April 25, 2023

Wallaby Medical
Joseph Tang
Quality Engineer
22901 Mill Creek Drive
Laguna Hills, California 92653

Re: K223139
Trade/Device Name: Wallaby 017 Micro Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA, QJP, DQY
Dated: March 23, 2023
Received: March 23, 2023

Dear Joseph Tang:

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)*

K223139

Device Name

Wallaby 017 Micro Catheter

Indications for Use *(Describe)*

The Wallaby 017 Micro Catheter is intended to access peripheral and neuro vasculature for the controlled selective infusion of physician-specified therapeutic devices such as embolization materials and of diagnostic materials such as contrast media as well as delivery of embolic coils.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K223139 510(k) Summary

As required by 21 CFR 807.92

Applicant:	Wallaby Medical 22901 Mill Creek Drive Laguna Hills, CA 92653
Contact:	Joseph Tang
Phone number:	714 904 6097
Date Prepared:	April 24, 2023
Device Trade Name:	Wallaby 017 Micro Catheter
Device Common Name:	Catheter, Continuous Flush, KRA, QJP, DQY
Classification Name:	Class II, KRA (21 CFR 870.1210), QJP and DQY (21 CFR 870.1250)
Predicate Device:	PROWLER SELECT LP ES Microcatheter (K214025)
Reference Device:	Tip-Shape Echelon Micro Catheter (K042187)

a. Device Description

The Wallaby 017 Micro Catheter is a single-use, vascular catheter consisting of a single lumen, variable stiffness, composite catheter. The device is a microcatheter with an inner diameter (ID) of 0.017", designed with a working length of 150 cm. The device has three different tip configurations: straight (0°), 45°, 90°, and is steam shapeable by the user. The device is supplied as a kit with an introducer sheath, shaping mandrel, and mandrel card provided with a single catheter. The distal tip of the Wallaby 017 Micro 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 microcatheter 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 vasculature.

The Wallaby 017 Micro Catheter is a non-active, surgically invasive device intended for limited duration use within the vasculature.

b. Indications for Use

The Wallaby 017 Micro Catheter is intended to access peripheral and neuro vasculature for the controlled selective infusion of physician-specified therapeutic devices such as embolization materials and of diagnostic materials such as contrast media as well as delivery of embolic coils.

c. Device Compatibility

The Wallaby 017 Micro Catheter is designed to introduce embolic coils up to an outer diameter (OD) of 0.0145" (0.3683 mm) and guide wires up to an OD of 0.014" (0.36 mm) and to infuse diagnostic agents or therapeutic devices such as embolization materials into the peripheral and neuro vasculature.

Non-clinical bench testing has been conducted to evaluate compatibility of the Wallaby 017 Micro Catheter with DMSO (dimethyl sulfoxide) and DMSO-based liquid embolic agents.

d. Predicate Device Comparison

The predicate device for the Wallaby 017 Micro Catheter is the PROWLER SELECT LP ES Microcatheter (K214025). The reference device for the Wallaby 017 Micro Catheter is the Tip-Shape Echelon Micro Catheter (K042187). The tables below describe the technological differences between the Wallaby 017 Micro Catheter, PROWLER SELECT LP ES Microcatheter and the Tip-Shape Echelon Micro Catheter, respectively:

Table 1. Technological Comparison to PROWLER SELECT LP ES Microcatheter and Tip-Shape Echelon Micro Catheter

