March 2, 2023

Wallaby Medical
David Ruiz
Staff Quality Engineer
22901 Mill Creek Drive
Laguna Hills, California 92653

Re: K222603
Trade/Device Name: 6F Wallaby Long Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, QJP
Dated: February 1, 2023
Received: February 1, 2023

Dear David Ruiz:

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 -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
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)*

K222603

Device Name
6F Wallaby Long Sheath

Indications for Use *(Describe)*
The 6F Wallaby Long Sheath 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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K222603 510(k) Summary

As required by 21 CFR 807.92:

Applicant:	Wallaby Medical 22901 Mill Creek Drive Laguna Hills, CA 92653
Contact:	David Ruiz
Phone Number:	(1)-951-818-7984
Date Prepared:	03/02/23
Device Trade Name:	6F Wallaby Long Sheath
Device Common Name:	Sheath, Access
Classification Name:	DQY (Catheter, Percutaneous) and QJP (Catheter, Percutaneous, Neurovasculature), 21 CFR 870.1250
Predicate Device Name:	Neuron MAX System (K111380)

a. Device Description

The 6F Wallaby Long Sheath is a single-use, vascular catheter consisting of a single lumen, variable stiffness, composite catheter. The device has an inner diameter (ID) of 0.088 inch and outer diameter (OD) of 0.105 inch designed with three different working lengths (80 cm, 90 cm, and 100 cm) and two different tip configurations (straight and multipurpose curve). The distal tip of the 6F Wallaby Long Sheath is visible under fluoroscopy and the distal shaft of the catheter is designed with an external hydrophilic coating to reduce friction during use. The proximal end of the catheter incorporates a strain relief and a standard Luer adapter to facilitate the attachment of accessories. The 6F Wallaby Long Sheath has a semi-rigid proximal shaft which transitions into a flexible distal shaft to facilitate the advancement of the catheter in tortuous anatomy.

The 6F Wallaby Long Sheath is a non-active, surgically invasive device intended for short term use within the vasculature.

b. Indications for Use

The 6F Wallaby Long Sheath is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

c. Predicate Comparison

The predicate device for the 6F Wallaby Long Sheath is the Neuron MAX System cleared under K111380. The table below describes the technological differences between the 6F Wallaby Long Sheath and the Neuron MAX System:

Table 1: 6F Wallaby Long Sheath Technological Comparison to Neuron MAX System

Device Name	**Predicate Device:** **Neuron MAX System**	**Subject Device:** **6F Wallaby Long Sheath**	**Rationale for Difference**
510(k) Number	K111380	K222603	
Classification	Class II, DQY	Class II, DQY and QJP	QJP product code added

Device Name	Predicate Device: Neuron MAX System	Subject Device: 6F Wallaby Long Sheath	Rationale for Difference
Indications for Use	The Neuron MAX System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The 6F Wallaby Long Sheath is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.	The 6F Wallaby Long Sheath is not indicated for use in the coronary vasculature.
Materials			
Shaft			
Extrusions	Outer layer: Polyurethane, polyamide Inner layer: PTFE	Outer layer: Neusoft (polyurethane), PEBAX, polyamide, PET Inner layer: PTFE	Both device materials are biocompatible, designed to be used in the vasculature.
Wire Reinforcement	Stainless Steel	Stainless Steel and Nitinol	
Components			
Hub	Polyamide	Polyamide	SAME
Coating	Hydrophilic Coating	Hydrophilic Coating	The subject device materials are biocompatible and designed to be used in vasculature.
Strain Relief	Stainless Steel	Pebax	
Colorant	Clear/Natural or Blue	Clear/Natural or Purple	The subject device colorants are biocompatible.
Marker Band	C-cut Pt/Ir Band	C-cut Pt/Ir Band	SAME
Tip Configuration	Straight and multipurpose	Straight and multipurpose	SAME
Accessories			
Dilator	HDPE	HDPE	SAME
Rotating Hemostasis Valve (RHV)	Not included	Polycarbonate, Silicone, Silicone Lubricant	The RHV materials are biocompatible.
Dimensions			
Shaft			
Proximal OD	0.110 in	0.105 in	Both devices are evaluated to achieve proper placement during advancement.
Distal OD	0.105 in	0.105 in	
Proximal ID	0.088 in	0.088 in	SAME
Distal ID	0.088 in	0.088 in	
Effective Length	80-100 cm	80-100 cm	SAME
Coating Length	12 cm	14 cm	Both devices are evaluated to achieve proper placement during advancement.
Accessories			
Dilator ID	0.039 in Min	0.039 in Min	SAME
Dilator OD	0.085 in Max	0.087 in Max	Both devices are evaluated for the insertion and removal of the dilator from the sheath.

