	1.9 (1.5)
Median	1
Min, Max	1, 10
IV Thrombolytic Administration	**n/N (%)**
TNK	66/180 (36.7%)
t-PA	30/180 (16.7%)
Type unknown	1/180 (0.6%)
Not administered	83/180 (46.1%)

Results

Effectiveness

The Primary Effectiveness Endpoint is the proportion of subjects with successful reperfusion, defined as achieving an mTICI score of 2b or greater after ≤3 passes with the Millipede System without additional therapy.

Core Lab adjudicated reperfusion success was achieved within three passes of the Millipede System without additional therapy in 160/180 (88.9%) subjects. The endpoint was tested by comparing the lower bound of the 2-sided 95% confidence interval (CI) to a Performance Goal of 63.7%. The lower bound of the 2-sided 95% CI was 84.3%, which was greater than the Performance Goal. Therefore, the Primary Effectiveness Endpoint was achieved.

An additional analysis was also conducted, where the use of any non-study device after the Millipede System was defined as a failure even if a Core Lab adjudicated mTICI ≥ 2b score was achieved within three passes of the Millipede System. This analysis resulted in a success rate of 73.3%. The lower bound of the 2-sided 95% CI was 66.9%, which was also greater than the Performance Goal of 63.7%.

Primary Effectiveness Endpoint – ITT Analysis Set	**n/N (%)**	**95% LB[1]**	**95% UB**
mTICI ≥2b within 3 passes of Millipede System without additional therapy	160/180 (88.9%)	84.3%	93.5%
mTICI ≥2b within 3 passes of Millipede System; use of any additional therapy after achieving mTICI ≥2b with the Millipede System defined as failure	132/180 (73.3%)	66.9%	79.8%
[1] 95% lower bound (LB) of two-sided confidence interval (CI) is equivalent to the LB of one-sided 97.5% CI. Wald normal approximation to the binomial distribution confidence intervals are presented.			

Supplementary analyses of the Primary Effectiveness Endpoint were also conducted in the Per Protocol Analysis Set, as summarized below.

Primary Effectiveness Endpoint – Per Protocol Analysis Set	**n/N (%)**	**95% LB[2]**	**95% UB**
mTICI ≥2b within 3 passes of Millipede System without additional therapy	129/142 (90.8%)	86.1%	95.6%
mTICI ≥2b within 3 passes of Millipede System; use of any additional therapy after achieving mTICI ≥2b with the Millipede System defined as failure	107/142 (75.4%)	68.3%	82.4%
[2] 95% lower bound (LB) of two-sided confidence interval (CI) is equivalent to the LB of one-sided 97.5% CI. Wald normal approximation to the binomial distribution confidence intervals are presented.			

The study included secondary endpoints for Core Lab adjudicated reperfusion success at the end of the procedure and good clinical outcome (mRS ≤ 2) at 90 days. The proportion of ITT subjects with mTICI ≥ 2b and mTICI ≥ 2c at the end of the procedure was 98.3% and 82.2%, respectively. The proportion of ITT subjects achieving mRS ≤ 2 at 90 days was 52.5%.

ITT Analysis Set	n/N (%)	95% LB[3]	95% UB
Angiographic Outcomes at End of Procedure			
End of Procedure mTICI ≥ 2b	177/180 (98.3%)	95.2%	99.7%
End of Procedure mTICI ≥ 2c	148/180 (82.2%)	76.6%	87.8%
Clinical Outcome			
mRS ≤ 2 at 90 Days[4]	93/177 (52.5%)	45.2%	59.9%

[3] 95% lower bound (LB) of two-sided confidence interval is equivalent to the LB of one-sided 97.5% CI.
[4] One subject lost to follow-up at 90 days. Two subjects completed the study but had no mRS assessment at 90 days.
Exact binomial distribution confidence intervals are presented in cases with 5 or fewer successes or failures.
Wald normal approximation to the binomial distribution confidence intervals are presented in other cases.

Supplementary analyses of reperfusion success at the end of the procedure and good clinical outcome at 90 days were also conducted in the Per Protocol Analysis Set, as summarized below.

Per Protocol Analysis Set	n/N (%)	95% LB[5]	95% UB
Angiographic Outcomes at End of Procedure			
End of Procedure mTICI ≥ 2b	140/142 (98.6%)	95.0%	99.8%
End of Procedure mTICI ≥ 2c	118/142 (83.1%)	76.9%	89.3%
Clinical Outcome			
mRS ≤ 2 at 90 Days[6]	81/140 (57.9%)	49.7%	66.0%

[5] 95% lower bound (LB) of two-sided confidence interval is equivalent to the LB of one-sided 97.5% CI.
[6] One subject lost to follow-up at 90 days. One subject completed the study but had no mRS assessment at 90 days.
Exact binomial distribution confidence intervals are presented in cases with 5 or fewer successes or failures.
Wald normal approximation to the binomial distribution confidence intervals are presented in other cases.