Device Name	**Predicate Device: PROWLER SELECT LP ES Microcatheter**	**Reference Device: Tip-Shape Echelon Micro Catheter**	**Subject Device: Wallaby 017 Micro Catheter**	**Rationale for Difference (if applicable)**
510(k) Number	K214025	K042187	K223139	
Classification	Class II, KRA, DQY, QJP	Class II, KRA	Class II, KRA, DQY, QJP	SAME as predicate
Indications for Use	The PROWLER SELECT LP ES Microcatheter is intended for the introduction of embolic devices and infusion of diagnostic agents into the peripheral and neuro vasculature.	The Tip-Shape Echelon Micro Catheter is intended to access peripheral and neuro vasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and of diagnostic materials such as contrast media.	The Wallaby 017 Micro Catheter is intended to access peripheral and neuro vasculature for the controlled selective infusion of physician-specified therapeutic devices such as embolization materials and of diagnostic materials such as contrast media as well as delivery of embolic coils.	SAME
	Materials			
Shaft				
Extrusions	Outer layer: Nylon and Pellethane Inner layer: PTFE	Outer layer: Pebax (polyether block amide), Polyamide Inner layer: PTFE	Outer layer: Pebax (polyether block amide), Barium Sulfate Infused Pebax, Aesno Med (Polyamide) Inner layer: PTFE	Device materials are biocompatible and the subject device passed all testing.
Wire Reinforcement	Stainless-steel Braid	Nitinol Braid	Nitinol Braid	
Components				
Hub	Grilamid	Polyamide	Polyamide (Trogamid)	Device materials are biocompatible and the subject device passed all testing.
Coating	Hydrophilic Coating	Hydrophilic Coating	Hydrophilic Coating	
Strain Relief	Not provided	Pebax, Polyolefin	Pebax	
Colorant	Blue or Purple	Clear/Natural or Purple	Natural or Green or Blue	The subject device colorants are biocompatible.
Marker Band	Pt-W Coil	Pt/Ir Band	Pt/Ir Band	SAME
Tip Configuration	Straight, 45°, 90°	Straight, 45°, 90°, steam shapeable by user	Straight, 45°, 90°, steam shapeable by user	SAME
Accessories				

Device Name	Predicate Device: PROWLER SELECT LP ES Microcatheter	Reference Device: Tip-Shape Echelon Micro Catheter	Subject Device: Wallaby 017 Micro Catheter	Rationale for Difference (if applicable)
Shaping Mandrel	Stainless Steel	Stainless Steel	Stainless Steel	SAME
Introducer Sheath	N/A	Polyamide	HDPE	The device materials are biocompatible and the subject device passed all testing.
	Dimensions			
Shaft				
Proximal OD	0.03 in	0.0275 in	0.028 in	SIMILAR
Distal OD	0.02 in	0.024 in	0.025 in	
ID	0.0165 in	0.017 in	0.017 in	SAME
Effective Length	150 cm	150 cm	150 cm	SAME
Coating Length	30 cm	100 cm	100 cm	SAME as the reference.
Accessories				
Introducer Sheath ID	N/A	0.041 in	0.044 in	The introducer sheath of the subject device was evaluated to allow introduction of the microcatheter into compatible guide catheters.
Introducer Sheath OD	N/A	0.054 in	0.055 in	
Introducer Sheath Length	N/A	4.5 in	5.1 in	
Shaping Mandrel OD	Not provided	0.014 in	0.014 in	SAME as the reference.
	Packaging Materials			
Pouch	Tyvek and PET/PE film	Tyvek and nylon	Tyvek and nylon	Packaging materials are similar and typical for medical devices. The packaging maintains sterility of the device throughout shelf life.
Packaging	HDPE Hoop	Polyethylene tube	PET Tray	
Mandrel Card	Not provided	HDPE	HDPE	
Display Carton	SBS Paperboard	SBS Paperboard	SBS Paperboard	SAME
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	SAME
How Supplied	Sterile, Single Use	Sterile, Single Use	Sterile, Single Use	SAME
Shelf Life	27 months	36 months	12 months	A 12-month shelf life was validated for the subject device.

e. Performance Testing

To establish substantial equivalence of the Wallaby 017 Micro Catheter to the PROWLER SELECT LP ES Microcatheter and the Tip-Shape Echelon Micro Catheter and to meet the requirements of the risk analysis, non-clinical bench and biological compatibility testing were conducted. The testing performed and results are summarized below.

Design Verification Testing - Bench

Performance testing was conducted to support the premarket submission. The results of the design verification and validation testing performed confirm that the Wallaby 017 Micro Catheter conforms to the pre-defined acceptance criteria. Testing included:

Table 2. Wallaby 017 Micro Catheter Bench Testing Summary

Test	Methods and Results
Visual Inspection	The device was visually inspected. The device met all pre-defined acceptance criteria.
Dimensional Inspection	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 the preparation and ease of assembly, introducer sheath compatibility and peel away, ancillary device compatibility with guidewire and guide catheter, trackability, compatibility with embolic coil, lubricity and durability of hydrophilic coating, and kink resistance. The device performs as intended and met all pre-defined acceptance criteria under simulated use conditions.
Physician Validation (Usability)	The device was evaluated in a simulated anatomy model by physicians in comparison with the predicate. The device performs as intended and demonstrates equivalency to the comparator device under simulated use conditions.
Delivery and Retrieval	The device was subjected to delivery and retrieval testing, including delivery and retrieval of a guidewire and embolic coil, in a vascular model and met all pre-defined acceptance criteria.
Tip Stiffness	The device tip was deflected on a universal testing machine and met the 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 strength requirement. The device met the predefined acceptance criteria.
Elongation to Failure	The device elongation was evaluated during the shaft tensile testing. The device met all pre-defined acceptance criteria.
Torque To Failure	The device was evaluated for catheter integrity during hub rotations with distal end held stationary. The device met all pre-defined acceptance criteria.
Coating Integrity	The device coating integrity was inspected pre- and post-insertion and retrieval using 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 Dynamic and Static 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.
Leak (Liquid)	
Leak (Air)	
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 for particulate generation. The device met all pre-defined acceptance criteria and was comparable to the reference device.
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.
DMSO and Liquid Embolic Compatibility	The device was evaluated for DMSO and liquid embolic compatibility and met the pre-defined acceptance criteria.

Design Verification Testing – Animal

No animal testing was deemed necessary to support the substantial equivalence of the Wallaby 017 Micro Catheter.

Sterilization and Shelf Life

The Wallaby 017 Micro Catheter 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 Wallaby 017 Micro Catheter have established that the device and packaging remain functional for the 12-month shelf-life. Aging studies for packaging integrity, seal strength, and device functionality were performed and met all acceptance criteria.

Biocompatibility

Biocompatibility testing for the Wallaby 017 Micro Catheter and accessories was performed in accordance with ISO 10993-1:2018, *Biological evaluation of medical devices – Evaluation and testing within a risk management process*. Biocompatibility testing completed for the device included:

Table 3. Biocompatibility Testing

Test	Standard	Results	Conclusion
Catheter			
MTT – L-929 Cytotoxicity Study	ISO 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	ISO 10993-10	The difference between the average scores of the test article extract and the vehicle control are 0.0; 0.1.	Non-irritant
ISO Guinea Pig Maximization Sensitization	ISO 10993-10	Test and control animals' responses are not greater than "0".	Non-sensitizing
ISO Acute Systemic Toxicity	ISO 10993-11	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
Materials Mediated Rabbit Pyrogen	USP <151>	No rabbit temperature rise ≥ 0.5°C.	Non-pyrogenic
Complement Activation – SC5b-9 Assay	ISO 10993-4	Results within acceptable range and not statistically different than activated NHS control or negative control.	Not a potential activator of complement system
ASTM Hemolysis – Direct Contact and Extract Method		Blank corrected hemolytic index: 0.4; 0.0.	Non-hemolytic
Thromboresistance Evaluation		No adverse effects or clinical signs during test period and no thrombus score > 3 for either test or control device.	Thromboresistance of test device similar to control device

Chemical Characterization-Physiochemical Tests for Plastics	ISO 10993-18	Extractable and leachable chemical characterization and the toxicological risk assessment (buffering capacity, non-volatile residue (NVR) and heavy metals) of the Wallaby 017 Micro Catheter demonstrated that the extractables and leachables of the subject device were similar to that of the reference device.	Pass
Steam Shaping Mandrel	The shaping mandrel was excluded from any direct biocompatibility testing and instead was included during testing of the Wallaby 017 Micro Catheter as part of sample preparation by inserting the shaping mandrel into the tip for a timed minimum of 5 minutes, when applicable.		
Mandrel Card	The mandrel card was excluded since it has no patient contact and only contacts the shaping mandrel which was included during sample preparation.		
Introducer Sheath Subassembly	The introducer sheath subassembly was not tested for biocompatibility because the introducer sheath was previously cleared with the Wallaby Avenir Coil System.		

Clinical

No clinical testing was deemed necessary to support the substantial equivalence of the Wallaby 017 Micro Catheter.

Conclusion

The Wallaby 017 Micro Catheter is substantially equivalent to the predicate PROWLER SELECT LP ES Microcatheter 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 new questions of safety and effectiveness.