Device Name	Predicate Device: Neuron MAX System	Subject Device: 6F Wallaby Long Sheath	Rationale for Difference
Packaging Material			
Pouch	PET/PE/Tyvek Pouch	PA/Tyvek pouch	Packaging materials are similar and common for medical devices. Both packaging configurations maintain sterility of the device throughout the shelf life.
Tubing	HDPE	HDPE	SAME
Packaging Card	Polyethylene	Polyethylene	SAME
Display Carton	SBS Paperboard	SBS Paperboard	SAME
Sterilization Method	Ethylene Oxide	Ethylene Oxide	SAME
How Supplied	Sterile, Single Use	Sterile, Single Use	SAME
Shelf Life	36 Months	12 months	A 12-month shelf life was validated for the subject device.

d. Non-Clinical Performance Tests

To establish the substantial equivalence of the 6F Wallaby Long Sheath to the predicate Neuron MAX System and to meet the requirements of the risk analysis , non-clinical bench and biological compatibility testing was conducted and driven by the risk analysis. The testing and results are summarized below:

Design Verification Testing - Bench

Performance testing was conducted. The results of the design verification and validation testing confirm that the 6F Wallaby Long Sheath conforms to the pre-defined acceptance criteria. Testing included:

Table 2: 6F Wallaby Long Sheath Bench Testing Summary

Test	Methods and Results
Visual Inspection	The 6F Wallaby Long Sheath was evaluated to verify the visual inspection requirements were met. The device met all pre-defined acceptance criteria.
Dimensional Inspection	The 6F Wallaby Long Sheath was evaluated to verify the dimensional requirements for ID, OD, overall length, working length, and coating length were met. The subject device met all pre-defined acceptance criteria.
Simulated Use	The 6F Wallaby Long Sheath was evaluated under a simulated use in a representative tortuous anatomical model. Subject device compatibility with 6F and 8F catheters, the RHV, guidewire, and stent retriever were evaluated. The device performed as intended.
Physician Validation	The 6F Wallaby Long Sheath was evaluated under a simulated use in a representative tortuous anatomical model by physicians in comparison to the predicate device, including preparation and ease of assembly, 8F short sheath interaction, RHV Luer connection interaction, dilator interaction, compatibility with guidewire, guide and aspiration catheters, and kink resistance. The subject device performed as intended.
Delivery and Retrieval	The 6F Wallaby Long Sheath was evaluated under a simulated use in a representative tortuous anatomical model for delivery and retrieval forces in comparison to the predicate device. The forces required to deliver and retrieve the subject device with ancillary devices were compared to the predicate device, which demonstrated similar forces.

Test	Methods and Results
Tip Stiffness	The tip stiffness of the 6F Wallaby Long Sheath was evaluated and compared to the predicate device. The results demonstrated tip stiffness is similar to the predicate.
Tensile Strength and Elongation to Failure	The 6F Wallaby Long Sheath was evaluated to verify the tensile strength of the distal shaft and the proximal hub and met the minimum tensile requirement. The 6F Wallaby Long Sheath was evaluated to verify the shaft elongation to failure. The device met all predefined acceptance criteria.
Torque Strength	The 6F Wallaby Long Sheath was tested for torque to failure in a simulated use test model. Test results demonstrated the torque strength of the subject device is similar to the predicate device.
Coating Integrity	The 6F Wallaby Long Sheath coating integrity was inspected after the particulate testing and no visible defects or sign of irregularity were observed.
Coating Lubricity	The 6F Wallaby Long Sheath was evaluated for frictional forces in a simulated use test model and demonstrated similar results between the subject device and the predicate device.
Catheter Dynamic and Static Burst (Pressure)	The 6F Wallaby Long Sheath was evaluated for leakage and burst and is compatible with accessories per ISO 10555-1.
Leak (Liquid)	
Leak (Air)	
Kink Resistance	The 6F Wallaby Long Sheath was evaluated for resistance to kinking around bends with clinically relevant radii at specific locations along the shaft and met the acceptance criteria.
Particulate	The 6F Wallaby Long Sheath was evaluated within a simulated use anatomical model to verify the amount of particulate generated. The number of particulates was comparable to the predicate. The device met the acceptance criteria.
Corrosion Resistance	The 6F Wallaby Long Sheath was evaluated for corrosion resistance per ISO 10555-1 and met the acceptance criteria.
Insertion and Retrieval Forces	The 6F Wallaby Long Sheath was evaluated for insertion and retrieval forces with a dilator. The results demonstrated similar forces for the subject device and the predicate device.
Radiopacity	The 6F Wallaby Long Sheath was evaluated for marker band visibility under fluoroscopy during the physician validation testing and demonstrated results similar to the predicate device.

Design Verification Testing – Animal

No animal testing was deemed necessary to support the substantial equivalence of the 6F Wallaby Long Sheath.

