May 4, 2018

Wallaby Medical, Inc.
Rebecca K. Pine
Official Correspondent
23181 Verdugo Drive, Suite 104A
Laguna Hills, California 92653

Re: K173711
Trade/Device Name: Wallaby Avenir Coil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: April 4, 2018
Received: April 5, 2018

Dear Rebecca K. Pine:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173711

Device Name
Wallaby Avenir Coil System

Indications for Use *(Describe)*
The Wallaby Avenir Coil System is intended for endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The Wallaby Avenir Coil System is also intended for arterial and venous embolization in the peripheral 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.

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

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510(k) Summary- K173711

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Wallaby Medical, Inc.
DATE PREPARED:	May 2, 2018
CONTACT PERSON:	Rebecca K Pine 23181 Verdugo Dr. Suite 104A Laguna Hills, CA 92653 (760) 809-5178
TRADE NAME:	Wallaby Avenir Coil System
COMMON NAME:	Neurovascular embolization device
CLASSIFICATION NAME:	Neurovascular embolization device
DEVICE CLASSIFICATION:	Class 2, per 21 CFR 882.5950
PRODUCT CODE	HCG, KRD
PREDICATE DEVICES:	Primary Axium Detachable Coil System, K162704 Reference Microplex Coil System, K102365

Reason for submission:
Commercialization of new embolization coil system.

Description of the Device Subject to Premarket Notification:
The Wallaby Avenir Coil System is a series specialized coils that are inserted into the vasculature under angiographic visualization to embolize intracranial aneurysms and other vascular anomalies. The system consists of an embolization coil implant comprised of platinum/tungsten, affixed to a delivery pusher to facilitate insertion into the hub of a microcatheter. The system is available in various shapes, lengths and sizes. The devices are to be placed into aneurysms to create blood stasis, reducing flow into the aneurysm and thrombosing the aneurysm. Upon positioning coils into the aneurysm, the coils are mechanically detached from the delivery pusher in serial manner until the aneurysm is occluded.

Indication for Use:
The Wallaby Avenir Coil System is intended for endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The Wallaby Avenir Coil System is also intended for arterial and venous embolization in the peripheral vasculature.

Technical Characteristics:
The Wallaby Avenir Coil System has similar physical and technical characteristics to the predicate devices, as shown in the table below.

	Wallaby Avenir Coil System	**Primary Predicate Axium Detachable Coil System (K162704)**	**Similarities/ Differences**
Intended Use	Endovascular embolization of blood flow in the human neuro and peripheral vasculature.	Endovascular embolization of blood flow in the human neuro and peripheral vasculature.	SAME
Anatomical Site	Neurovasculature Peripheral vasculature (arterial/venous)	Neurovasculature Peripheral vasculature (arterial/venous)	SAME
Delivery to Site	Via delivery wire through microcatheter	Via delivery wire through microcatheter	SAME
Coil selection	Physician determined	Physician determined	SAME
Visualization	Visible under radiographic imaging	Visible under radiographic imaging	SAME
Implant characteristics			
Coil Types	Frame, fill, finish	Frame, Fill, finish	SAME
Secondary Shapes	Complex/Helical	Complex/Helical	SAME
Flexibility	Coil-like, highly flexible	Coil-like, highly flexible	SAME
Main coil material	Pt/W alloy (92/8%)	Pt/W alloy (92/8%)	SAME
Stretch Resistant Member	Polyolefin	Polyolefin	SAME
Coil Delivery Mechanism	Stainless Steel Hypotube	Stainless Steel Hypotube	SAME
Coil detachment	Mechanical	Mechanical	SAME
Primary Coil Diameter	0.011” – 0.0145”	0.0108” – 0.0145”	SAME
Coil Secondary Diameter	1mm – 25mm	1mm – 25mm	SAME
Coil Wire Diameter	0.0013” – 0.003”	0.0013” – 0.003”	SAME
Coil Length	1cm – 60cm	1cm – 50cm	The available Coil Length is slightly (10cm) greater than the Axium predicate however this length range is represented in the reference predicate device (K102365)
Delivery wire/pusher characteristics			
Working length	180cm	180cm	SAME
OD	0.014”	0.014”	SAME
Materials of Construction	SS 304 PTFE PET shrink Tubing	SS 304 PTFE PET shrink tubing	Although adhesive/epoxy is utilized to facilitate the

