November 16, 2021

Wallaby Medical
Nathaniel Knock
Director of Quality and Regulatory Affairs
22901 Mill Creek Drive
Laguna Hills, California 92653

Re: K211697
Trade/Device Name: Esperance Aspiration Catheter System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: October 15, 2021
Received: October 19, 2021

Dear Nathaniel Knock:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K211697

Device Name
Esperance Aspiration Catheter System

Indications for Use *(Describe)*
The Esperance Aspiration Catheter with the Medela Dominant Flex Surgical Suction Pump and Wallaby Aspiration Tubing set is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within internal carotid, middle cerebral - Ml 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.

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) Number: K211697

As required by 21 CFR 807.92:

Applicant:	Wallaby Medical 22901 Mill Creek Drive Laguna Hills, CA 92653
Contact:	Nathaniel Knock
Phone Number	1 949.480.9466
Date Prepared:	10/15/21
Device Trade Name:	Esperance Aspiration Catheter System
Device Common Name:	Catheter, Thrombus Retriever
Product Code	NRY
Classification Name:	Percutaneous Catheter, 21 CFR 870.1250
5F Predicate Device Name:	Penumbra Reperfusion Catheter 054, Penumbra Separator 054 (K090752)
6F Predicate Device Name:	Penumbra System ACE 64 and ACE 68 Reperfusion Catheters (K142458)

a. Device Description

The Esperance Aspiration Catheter System is a single-use, vascular catheter consisting of a single lumen, variable stiffness, composite catheter. The device system includes 5F and 6F catheters with inner diameters of 0.055" and 0.071", respectively, designed with three different working lengths for both sizes: 115 cm, 125 cm, and 131 cm. The device is supplied as a kit with Wallaby Aspiration Tubing Set provided with a single catheter. The distal tip of each catheter is visible under fluoroscopy and the distal shaft of each catheter is designed with an external hydrophilic coating to reduce friction during use. The proximal end of each catheter incorporates a strain relief and a standard Luer adapter to facilitate the attachment of accessories. Each catheter has a semi-rigid proximal shaft which transitions into a flexible distal shaft to facilitate the advancement of the catheter in tortuous anatomy.
The Esperance Aspiration Catheter System is a non-active, surgically invasive device intended for short term use within the vasculature.

b. Indication for Use

The Esperance Aspiration Catheter with the Medela Dominant Flex Surgical Suction Pump and Wallaby Aspiration Tubing set is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within 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.

c. Predicate Comparison

The predicate devices for the 5F and 6F Esperance Aspiration Catheter System models are the Penumbra Reperfusion Catheter 054, Penumbra Separator 054 (K090752) and the Penumbra System ACE 64 and ACE 68 Reperfusion Catheters (K142458), respectively. The tables below describe the technological differences between the 5F and 6F Esperance Aspiration Catheter and the predicate Penumbra Reperfusion Catheters 054 and ACE68, respectively:

Table 1 5F Esperance Aspiration Catheter System Technological Comparison to Predicate Penumbra Reperfusion Catheter 054

Device Name	**Predicate Device: Penumbra Reperfusion Catheter 054**	**Subject Device: Esperance Aspiration Catheter System (5F)**	**Rationale for Difference (if applicable)**
510(k) No.	K090752	K211697	
Classification	Class II, NRY	SAME	N/A- SAME
Intended Use	The Penumbra System 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.	The Esperance Aspiration Catheter with the Medela Dominant Flex Surgical Suction Pump and Wallaby Aspiration Tubing set is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within 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.	Both devices utilize an aspiration pump as part of the revascularization process
Materials			
Shaft			
Extrusions	Outer layer: Tecoflex (thermoplastic polyurethane), Pellethane (thermoplastic polyurethane), Pebax (polyether block amide), Vestamid (polyamide) Inner layer: PTFE	Outer layer: Tecothane (polyurethane elastomer), Pebax (polyether block amide), Vestamid (polyamide) Inner layer: PTFE	Both device materials are biocompatible, designed to be used in vasculature
Wire Reinforcement	SS flat coil	Nitinol coil and braid	
Components			
Hub	Grilamid (TR55)	Nylon	Both device materials are biocompatible, designed to be used in vasculature
Coating	Hydrophilic Coating	Hydrophilic Coating	
Strain Relief	Stainless Steel 304	Thermoplastic vulcanizate, polypropylene	
Strain Relief [Hub Sleeve]	Grilamid (TR55)	N/A	N/A- subject device has no strain relief hub sleeve
ID Band	Polyolefin, PET yellow [black ink]	N/A	N/A- subject device has no ID band
Colorant	Clear/Natural or Purple	Natural or Green or Blue	Both device colorants are approved for use in medical device applications
Marker Band	C-cut Pt/Ir Band	SAME	N/A- SAME