Safety

The safety of the Millipede System was determined through a review of adverse events (AEs) recorded during the study. A summary of key safety metrics is provided below.

Key Safety Endpoints – ITT Analysis Set	N	n	%	95% LB[7]	95% UB[7]
Symptomatic intracranial hemorrhage (sICH) at 24 hours[8]	177	4	2.3%	0.6%	5.7%
All intracranial hemorrhage (ICH) at 24 hours[9]	177	55	31.1%	24.3%	37.9%
All-cause mortality at 90 days	180	25	13.9%	8.8%	18.9%
Device-related serious adverse events (SAEs)[10]	180	6	3.3%	0.7%	6.0%
Procedure-related SAEs	180	19	10.6%	6.1%	15.0%

[7] Exact binomial confidence intervals are presented for sICH since there are <5 instances.
Wald normal approximation to the binomial distribution confidence intervals are presented in all other cases.
[8] sICH was defined as local or remote parenchymal hematoma type 2, subarachnoid hemorrhage, and/or intraventricular hemorrhage identified by the Core Lab on the post-treatment imaging scan and associated with a neurological deterioration of 4 points or more on the NIHSS scale from baseline, or leading to death, that the CEC judges is causative of the deterioration. Three subjects had no imaging at 24 hours.
[9] Core Lab adjudicated. Three subjects had no imaging at 24 hours.
[10] The CEC adjudicated 6 subjects as having events that were possibly related to the device. No events were adjudicated as probably or causally related to the device.

24H ICH Type as Classified by the Core Lab	N	n	%	95% LB*	95% UB*
Overall	**177**	**55**	**31.1%**	**24.3%**	**37.9%**
HI1	177	15	8.5%	4.8%	13.6%
HI2	177	22	12.4%	8.0%	18.2%
PH1	177	6	3.4%	1.3%	7.2%
PH2	177	2	1.1%	0.1%	4.0%
SAH	177	2	1.1%	0.1%	4.0%
RIH	177	1	0.6%	0.0%	3.1%
HI2 + IVH	177	1	0.6%	0.0%	3.1%

24H ICH Type as Classified by the Core Lab	N	n	%	95% LB*	95% UB*
HI2 + SAH	177	1	0.6%	0.0%	3.1%
PH1 + SAH	177	1	0.6%	0.0%	3.1%
PH2 + SAH	177	1	0.6%	0.0%	3.1%
PH2 + IVH	177	2	1.1%	0.1%	4.0%
PH1 + IVH + SAH	177	1	0.6%	0.0%	3.1%

*Wald Approximation to the Binomial 95% Confidence Intervals presented for overall ICH.
Exact Binomial 95% Confidence Intervals presented for all subcategories of ICH.

The majority of AEs were classified as nervous system disorders. These AEs are summarized below for the ITT analysis set.

	Overall (N=180)	
	Subjects	%
Nervous system disorders	**90**	**50.0%**
Amnesia	1	0.6%
Ballismus	1	0.6%
Brain oedema	9	5.0%
Carotid artery occlusion	1	0.6%
Cerebral artery embolism	6	3.3%
Cerebral artery occlusion	2	1.1%
Cerebral infarction	3	1.7%
Cerebral mass effect	2	1.1%
Cerebral vasoconstriction	5	2.8%
Cerebrovascular accident	1	0.6%
Dysarthria	1	0.6%
Epilepsia partialis continua	1	0.6%
Epilepsy	1	0.6%
Haemorrhage intracranial	8	4.4%
Haemorrhagic transformation stroke	47	26.1%
Headache	5	2.8%
IIIrd nerve paralysis	1	0.6%
Intracranial artery dissection	2	1.1%
Ischaemic stroke	12	6.7%
Neurological decompensation	2	1.1%
Neuropathy peripheral	1	0.6%
Partial seizures	1	0.6%
Stroke in evolution	7	3.9%
Subarachnoid haemorrhage (All)	6	3.4%
Subarachnoid haemorrhage (without other haemorrhage types)	2	1.1%
Syncope	1	0.6%

MARRS Study Conclusions

Mechanical neurothrombectomy with the Millipede System was performed to achieve revascularization in subjects with large vessel occlusions within eight hours of last known well. The primary effectiveness and primary safety endpoints were met.

Conclusion

The Millipede System, consisting of the Millipede88 Aspiration Catheter, Millipede70 Aspiration Catheter, and Perfuze Aspiration Tube Set, has the same intended use, similar technological characteristics, and similar principles of operation as the predicate device. Differences between the subject and predicate devices do not raise new questions of safety and effectiveness. The non-clinical data for the subject device and the results of the MARRS clinical study demonstrate that the Millipede System is substantially equivalent to the predicate device.