	Wallaby Avenir Coil System	Primary Predicate Axium Detachable Coil System (K162704)	Similarities/ Differences
	Platinum/Ir alloy (80/20%) Platinum/iridium alloy (90/10%) Loctite 4311 Epoxy	Platinum/Tungsten alloy (92/8%)	joining of components, this does not pose a fundamental difference; the materials of construction is the SAME
Sheath Characteristics			
Working length	120cm	119cm	Although the working length dimension is not identical, the difference is minor (1cm); therefore, the fundamental construction is the SAME
OD	0.028"	0.030"	Although the outside diameter dimension is not identical, the difference is minor (.002"); therefore, the fundamental construction is the SAME
ID	0.017"	0.019"	Although the inside diameter dimension is not identical, the difference is minor (.002"); therefore, the fundamental construction is the SAME
Materials of Construction	HDPE	HDPE Polypropylene	Although the polymers vary, all are common endovascular materials; therefore, the fundamental materials of construction are the SAME
Detachment equipment			
Detachment equipment components	None required	Instant Detacher	Mechanical detachment fulfilled through manual means-substantially equivalent
User interface	Delivery wire	Handpiece + delivery wire (primary method) Delivery wire only (secondary method)	SAME - The Wallaby mechanical detachment method is the same as the Axium detachment coil method using only the delivery wire.
Power Source	Mechanical	Mechanical	SAME
Connection	Direct attachment to delivery wire	Direct attachment to delivery wire	SAME

	Wallaby Avenir Coil System	Primary Predicate Axium Detachable Coil System (K162704)	Similarities/ Differences
How Provided			
Sterilization	EO	EO	SAME
Use	Sterile, single use	Sterile, single use	SAME
Packaged configuration	Stored within dispenser coil, Tyvek pouch, & shipping carton	Stored within dispenser coil, Tyvek pouch, & shipping carton	SAME

Each of the technical attributes of the Wallaby Avenir Coil System are present in the predicate device.

Performance Data:

All necessary testing has been performed for the Wallaby Avenir Coil System to assure substantial equivalence to the predicate device and demonstrate the device performs as intended. All testing was performed on test units representative of finished devices.

Test	Test Method Summary	Results
Dimensional Analysis	Verified established device specification through dimensional measurement	All device met the established criteria
Delivery and retrieval Forces	Characterization of the maximum force required to deliver and retrieve the coil through the microcatheter	All devices performed as intended
Resheathability	Testing performed in simulated use condition to demonstrate that the device meets product multiple resheathing requirement within worst case tortuosity vessel conditions	All devices performed as intended
Detachment Characterization	Verified through anatomical model testing for detachment force, and detachment reliability. Verified activation of detachment system.	All devices performed as intended
Tensile Testing	Verified stretch resistant member tensile strength, full system tensile strength, and detachment wire joint tensile strength by mechanical test equipment	All devices performed as intended
Coil Stiffness	Using wire diameter and coil diameter measurements to perform verification by analysis on coil stiffness, to show equivalence of the device characteristics to the predicate	All devices performed as intended
Physician Simulated Use Validation	Verified through anatomical model in simulated use environment that the physician users evaluated device clinical equivalence to predicate device	All devices performed as intended
GLP Survival Animal Study	Animal testing to evaluate the *in vivo* performance of the device in a chronic canine model. Histopathology performance metrics were compared to the predicate device	All devices performed as intended
Pitting Corrosion Resistance (implant)	Corrosion resistance testing per ASTM F2129	All devices performed as intended
Galvanic Corrosion	Galvanic corrosion resistance testing per	All devices performed as intended