Device Name	Predicate Device: Penumbra Reperfusion Catheter 054	Subject Device: Esperance Aspiration Catheter System (5F)	Rationale for Difference (if applicable)
Tip Configuration	Straight, steam shapeable by user	Straight, steam shapeable by user	N/A- SAME
Accessories			
Shaping Mandrel	Not Reported	Stainless Steel	The shaping mandrel supplied with the Esperance Aspiration Catheter System was considered in biocompatibility assessments
Peelable Sheath	PTFE	PTFE	N/A- SAME
Rotating Hemostasis Valve	Polycarbonate, silicone ring	Polycarbonate, silicone ring	N/A- SAME
Dimensions			
Shaft			
Proximal OD	0.080 in Max	0.069 in Max	Both devices are evaluated to achieve proper placement during revascularization.
Distal OD	0.066 in Max	0.065 in Max	
Proximal ID	0.064 in Min	0.054 in Min	Both devices are evaluated to allow for revascularization through the ID of the device
Distal ID	0.054 in Min	0.054 in Min	
Effective Length	125 – 132 cm	115 – 131 cm	Both devices are evaluated to achieve proper placement during revascularization
Coating Length	30 cm	60 cm	Both devices are evaluated to achieve proper placement during revascularization
Accessories			
Peelable Sheath	Not Reported	0.092 in ID	The peelable sheath ID is designed to be compatible with the 5F Esperance Aspiration Catheter System
Shaping Mandrel	0.038 in OD	0.035 in OD	Both devices are evaluated for ability to retain shape after shaping with the mandrel
Packaging Material			
Pouch	Polyester/polyethylene/Tyvek	Tyvek to nylon	Packaging materials are similar and common for medical devices. Both packaging configurations maintain sterility of the device through shelf life
Packaging Hoop	Polyethylene	HDPE	
Packaging Card	Polyethylene	HDPE	
Display Carton	SBS Paperboard	SBS Paperboard	N/A- SAME
Sterilization Method	Ethylene Oxide	Ethylene Oxide	N/A- SAME
How Supplied	Sterile, Single Use	Sterile, Single Use	N/A- SAME
Shelf Life	36 Months	12 months	A 1 year shelf life is sufficient to allow for use of the device
Aspiration Pump and Tubing			
Aspiration Pump	Penumbra System with Penumbra ENGINE Vacuum Pump (cleared under K180008) of -29.2 in Hg with disposable canister	Medela Dominant Flex Surgical Suction Pump Vacuum of -29.2 in Hg with disposable canister	Both pumps are evaluated with their respective system to allow for revascularization

Device Name	Predicate Device: Penumbra Reperfusion Catheter 054	Subject Device: Esperance Aspiration Catheter System (5F)	Rationale for Difference (if applicable)
Aspiration Tubing	112 inch length Tubing ID = 0.110 inch	112 inch length Tubing ID = 0.110 inch Integrated valve for vacuum control	Both aspiration tubing sets are evaluated with their respective system to allow for revascularization

Table 2 6F Esperance Aspiration Catheter System Technological Comparison to Predicate Penumbra System ACE 68 Reperfusion Catheter

