October 1, 2024

Wallaby Medical
Rachel McDaid
Senior Regulatory Affairs Specialist
22901 Mill Creek Drive
Laguna Hills, California 92653

Re: K240917
Trade/Device Name: Esperance 3+ Aspiration Catheter System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: August 30, 2024
Received: August 30, 2024

Dear Rachel McDaid:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
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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)*
K240917

Device Name
Esperance 3+ Aspiration Catheter System

Indications for Use *(Describe)*
The Esperance 3+ Aspiration Catheter with the Wallaby Aspiration Tubing set and a compatible aspiration pump 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.

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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K240917 510(k) Summary (21 CFR 807.92)

I. SUBMITTER

Wallaby Medical
22901 Mill Creek Drive
Laguna Hills, California 92653

Contact Person: Rachel McDaid
Phone: +353 (0)91 740128
Date Prepared: September 30, 2024

II. DEVICE

Device Trade Name: Esperance 3+ Aspiration Catheter System
Common or Usual Name: Catheter, Thrombus Retriever
Classification: Class II
Regulation Number: 21 CFR 870.1250
Product Code: NRY

III. PREDICATE DEVICE

Name: Penumbra System MAX
Manufacturer: Penumbra, Inc.
510(k) number: K113163

IV. DEVICE DESCRIPTION

Device Description:

The Esperance® 3+ Aspiration Catheter is a single-use, vascular catheter consisting of a single lumen, variable stiffness, composite catheter. The device has a tapered shaft with tapered inner diameter (ID) from 0.054'' (proximal) to 0.041'' (distal) and tapered outer diameter (OD) from 0.066'' (proximal) to 0.050'' (distal). It has five different working lengths: 120 cm, 133 cm, 145 cm, 153 cm, and 160 cm. The device is supplied as a kit with the 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 3+ Aspiration Catheter System is a non-active, surgically invasive device intended for short term use within the neurovasculature.

Environment of Use:

The Esperance 3+ Aspiration Catheter System is solely intended for use by trained physicians in a healthcare facility/hospital.

V. INDICATIONS FOR USE

The Esperance 3+ Aspiration Catheter with the Wallaby Aspiration Tubing set and a compatible aspiration pump 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.

The Indications for Use statement of the subject device is similar to the predicate device. The differences do not raise new or different questions of safety or effectiveness.

Table 1: Comparison of Indications for Use of the Esperance 3+ Aspiration Catheter System with the predicate and reference devices

Parameter	Reference Device Esperance Aspiration Catheter System (K211697)	Predicate Device Penumbra System MAX (K113163)	Subject Device Esperance 3+ Aspiration Catheter System (K240917)
Indications 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-tPA) or who fail IV t-PA therapy are candidates for treatment.	The Penumbra System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (in the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.	The Esperance 3+ Aspiration Catheter with the Wallaby Aspiration Tubing set and a compatible aspiration pump 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 2: Comparison of technological characteristics of the Esperance 3+ Aspiration Catheter System with predicate and reference devices

Parameter	Reference Device (K211697)		Predicate Device (K113163)	Subject Device (K240917)
Device Name	Esperance Aspiration Catheter System		Penumbra System MAX	Esperance 3+ Aspiration Catheter System
Model #	ASP6F131KIT ASP6F125KIT ASP6F115KIT ASP6F131 ASP6F125 ASP6F115	6F	3MAXC	ASP3F160KIT ASP3F153KIT ASP3F145KIT ASP3F133KIT ASP3F120KIT
	ASP5F131KIT ASP5F125KIT ASP5F115KIT ASP5F131 ASP5F125 ASP5F115	5F		
510(k) Number	K211697		K113163	K240917
Classification	Class II		Class II	Class II
Product Code	NRY		NRY	NRY
Device Design/Materials	Nitinol braided shaft, nitinol coil, polymeric exterior		Stainless steel and Nitinol coiled shaft, polymeric exterior	Inner shaft: Stainless steel braided shaft, Nitinol coil Outer layer: Polymeric exterior Tecoflex (thermoplastic polyurethane), Pellethane (thermoplastic polyurethane), Pebax (polyether block amide), Vestamid (polyamide) Inner layer: PTFE Hub: Polyamide
Wire Reinforcement	Nitinol coil and braid		Stainless steel and Nitinol coiled shaft	Stainless steel braided shaft, Nitinol coil
Strain Relief	Thermoplastic vulcanizate, polypropylene		Unknown	Silicone
Colorant	Natural or Green or Blue		Unknown	Green/Blue/White