Resistance (implant)	ASTM F3044	
Corrosion Resistance (pusher)	Corrosion resistance testing per ISO 10555-1 and ISO 11070	All devices performed as intended
Particulate Testing	Particulate testing per USP 788 for ≥10µm and ≥25µm particles.	All devices performed as intended
MR Compatibility	MR testing performed per ASTM F2119, ASTM F2213, ASTM F2052, ASTM F2128 and additional MRA characterization testing.	Testing demonstrated the device is MR conditional
Packaging and Shelf Life Validation	Sterile barrier integrity and seal strength testing performed per ISO 11607-1/-2, ASTM F88, ASTM F1980, ASTM F2096, ASTM D4169, ISTA 2A. Sterile barrier integrity and seal strength also tested post accelerated aging conditions.	Packaging and device demonstrates the ability to perform as intended through the labeled shelf life of the device.
Sterilization Validation	Per ISO 11135, Annex B Overkill Method	Sterilization process achieves sterility assurance level of 10^{-6}
Endotoxin Testing	Bacterial endotoxin assay validation per USP 85 and USP 161	there are no interfering factors associated with the device. The endotoxin levels for the device are below 2.15 EU/device.
Biocompatibility Testing – Cytotoxicity (implant, pusher, sheath)	Cytotoxicity - MEM Elution (GLP) - 72 hour extract per ISO 10993-5	Non-cytotoxic
Biocompatibility Testing – Cytotoxicity (implant, pusher, sheath)	MTT Cytotoxicity Assay Using L-929 Mouse Fibroblast Cells per ISO 10993-5	Non-cytotoxic
Biocompatibility-Sensitization (implant, pusher, sheath)	Sensitization - ISO Guinea Pig Maximization Sensitization Test (polar/nonpolar extracts) ISO 10993-10	Did not elicit sensitization response
Biocompatibility - Irritation (implant, pusher, sheath)	Irritation or Intracutaneous irritation reactivity - ISO Intracutaneous Irritation Test (polar/nonpolar extracts) ISO 10993-10	Non-irritant
Biocompatibility - Acute Toxicity (implant, pusher, sheath)	Acute systemic toxicity - ISO Acute Systemic Injection Test (polar/non polar extracts) per ISO 10993-11	No signs of toxicity
Biocompatibility-Pyrogenicity (implant, pusher, sheath)	Pyrogenicity- ISO Material Mediated Rabbit pyrogen per ISO 10993-11	Non-pyrogenic
Biocompatibility-Hemocompatibility (implant, pusher, sheath [extract only])	Hemocompatibility - ASTM Hemolysis Assay – Direct Contact and Extract Method per ISO 10993-4	Non-hemolytic
Biocompatibility-Hemocompatibility (implant, pusher)	Complement Activation SC5b-9 Assay per ISO 10993-4	The test article results are satisfactory under the test conditions employed
Biocompatibility-Hemocompatibility (implant, pusher)	Partial Thromboplastin Time (PTT) per ISO 10993-4	The test article does not pose a greater biocompatibility risk than the existing commercial devices
Biocompatibility-Hemocompatibility (implant, pusher)	Platelet and Leukocyte Counts per ISO 10993-4	The test article does not pose a greater biocompatibility risk than existing commercial devices.
Biocompatibility-Hemocompatibility (pusher)	Thromboresistance Evaluation- 4hr dog per ISO 10993-4	Non-thrombolytic

Biocompatibility-Genotoxicity (implant)	ISO In Vitro Mouse Lymphoma with Extended Treatment per ISO 10993-3	Non-mutagenic and non-clastogenic
Biocompatibility-Genotoxicity (implant)	ISO Bacterial Mutagenicity Test - Ames Assay (5 Salmonella Strains and 1 E. Coli Strain - 2 Extracts) per ISO 10993-3	Non-mutagenic
Biocompatibility-Implantation (implant)	ISO Intramuscular Implantation Test- 2 weeks, 6 weeks, 13 weeks per ISO 10993-6	Non-irritant
Biocompatibility – extractables (implant, pusher)	Exhaustive chemical extraction per ISO 10993-17/-18	Device is biologically safe for its intended use

The Wallaby Avenir Coil System met all specified criteria and did not raise new safety or performance questions.

Basis for Determination of Substantial Equivalence:

Conclusion
Wallaby Avenir Coil System has the same intended use, technological characteristics and performance and is substantially equivalent to the predicate device.