Device Name	Predicate Device: Penumbra System ACE 68 Reperfusion Catheter	Subject Device: Esperance Aspiration Catheter System (6F)	Rationale for Difference (if applicable)
510(k) No.	K142458	K211697	
Classification	Class II, NRY	SAME	N/A- SAME
Intended Use	The Penumbra System 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. The Reperfusion Catheters ACE 64 and ACE 68 are intended for use in revascularization within the Internal Carotid Artery (ICA) within 8 hours of symptom onset.	The Esperance Aspiration Catheter with the Medela Dominant Flex Surgical Suction Pump and Wallaby Aspiration Tubing set is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within 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.	Both devices utilize an aspiration pump as part of the revascularization process
Materials			
Shaft			
Extrusions	Outer layer: Tecoflex (thermoplastic polyurethane), Pellethane (thermoplastic polyurethane), Pebax (polyether block amide), Vestamid (polyamide) Inner layer: PTFE	Outer layer: Tecothane (polyurethane elastomer), Pebax (polyether block amide), Vestamid (polyamide) Inner layer: PTFE	Both device materials are biocompatible, designed to be used in vasculature
Wire Reinforcement	SS and Nitinol coil	Nitinol coil and braid	
Components			
Hub	Grilamid (TR55)	Nylon	Both device materials are biocompatible, designed to be used in vasculature
Coating	Hydrophilic Coating	Hydrophilic Coating	
Strain Relief	Stainless Steel 304	Thermoplastic vulcanizate, polypropylene	
Strain Relief [Hub Sleeve]	Grilamid (TR55)	N/A	N/A- subject device has no strain relief hub sleeve

Device Name	Predicate Device: Penumbra System ACE 68 Reperfusion Catheter	Subject Device: Esperance Aspiration Catheter System (6F)	Rationale for Difference (if applicable)
ID Band	Polyolefin, PET yellow [black ink]	N/A	N/A- subject device has no ID band
Colorant	Clear/Natural or Purple	Natural or Green or Blue	Both device colorants are approved for use in medical device applications
Marker Band	C-cut Pt/Ir Band	C-cut Pt/Ir Band	N/A- SAME
Tip Configuration	Straight, steam shapeable by user	Straight, steam shapeable by user	N/A- SAME
Accessories			
Shaping Mandrel	Not Reported	Stainless Steel	The shaping mandrel supplied with the Esperance Aspiration Catheter System was considered in biocompatibility assessments
Peelable Sheath	PTFE	PTFE	N/A- SAME
Rotating Hemostasis Valve	Polycarbonate, silicone ring	Polycarbonate, silicone ring	N/A- SAME
Dimensions			
Shaft			
Proximal OD	0.084 in Max	SAME	N/A- SAME
Distal OD	0.084 in Max	SAME	
Proximal ID	0.068 in Min	0.070 in Min	Both devices are evaluated to allow for revascularization through the ID of the device
Distal ID	0.068 in Min	0.070 in Min	
Effective Length	115 – 132 cm	115 – 131 cm	Both devices are evaluated to achieve proper placement during revascularization
Coating Length	30 cm	60 cm	Both devices are evaluated to achieve proper placement during revascularization
Accessories			
Peelable Sheath	Not Reported	0.092 in ID	The peelable sheath ID is designed to be compatible with the 6F Esperance Aspiration Catheter System
Shaping Mandrel	0.038 in OD	0.035 in OD	Both devices are evaluated for ability to retain shape after shaping with the mandrel
Packaging Material			
Pouch	Polyester/polyethylene/Tyvek	Tyvek to nylon	Packaging materials are similar and common for medical devices. Both packaging configurations maintain sterility of the device through shelf life.
Packaging Hoop	Polyethylene	HDPE	
Packaging Card	Polyethylene	HDPE	
Display Carton	SBS Paperboard	SBS Paperboard	N/A- SAME
Sterilization Method	Ethylene Oxide	Ethylene Oxide	N/A- SAME
How Supplied	Sterile, Single Use	Sterile, Single Use	N/A- SAME
Shelf Life	36 Months	12 months	A 1 year shelf life is sufficient to allow for use of the device
Aspiration Pump and Tubing			

Device Name	Predicate Device: Penumbra System ACE 68 Reperfusion Catheter	Subject Device: Esperance Aspiration Catheter System (6F)	Rationale for Difference (if applicable)
Aspiration Pump	Penumbra System with Penumbra ENGINE Vacuum Pump (cleared under K180008) of -29.2 in Hg with disposable canister	Medela Dominant Flex Surgical Suction Pump Vacuum of -29.2 in Hg with disposable canister	Both pumps are evaluated with their respective system to allow for revascularization
Aspiration Tubing	112 inch length Tubing ID = 0.110 inch	112 inch length Tubing ID = 0.110 inch Integrated valve for vacuum control	Both aspiration tubing sets are evaluated with their respective system to allow for revascularization