Tip Configuration	Straight, steam shapeable by user		Straight, steam shapeable by user	Straight, steam shapeable by user
Marker Band Material/ Radiopacity	Radiopaque C-cut Platinum/Iridium		Radiopaque	Radiopaque Platinum/Iridium
Hub Material	Nylon		Unknown	Polyamide
Coating and Length	Hydrophilic coating Length: 60 cm		Hydrophilic coating Length: 95 cm	Hydrophilic coating Length: 100 cm
Working Length	115 cm 125 cm 131 cm		153 cm	120 cm 133 cm 145 cm 153 cm 160 cm
Outer Diameter	6F	0.084" Distal 0.084" Proximal	0.050" Distal 0.062" Proximal	0.050" Distal 0.066" Proximal
	5F	0.065" Distal 0.069" Proximal		
Inner Diameter	6F	0.070"	0.035" min	0.041" Distal 0.054" Proximal
	5F	0.054"		
Use	Single Use Device		Single Use Device	Single Use Device
Sterilization	Ethylene Oxide		Ethylene Oxide	Ethylene Oxide
Shelf Life	12 months		Unknown	12 months
Accessory Devices	Aspiration Tubing		Aspiration Tubing	Aspiration Tubing
	Introducer Sheath		Introducer Sheath	Introducer Sheath
	Shaping Mandrel		Shaping Mandrel	Shaping Mandrel
	Rotating Haemostasis Valve		Rotating Haemostasis Valve	Rotating Haemostasis Valve
Aspiration Tubing Dimensions	112 inch length Tubing ID = 0.110 inch Integrated valve for vacuum control		112 inch length Tubing ID = 0.110 inch	112 inch length Tubing ID = 0.110 inch Integrated valve for vacuum control
Aspiration Tubing Materials	Polyurethane & Nylon		Polyurethane & Nylon	Polyurethane & Nylon
Packaging Components/ Configuration	Device is stored within a HDPE packaging hoop		Supplied within a dispenser hoop	Device is stored within a HDPE packaging hoop
	Packaging hoop is contained within a sterile barrier Tyvek to nylon pouch		Dispenser hoop is contained within a sterile barrier pouch	Packaging hoop is contained within a sterile barrier Tyvek to nylon pouch
	Packaged within a shipping carton		Packaged within a shipping carton	Packaged within a shipping carton

VII. PERFORMANCE DATA

Biocompatibility

Biocompatibility testing for the Esperance 3+ Aspiration Catheter System was conducted based on International Organization for Standardization (ISO) 10993-1:2018 "Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process," and the FDA guidance document "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process"" (2020).

Table 3 below summarizes biocompatibility testing performed on the Esperance 3+ Aspiration Catheter System and accessories to be marketed with the device.

Table 3: Biocompatibility Testing Results for the Esperance 3+ Aspiration Catheter System

Test	Test Description	Conclusion
Esperance 3+ Aspiration Catheter Test Results		
Cytotoxicity ISO 10993-5	MTT- L929 Cytotoxicity Study	No cytotoxic effect.
Skin Irritation ISO 10993-10	ISO Intracutaneous Irritation	No sensitization indicated.
Sensitization ISO 10993-10	ISO Guinea Pig Maximization Sensitization	No sensitization indicated.
Systemic Toxicity ISO 10993-11	ISO Acute Systemic Toxicity	No acute systemic toxicity indicated.
	ISO Material Mediated Rabbit Pyrogen (GLP)	Esperance 3+ Aspiration Catheter is deemed non-pyrogenic.
Hemocompatibility ISO 10993-4	Hemolysis (ASTM method) Indirect Extract	No hemolysis indicated.
	ASTM Hemolysis - Direct Contact and Extract Method (GLP)	No hemolysis indicated.
	Complement Activation	Esperance 3+ Aspiration Catheter is deemed comparable to predicate.
	Thromboresistance Evaluation	Esperance 3+ Aspiration Catheter is deemed comparable to predicate.
	Partial Thromboplastin Time	Esperance 3+ Aspiration Catheter is deemed comparable to predicate.
Accessory Test Results - Introducer Sheath		
Cytotoxicity ISO 10993-5	ISO MEM elution- L929	No cytotoxic effect.
Sensitization ISO 10993-10	ISO Guinea Pig Maximization Sensitization	No sensitization indicated.
Skin Irritation ISO 10993-10	ISO Intracutaneous Irritation	No sensitization indicated.
Systemic Toxicity ISO 10993-11	Systemic Toxicity - Acute Systemic Injection	No acute systemic toxicity indicated.