Sterilization and Shelf Life

The 6F Wallaby Long Sheath is 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 6F Wallaby Long Sheath have established the device and its packaging remains functional for the 12-month shelf life. Aging studies for packaging integrity, seal strength, and device functionality were performed and met the acceptance criteria.

Biocompatibility

Biocompatibility testing for the 6F Wallaby Long Sheath and accessories was performed in accordance with ISO 10993- 1:2018, *Biological evaluation of medical devices – Evaluation and testing within a risk management process*.

Table 3: Biocompatibility Testing

Test	Results	Conclusion
Sheath (100 cm model)		
MTT – L-929 Cytotoxicity Study	1X MEM test extract showed no cytotoxic potential to L-929 mouse fibroblast cells undiluted or at any dilution; viability ≥ 70%; 80-91%.	Non-cytotoxic
ISO Intracutaneous Irritation	The difference between the average scores of the test article extract and the vehicle control are: 0; 0.	Non-irritant
ISO Guinea Pig Maximization Sensitization	Test and control animals' responses are not greater than "0".	Non-sensitizing
ISO Acute Systemic Toxicity	No abnormal clinical signs indicative of toxicity were observed for 72 hours. All animals were alive at the end of 72 hours and body weight changes were within acceptable parameters.	Non-toxic
ISO Material Mediated Rabbit Pyrogen	No rabbit temperature rise ≥ 0.5°C.	Non-pyrogenic
Complement Activation - SC5b-9 Assays with Sponsor-Supplied Comparison	Results within acceptable range as compared to the comparator device.	The test article complement activation was similar to the comparator device
ASTM Hemolysis - Direct Contact and Extract Method	Blank corrected Hemolytic index: 0.4, 0.1.	Non-hemolytic
Platelet and Leukocyte counts	No ranges or levels outside an acceptable range and comparable to Control Device.	Counts from subject device are within acceptable ranges and are similar to the control
Partial Thromboplastin Time (PTT)	Test and predicate devices have similar performance.	The test article is not considered an activator of the intrinsic coagulation pathway
Thromboresistance Evaluation	No adverse effects or clinical signs during test period and no thrombus score > 3 for either test or control device.	Thrombogenic risk potential similar to the control device
Dilator		
MTT – L-929 Cytotoxicity Study	1XMEM test extract showed no cytotoxic potential to L-929 mouse fibroblast cells undiluted or at any dilution; viability ≥70%; 79.8%.	Non-cytotoxic
ISO Intracutaneous Irritation	The difference between the average scores of the test article extract and the vehicle control are: 0; 0.	Non-irritant
ISO Guinea Pig Maximization Sensitization	Test and control animals' responses are not greater than "0".	Non-sensitizing
ISO Acute Systemic Toxicity	No abnormal clinical signs indicative of toxicity were observed for 72 hours. All animals were alive at the end of 72 hours and body weight changes were within acceptable parameters.	Non-toxic
ISO Material Mediated Rabbit Pyrogen	No rabbit temperature rise ≥ 0.5°C.	Non-pyrogenic
Complement Activation - SC5b-9 Assays with Sponsor-Supplied Comparison	Results within acceptable range as compared to the negative reference material.	Non-activator of complement system
ASTM Hemolysis - Direct Contact and Extract Method	Blank corrected Hemolytic index: 0.3, 0.5.	Non-hemolytic

Thromboresistance Evaluation	No adverse effects or clinical signs during test period and no thrombus score > 3 for either test or control device.	Thrombogenic risk potential similar to the control device
RHV		
Cytotoxicity MEM Elution	Percent Cell Lysis: 0% Cytotoxic Score: 0	Non-cytotoxic
ISO Intracutaneous Irritation	The difference between the average scores of the test article extract and the vehicle control are: 0; 0.	Non-irritant
ISO Guinea Pig Maximization Sensitization	Test and control animals' response not greater than "0".	Non-sensitizing
ISO Acute Systemic Toxicity	No abnormal clinical signs indicative of toxicity were observed for 72 hours. All animals were alive at the end of 72 hours and body weight changes were within acceptable parameters.	Non-toxic
ISO Material Mediated Rabbit Pyrogen	No rabbit temperature rise ≥ 0.5°C.	Non-pyrogenic
ASTM Hemolysis - Direct Contact and Extract Method	Blank corrected Hemolytic index: 0.0, 0.1.	Non-hemolytic

Clinical

No clinical testing was deemed necessary to support the substantial equivalence of the 6F Wallaby Long Sheath.

Conclusion

The 6F Wallaby Long Sheath is substantially equivalent to the predicate Neuron MAX System based on the non-clinical testing results, as well as similar principles of operation, materials of construction, packaging, usability, and the indications for use. Any differences between the subject device and the predicate device do not raise different questions of safety and effectiveness.