To establish the substantial equivalence of the Esperance Aspiration Catheter System to the predicate devices and meet the requirements of the risk analysis (FMECA), non-clinical bench, animal, and biological compatibility testing was conducted and driven by the risk analysis. The testing performed, and results, are summarized below:

Design Verification Testing - Bench

Performance testing was conducted to support the Esperance Aspiration Catheter System submission. The results of the design verification and validation testing performed confirm that the Esperance Aspiration Catheter System conforms to the pre-defined acceptance criteria. Testing included:

Table 3. 5F and 6F Catheter Bench Testing Summary

Test	5F Result	6F Result
Visual Inspection	The device was evaluated to verify the visual inspection requirements were met. The device met all pre-defined acceptance criteria.	
Dimensional Inspection (ID, OD, Overall Length, Working Length, Coating Length, Distal Tip to Marker Band, Hub/Strain Relief Length)	The device was evaluated to verify the dimensional requirements were met. The device met all pre-defined acceptance criteria.	
Aspiration Rate	The device was evaluated to verify the flow rate of saline. The device met all pre-defined acceptance criteria.	
Simulated Use	The device was evaluated in a simulated anatomy model for: preparation/ease of assembly, introducer sheath interaction, introducer peel away, compatibility with guidewire/microcatheter, lubricity and durability of hydrophilic coating, kink resistance, removal/aspiration of clots. Device performs as intended and met all pre-defined acceptance criteria under simulated use conditions.	
Physician Validation (simulated clot retrieval)	The device was evaluated in a simulated anatomy model by physicians with side by side comparison against the predicate for: preparation/ease of assembly, introducer sheath interaction, introducer peel away, compatibility with guidewire/microcatheter, lubricity and durability of hydrophilic coating, kink resistance, removal/aspiration of clots. Device performs as intended and demonstrates equivalency to its predicate device under simulated use conditions	
Delivery and Retrieval Forces (device, retrieval only for guidewire)	The device was subjected to delivery and retrieval forces testing in a vascular model under simulated use conditions and met all pre-defined acceptance criteria. The device results were evaluated and compared to the predicate in the same test conditions and deemed substantially equivalent.	

Test	5F Result	6F Result
Tip Stiffness	The device tip deflection force was measured on a universal testing machine and met acceptance criteria. The device results were evaluated and compared to the predicate in the same test conditions and deemed substantially equivalent.	
Tip Shaping	The device tip was shaped with the shaping mandrel and steam and met the pre-defined acceptance criteria.	
System Tensile (hub, shaft, tip)	The device was evaluated to verify the tensile strength of the full system meets the minimum tensile requirement. The device met all predefined acceptance criteria.	
Elongation to Failure	The device elongation was obtained from the shaft tensile testing data. The device met all pre-defined acceptance criteria.	
Torque Strength	The device torque response was assessed in a vascular model and met acceptance criteria.	
Coating Integrity (after particulate testing)	Utilized results of the 6F catheter testing since the larger size and surface area is worst case in terms of coating coverage, and device and model interaction.	The device coating integrity was inspected pre- and post-insertion and retrieval through a vascular model and met all pre-defined acceptance criteria.
Coating Lubricity	The device was evaluated for frictional forces on a universal testing machine and met all pre-defined acceptance criteria.	
Catheter Burst (Pressure)	The device was evaluated to verify the device does not leak, burst, and is compatible with accessories per ISO 10555-1 and ISO 594-1 and met acceptance criteria.	
Leak (Liquid)		
Leak (Air)		
Kink Resistance	The device was evaluated for resistance to kinking around bends with clinically relevant radii and met acceptance criteria.	
Vacuum Resistance	The device was evaluated for resistance to lumen collapse under vacuum and met all pre-defined acceptance criteria.	
Particulate	Utilized results of 6F catheter testing since the larger size and surface area is worst case in terms of coating coverage, and device and model interaction.	The device was evaluated within a simulated anatomy model to verify that any particulate generated is comparable to the predicate. The device met acceptance criteria.
Corrosion Resistance	The catheter is corrosion resistant per ISO 10555-1.	
Radiopacity	The device was evaluated for marker band visibility under fluoroscopy during the animal study and met the pre-defined acceptance criteria.	