	Material Mediated Pyrogenicity Test	Test articles are deemed non-pyrogenic.
Hemocompatibility ISO 10993-4	ASTM Hemolysis -Extract Method	No hemolysis indicated.
Accessory Test Results - Wallaby Aspiration Tubing		
Cytotoxicity ISO 10993-5	MTT- L929 Cytotoxicity Study	No cytotoxic effect.
Skin Irritation ISO 10993-10	ISO Intracutaneous Irritation	No sensitization indicated.
Sensitization ISO 10993-10	ISO Guinea Pig Maximization Sensitization	No sensitization indicated.
Accessory Test Results - Rotating Hemostasis Valve		
Cytotoxicity ISO 10993-5	ISO MEM elution- L929	No cytotoxic effect.
Skin Irritation ISO 10993-10	ISO Intracutaneous Irritation	No sensitization indicated.
Sensitization ISO 10993-10	ISO Guinea Pig Maximization Sensitization	No sensitization indicated.
Systemic Toxicity ISO 10993-11	ISO Acute Systemic Toxicity	No acute systemic toxicity indicated.
	ISO Material Mediated Rabbit Pyrogen (GLP)	RHV is deemed non- pyrogenic.
Hemocompatibility ISO 10993-4	ASTM Hemolysis -Extract Method	No hemolysis indicated.

Sterilization

The Esperance 3+ Aspiration Catheter System is sterilized by Ethylene Oxide. Sterilization takes place in Steris Sterilization Technologies (Suzhou) Ltd., Jiangsu, China. The sterilization cycle was verified to ensure a sterility assurance level (SAL) of 10^{-6}.

The Esperance 3+ Aspiration Catheter System has been adopted into an existing validated cycle per EN ISO 11135:2014 and AAMI TIR28:2009.

Standards utilized in regards to sterilization:
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."
FDA guidance documents utilized in regards to sterilization:
"Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labelled as Sterile" (2016).

The sterilization cycle has been validated via the half cycle method.

Shelf Life

Shelf life conditioning has been completed and testing has been performed on devices subjected to an accelerated aging (AA) process to represent 1 year of aged units. Devices subjected to 1 year AA were tested to ensure design and performance specification requirements were met after the one year shelf life that the Esperance 3+ Aspiration Catheter System will have at commercialization. Aging studies for the Esperance 3+ Aspiration Catheter System 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.

FDA guidance documents utilized in regards to shelf life:

"Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019).

Non-Clinical Performance Data

The following non-clinical performance tests were performed to support the substantial equivalence determination as summarized below.

PERFORMANCE TESTING - BENCH

A full suite of bench performance testing was carried out on the Esperance 3+ Aspiration Catheter System. The results of this testing demonstrated compliance to all the design attributes and that the device performs as intended. Table 4 below summarizes the bench performance tests and results.

Table 4: Summary of Non-Clinical Bench Testing

Test	Test Method Summary	Results
Dimensional Verification (Working Length, Coating Length, ID, OD)	The dimensions of the catheter and the introducer sheath are measured.	All samples met the acceptance criteria.

Test	Test Method Summary	Results
Navigability	The device is tested for its ability to reach target site in an anatomical model in comparison to the predicate.	All samples met the acceptance criteria.
Clot Removal	The subject device is tested for its ability to aspirate clots in an anatomical model in comparison to the predicate.	All samples met the acceptance criteria.
Kink Resistance	The catheter is tested at different locations for its ability to bend to clinically relevant radii without kinking in comparison to predicate.	All samples met the acceptance criteria.
Lubricity	The catheter's hydrophilic coating lubricity is tested by applying force to the coated section of the catheter and measuring the frictional force in comparison to the predicate.	All samples met the acceptance criteria.
Coating Integrity	The coated length of the catheter is inspected for defects post simulated use in comparison to the predicate.	All samples met the acceptance criteria.
Torque Strength	The catheter and predicate were evaluated for torque strength by rotating the test sample within an anatomical model until failure while the distal tip was not free to rotate.	All samples met the acceptance criteria.
Delivery and Retrieval Force	The subject device is tested for its ability to reach and be retracted from a target site in an anatomical model with application of force below a specified value. Delivery and retrieval forces were also compared to the predicate device.	All samples met the acceptance criteria.
Vacuum Resistance	The device is tested for its ability to withstand a specified vacuum pressure for a specified time without damage, lumen collapse, or kink.	All samples met the acceptance criteria.
Aspiration Flow Rate	The aspiration flow rate of the subject device at a specified vacuum pressure was measured in comparison to the predicate.	All samples met the acceptance criteria.
Elongation to Failure	The catheter elongation at break was obtained from the shaft tensile testing data.	All samples met the acceptance criteria.

