March 8, 2024

Wallaby Medical
Emily Dobosz
Senior Manager Regulatory Affairs
22901 Mill Creek Drive
Laguna Hills, California 92653

Re: K231056
Trade/Device Name: Esperance Distal Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: February 2, 2024
Received: February 5, 2024

Dear Emily Dobosz:

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

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

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

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

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
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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)*
K231056

Device Name
Esperance Distal Access Catheter

Indications for Use *(Describe)*
The Esperance Distal Access Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary (21 CFR 807.92)

510(k) Number: K231056

Date Prepared: March 06, 2024

510(k) Submitter: Wallaby Medical
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Contact: Emily Dobosz
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Device Trade Name: Esperance® Distal Access Catheter
Common or Usual Name: Catheter, Percutaneous, Neurovasculature
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Review Panel: Neurology, Cardiovascular
Device Class: Class II
Product Codes: QJP, DQY

PREDICATE AND REFERENCE DEVICES

Device Name	510(k) Number
Predicate: React™71 Catheter	K182097
Reference: Esperance Aspiration Catheter System	K211697

DEVICE DESCRIPTION

The Esperance® Distal Access Catheter is a single-use, single lumen, variable stiffness, composite catheter. The device 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 with a peelable introducer and shaping mandrel. 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® Distal Access Catheter is a non-active, surgically invasive device intended for short term use within the vasculature.

INDICATIONS FOR USE

The Esperance Distal Access Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

	Predicate Device	**Subject Device**	**Reference Device**
Trade Name	React™ 71 Catheter	Esperance® Distal Access Catheter	Esperance® Aspiration Catheter System
510(k) number	K182097	K231056	K211697
Product Classification	Class II	Class II	Class II
Regulation Number	21 CFR 870.1250	21 CFR 870.1250	21 CFR 870.1250
Regulation Name	Percutaneous Catheter	Catheter, Percutaneous, Neurovasculature	Catheter, Thrombus Retriever
Product Code	DQY	QJP, DQY	NRY
Intended Use/Indications for Use	The React™ 71 Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.	The Esperance Distal Access Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.	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.
Accessories	Peelable Sheath	Peelable Sheath, Shaping Mandrel	Peelable Sheath, Shaping Mandrel
Dimensions			
Working Length	132 cm	115 cm 125 cm 131 cm	115 cm 125 cm 131 cm
Proximal Outer Diameter (OD)	0.0855 in (Max)	5F: 0.069 in Max 6F: 0.084 in Max	5F: 0.069 in Max 6F: 0.084 in Max
Distal OD	0.0855 in (Max)	5F: 0.065 in Max 6F: 0.084 in Max	5F: 0.065 in Max 6F: 0.084 in Max
Inner Diameter	0.071 in	5F: 0.054 in Min	5F: 0.054 in Min

(ID)		6F: 0.070 in Min	6F: 0.070 in Min
Materials			
Hub	Trogamid	Nylon	Nylon
Strain Relief	DynaFlex	Thermoplastic vulcanizate, polypropylene	Thermoplastic vulcanizate, polypropylene
Inner Layer	PTFE, Polyolefin	PTFE	PTFE
Reinforcement	Nitinol	Nitinol	Nitinol
Outer Jacket	Polyamide, Polyolefin, Polyurethane	Tecothane (polyurethane elastomer), Pebax (polyether block amide), Vestamid (polyamide)	Tecothane (polyurethane elastomer), Pebax (polyether block amide), Vestamid (polyamide)
Marker Band	Platinum/Iridium	Platinum/Iridium	Platinum/Iridium
Adhesive	Cyanoacrylate	Cyanoacrylate	Cyanoacrylate
Coating	Hydrophilic	Hydrophilic	Hydrophilic
Packaging Configuration	Pouch, Packaging Card, Packaging Hoop	Pouch, Packaging Card, Packaging Hoop	Pouch, Packaging Card, Packaging Hoop
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
How Supplied	Sterile, Single Use	Sterile, Single Use	Sterile, Single Use

BIOCOMPATIBILITY

Biocompatibility of the subject Esperance® Distal Access Catheter is supported by the previously conducted biocompatibility evaluation of the reference device, the Esperance Aspiration Catheter System (K211697), because there are no changes in the design, materials, and manufacturing of the subject Esperance® Distal Access Catheter and accessories versus the respective components of the reference device system.

NON-CLINICAL PERFORMANCE DATA

Bench performance testing was conducted to support the subject Esperance® Distal Access Catheter submission. Because there are no changes in the design, materials, and manufacturing of the subject Esperance® Distal Access Catheter and accessories versus the respective components of the reference device, the Esperance Aspiration Catheter System (K211697), for tests marked with ***** in the table below performance data from the reference device were used in support of the subject device.

Test	Description / Results
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.
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, and kink resistance. Testing of the reference device, Esperance Aspiration Catheter System (K211697), was used and supplemented with additional testing conducted to support the intended use of the subject Esperance Distal Access Catheter. Device performs as intended and met all pre-defined acceptance criteria under simulated use conditions.
Physician Validation*	The device was evaluated in a simulated anatomy model by physicians. Device performs as intended under simulated use conditions.
Delivery and Retrieval Forces	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. Testing of the reference device, Esperance Aspiration Catheter System (K211697), was used and supplemented with additional testing conducted to support the intended use of the subject Esperance Distal Access Catheter.
Tip Stiffness*	The device tip was deflected on a universal testing machine and met acceptance criteria.
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 the predefined acceptance criteria.
Coating Integrity (after particulate testing)	Testing of the reference device, Esperance Aspiration Catheter System (K211697), was used and supplemented with additional testing conducted to support the intended use of the subject Esperance Distal Access Catheter. 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, Leak (Liquid and Air)	The device was evaluated to verify the device does not leak, burst, and is compatible with accessories per ISO 10555-1 and met acceptance criteria. Testing of the reference device, Esperance Aspiration Catheter System (K211697) was used and supplemented with additional testing conducted to support the intended use of the subject Esperance Distal Access Catheter.
Kink Resistance*	The device was evaluated for resistance to kinking around bends with clinically relevant radii and met acceptance criteria.
Particulate	The device was evaluated within a simulated anatomy model to verify that any particulate generated is comparable to cleared comparator devices. The device met acceptance criteria. Testing of the reference device, Esperance Aspiration Catheter System (K211697) was used and supplemented with additional testing conducted to support the intended use of the subject Esperance Distal Access Catheter.
Corrosion Resistance*	The catheter is corrosion resistant per ISO 10555-1.

Radiopacity*	The device was evaluated for marker band visibility under fluoroscopy and met the pre-defined acceptance criteria.
Luer Hub Testing*	The device was evaluated per ISO 80369-7 and ISO 80369-20 and met the pre-defined specifications.

PERFORMANCE DATA - ANIMAL

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

PERFORMANCE DATA - CLINICAL

A clinical study was not deemed necessary as substantial equivalence was established based upon successful completion of non-clinical bench testing.

CONCLUSION

The Esperance® Distal Access Catheter is substantially equivalent to the React™ 71 Catheter (K182097). The differences in technological characteristics do not raise new questions of safety or effectiveness.

Non-clinical testing supports a determination that the Esperance® Distal Access Catheter is substantially equivalent to the predicate device.