Table 4. Tubing Set Bench Testing Summary

Test	Tubing Set Results
Leak (Liquid)	The tubing set was evaluated for liquid leak under simulated use conditions and met acceptance criteria.
Leak (Air)	The tubing set was evaluated for air leak under simulated use conditions and met acceptance criteria.
Set Tensile (Luer connector, suction connector)	The Luer and suction connectors were evaluated to verify the tensile strength supports the minimum tensile requirement. The tubing set connectors met all predefined acceptance criteria.
Dimensions (ID, length)	The tubing set was evaluated to verify the dimensional requirements were met. The device met all pre-defined acceptance criteria.
Tubing Vacuum Resistance	The tubing set was evaluated for resistance to lumen collapse during vacuum and met all pre-defined acceptance criteria.
Tubing Set Functionality	Tubing set functionality was evaluated during simulated use testing and met all pre-defined acceptance criteria.
Tubing Label Verification	Tubing set labeling was evaluated during simulated use testing and met all pre-defined acceptance criteria.

Table 5. Luer Hub Bench Testing Summary

Test	Luer Hub Results
ISO 80369-7 Section 5 Dimension	The device Luer hub dimensions were verified against standard requirements and met the pre-defined specifications.
ISO 80369-7, Section 6.1.3 & 80369-20 Annex C Falling Drop Positive Pressure Liquid Leakage	The device Luer hub resistance to liquid leakage was verified against standard requirements and met the pre-defined specifications.
ISO 80369-7, Section 6.2 & 80369-20 Annex D Sub-atmospheric-pressure Air Leakage	The device Luer hub resistance to air leakage was verified against standard requirements and met the pre-defined specifications.
ISO 80369-7, Section 6.3 & 80369-20 Annex E Stress Cracking	The device Luer hub resistance to liquid leakage after being subjected to stress was verified against standard requirements and met the pre-defined specifications.
ISO 80369-7, Section 6.4 & 80369-20 Annex F Resistance to Separation form Axial Load	The device Luer hub resistance to separation while under axial load was verified against standard requirements and met the pre-defined specifications.
ISO 80369-7. Section 6.6 & 80369-20 Annex H Resistance to Overriding	The device Luer hub resistance to overriding a reference connector when under an applied torque was verified against standard requirements and met the pre-defined specifications.
ISO 80369-7, Section 6.5 & 80369-20 Annex G & J.2.5 Resistance to Separation from Unscrewing	The device Luer hub resistance force to unscrewing when under an applied torque was verified against standard requirements and met the pre-defined specifications.

Design Verification Testing – Animal

Non-clinical testing comparing the safety, usability, and performance of the 6F Esperance Aspiration Catheter to the Penumbra System ACE 68 Reperfusion Catheter was conducted on a porcine model. Sub-chronic and chronic (3- and 30-day, respectively) time points were assessed. The 6F Esperance Aspiration Catheter was considered worst case for tracking, vessel interaction and particulate generation due to larger dimensions and surface area.

An interventionalist assessed the safety and usability of the subject and predicate devices after each pass, which included preparation and ease of assembly, introducer sheath interaction, introducer peel away, compatibility with guidewire and microcatheter, lubricity and durability of hydrophilic coating, kink resistance, and device condition. In addition, the safety of the device was evaluated by gross necropsy and histopathology of the treated vessels and their downstream tissues and organs.

Sterilization and Shelf Life

The 6F and 5F Esperance Aspiration Catheters are sterilized using an Ethylene Oxide (EO) sterilization cycle. The sterilization cycle was verified to ensure a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135:2014, *Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices*.

Aging studies for the 5F and 6F Esperance Aspiration Catheters have established that the catheters and packaging remain functional for the labeled use by date. Aging studies for packaging integrity, seal strength, and device functionality were performed and met all acceptance criteria.