Test	Test Method Summary	Results
Tip Stiffness	The catheter tip is tested by bending in a test fixture and measuring the maximum load that caused deflection. Tip stiffness was also compared to the predicate.	All samples met the acceptance criteria.
Atraumatic Distal Tip	The catheter tip is inspected for smoothness.	All samples met the acceptance criteria.
Tip Shaping Ability	The distal tip of the catheter is shaped using the shaping mandrel supplied with the Esperance 3+ Aspiration Catheter System and the distal tip is assessed for damage and the ability to hold the tip shape.	All samples met the acceptance criteria.
Introducer Sheath Compatibility	The supplied introducer sheath is tested for compatibility with the Esperance 3+ Aspiration Catheter System.	All samples met the acceptance criteria.
Device Compatibility	An appropriately sized guidewire is delivered and retrieved through the catheter. The catheter is delivered and retrieved through an appropriately sized sheath.	All samples met the acceptance criteria.
Surface Defects	The catheter and introducer sheath are examined under magnification for extraneous matter.	All samples met the acceptance criteria.
Tensile Force	The peak tensile force of the subject catheter is measured at different locations in comparison to the predicate.	All samples met the acceptance criteria.
Liquid Leakage	The subject catheter is tested for leakage per ISO 10555-1 and compared to the reference device .	All samples met the acceptance criteria.
Air Leak	The subject catheter is tested for air leakage per ISO 10555-1 and compared to the reference device.	All samples met the acceptance criteria.
Static Burst	The subject catheter is tested to withstand a specified static pressure.	All samples met the acceptance criteria.

Test	Test Method Summary	Results
Power Injection	The distal tip of the catheter was blocked, and fluid was injected into the lumen using a power injector until the catheter burst.	All samples met the acceptance criteria.
Corrosion	The subject device is visually inspected for signs of corrosion post exposure to required conditions per ISO 10555-1.	All samples met the acceptance criteria.
Particulate Testing	The size and number of particulates generated during simulated use of the device in a neurovascular model were measured and calculated. Particulate generation was compared to the reference device.	Particulate generation was similar between the subject and reference device.
Hub/Luer Fitting	The catheter hub is tested as per ISO 80369-7.	All samples met the acceptance criteria.

Standards utilized in regards to bench testing:
ISO 10555-1:2013/A1:2017 "Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements."
ISO 80369-20 "Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods."
ISO 80369-7:2016 "Small-bore connectors for liquids and gases in healthcare application - Part 7: Connectors for intravascular or hypodermic applications."
ISO 62366-1: 2015 + AC:2015 & A1 2020 "Medical Devices- Part 1: Application of Usability Engineering to Medical Devices."

FDA guidance documents utilized in regards to bench testing:
"Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019).
"Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters - Class II Special Controls Guidance for Industry and FDA" (2010).
"Applying Human Factors and Usability Engineering to Medical Devices" (2016).

Clinical Testing

Clinical testing was not performed on the Esperance 3+ Aspiration Catheter System as clinical data were not deemed necessary to establish substantial equivalence.

Animal Testing

Animal data were not deemed necessary as substantial equivalence was established based upon successful completion of non-clinical performance testing presented above.

VIII. CONCLUSIONS

Wallaby Medical has demonstrated that the Esperance 3+ Aspiration Catheter System is substantially equivalent to the predicate device Penumbra System MAX (K113163). The subject device has the same intended use, similar technological characteristics, similar materials, and the same operating principle as the predicate device. The differences do not raise new questions of safety or effectiveness. The subject device has been demonstrated to perform as intended through successful non-clinical performance testing.