Biocompatibility

Biocompatibility data for the Esperance Aspiration Catheter System was collected in accordance with ISO 10993-1:2018, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*. Biocompatibility testing completed for the device included:

Table 6. 510(k) Summary - Biocompatibility Testing

Test	Standard	Results	Conclusion
Catheter			
MTT – L-929 Cytotoxicity Study	Cytotoxicity 10993-5	1XMEM test extract showed no cytotoxic potential to L-929 mouse fibroblast cells undiluted or at any dilution.	Non-cytotoxic
ISO Intracutaneous Irritation (GLP - 2 Extracts)	Irritation or Intracutaneous Reactivity 10993-10	The delta between the average scores of the extract of the test article and the vehicle control are 0.0; 0.2.	Non-irritant
ISO Guinea Pig Maximization Sensitization (GLP - 2 Extracts)	Sensitization 10993-10	Test and control animal's response not greater than "0".	Did not elicit sensitization response
ISO Acute Systemic Toxicity (GLP - 2 Extracts)	Systemic Toxicity 10993-11	None of the animals were observed with abnormal clinical signs indicative of toxicity for 72 hours. All were alive at the end of 72 hours and body weight changes within acceptable parameters.	Non-toxic
ISO Material Mediated Rabbit Pyrogen (GLP)	Pyrogen 10993-11	No rabbit temp rise >= 0.5°C.	Non-pyrogenic
Complement Activation - SC5b-9 Assays with Sponsor-Supplied Comparator (GLP)	Hemocompatibility 10993-4	Results with acceptable range as compared to Control Device.	Test article complement activation has similar performance as the control
ASTM Hemolysis - Direct Contact and Extract Method (GLP)		Blank corrected Hemolytic index: 0.1.	Test device is non-hemolytic
Platelet and Leukocyte counts (GLP)		No ranges or levels outside an acceptable range and comparable to Control Device.	Counts of test device are within acceptable ranges and similar to control
Partial Thromboplastin Time (PTT) GLP		Test and predicate device have similar performance.	Test and control articles are not considered an activator of the intrinsic coagulation pathway
Thromboresistance Evaluation (GLP - 4 Hour - 3 Dog)		No adverse effects or clinical signs during test period and no thrombus score >3 for either test or control device	Thromboresistance of test device is similar to control
Peelable Introducer			
MTT – L-929 Cytotoxicity Study	Cytotoxicity 10993-5	Percent Cell Lysis: 0% Cytotoxic Score: 0	Non-cytotoxic
ISO Intracutaneous Irritation (GLP - 2 Extracts)	Irritation or Intracutaneous Reactivity 10993-10	The delta between the average scores of the extract of the test article and the vehicle control are 0.0; 0.1.	Non-irritant
ISO Guinea Pig Maximization	Sensitization 10993-10	Test and control animal's response not greater than "0".	Did not elicit sensitization response

Sensitization (GLP - 2 Extracts)			
ISO Acute Systemic Toxicity (GLP - 2 Extracts)	Systemic Toxicity 10993-11	None of the animals were observed with abnormal clinical signs indicative of toxicity for 72 hours. All were alive at the end of 72 hours and body weight changes within acceptable parameters.	Non-toxic
ISO Material Mediated Rabbit Pyrogen (GLP)	Pyrogen 10993-11	No rabbit temp rise >= 0.5°C.	Non-pyrogenic
ASTM Hemolysis - Direct Contact and Extract Method (GLP)	Hemocompatibility 10993-4	Blank corrected Hemolytic index: 0.6.	Non-hemolytic
Wallaby Aspiration Tubing Set			
MTT – L-929 Cytotoxicity Study	Cytotoxicity 10993-5	Percent Cell Lysis: 0% Cytotoxic Score: 0	Non-cytotoxic
ISO Intracutaneous Irritation (GLP - 2 Extracts)	Irritation or Intracutaneous Reactivity 10993-10	The delta between the average scores of the extract of the test article and the vehicle control are 0.0; 0.1.	Non-irritant
ISO Guinea Pig Maximization Sensitization (GLP - 2 Extracts)	Sensitization 10993-10	Test and control animal's response not greater than "0".	Did not elicit sensitization response

Clinical Testing

None. The substantial equivalence was established based on non-clinical performance data. The safety and usability results from the animal studies with both the 6F Esperance Aspiration Catheter and the Penumbra System ACE 68 Reperfusion Catheter were used to demonstrate the subject device is safe, usable, and is substantially equivalent to the predicate device.

Conclusion

The 5F and 6F Esperance Aspiration Catheter Systems are substantially equivalent to the Penumbra Reperfusion Catheter 054 and Penumbra System ACE 68 Reperfusion Catheter, respectively, based on the successful completion of non-clinical testing as well as similar principles of operation, materials of construction, packaging, usability, and the same intended use.