April 8, 2022

Balt USA, LLC
Michael Peters
Manager, Regulatory Affairs
29 Parker
Irvine, California 92618

Re: K220699
Trade/Device Name: Prestige Coil System
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: March 8, 2022
Received: March 10, 2022

Dear Michael Peters:

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,

Finn Donaldson
Acting Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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)*
K220069

Device Name
Prestige Coil System

Indications for Use *(Describe)*
The Prestige Coil System is indicated for arterial and venous embolizations 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.

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K220069 510(k) Summary

Applicant:	Balt USA, LLC 29 Parker Irvine, CA 92618 Registration No.: 3014162263
Contact Person:	Michael Peters Manager, Regulatory Affairs Telephone: (949) 788-1443 Email: michael.peters@baltgroup.com

Date Summary Prepared:	April 7, 2022
Trade Name:	Prestige Coil System
Common Name:	Vascular embolization device
Review Panel:	Cardiovascular
Product Code:	KRD
Regulation Number:	21 CFR 870.3300
Regulation Name:	Device, Vascular, for Promoting Embolization
Device Classification:	Class II
Predicate Device:	Prestige Coil System, 510(k)#: K200030 Originally cleared under trade name Optima Coil System

Device Description:
The Prestige Coil System is a series of specialized coils that are inserted into the vasculature under angiographic visualization to embolize peripheral 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 anomalies to create blood stasis, reducing flow in the target vasculature, and inducing thrombosis. Upon positioning coils into the vasculature, the coils are thermally detached from the delivery pusher in serial manner until the target vasculature is occluded.

Indications for Use:
The Prestige Coil System is indicated for arterial and venous embolizations in the peripheral vasculature.

Intended Use:
The Prestige Coil System is intended for use in the peripheral vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the peripheral vessels.

Device Comparison:

	Predicate Device (K200030)	Prestige Coil System (Subject Device, K220069)
Indications for Use	The Optima Coil System is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The Optima Coil System is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.	Prestige Coil System is indicated for arterial and venous embolizations in the peripheral vasculature. *These Indications for Use for the Prestige Coil System are a subset of those cleared for the Predicate.
Intended Use	The Optima Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.	The Prestige Coil System is intended for use in the peripheral vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the peripheral vessels. *This Intended Use for the Prestige Coil System is a subset of that cleared for the Predicate.
Anatomical Site	Neurovasculature Peripheral Vasculature	Peripheral Vasculature *The target anatomy for the Prestige Coil System is a subset of the cleared anatomy for the Predicate.
Delivery to site	Via delivery wire through microcatheter	Same as K200030
System Components	Coil (implant) Delivery System Detachment Controller	Same as K200030
Method of Supply	Sterile, single use	Same as K200030
Coil (Implant)		
Main Coil Material	Platinum/Tungsten	Same as K200030
Primary Coil Wind Diameter	0.010”–0.014”	Same as K200030
Coil Wire Diameter	0.00125”–0.0035”	Same as K200030
Coil Length	1-65cm	Same as K200030
Coil Secondary Diameter	1-24mm	Same as K200030
Number of Sizes Offered	209	267
Secondary Shapes	Complex, Helical	Same as K200030
Coil Types	Framing, Filling, Finishing	Same as K200030

	Predicate Device (K200030)		**Prestige Coil System (Subject Device, K220069)**	
No. & Size of Helical Loops on Distalmost End (Complex only)	1.5 x 70%		1.5 x 70% 3 x 70% 3 x 100%	
Primary Wind (Coil OD) x Filar (Wire Diameter) combinations	Complex .010" x .00125" .011" x .0015" .010" x .0015" .011" x .00175" .012" x .002" .013" x .00225" .014" x .003" .014" x .0035" .012" x .00125" .014" x .0015" .014" x .00175" .014" x .002"	Helical .012" x .002" .011" x .0015" .010" x .00125" .012" x .00125" .014" x .0015" .014" x .00175" .014" x .002"	Complex .010" x .00125" .011" x .0015" .010" x .0015" .011" x .00175" .012" x .002" .013" x .00225" .014" x .003" .014" x .0035" .012" x .00125" .014" x .0015" .014" x .00175" .014" x .002" .014" x .00275" .014" x .0025"	Helical .012" x .002" .011" x .0015" .010" x .00125" .012" x .00125" .014" x .0015" .014" x .00175" .014" x .002"
Stretch-resistance thread / attachment thread	Polyolefin Engage Thread		Same as K200030	
Coupler/Markerband	Platinum/Iridium Alloy		Same as K200030	
Delivery System (Pusher)				
Construction/Design	Body coil laser welded to hypotube		Same as K200030	
Body Coil	4-part coil: A. Heater Coil (92/8 Pt/W) B. Distal Coil (SSTL) C. Radio-opaque (RO, 92/8 Pt/W) Coil D. Proximal Coil (SSTL)		Same as K200030	
Hypotube	SSTL Hypotube		Same as K200030	
Connector	Gold plated, SSTL Hypotube		Same as K200030	
Adhesive	Dymax 1128A-M-VT		Same as K200030	
Jacket	PET		Same as K200030	
Fluorosafe Markers	Pad Printed PET Shrink Tube		Same as K200030	
Epoxy	Epoxy 353 ND		Same as K200030	
Lead Wires	Polyimide coated silver lead wires		Same as K200030	

	Predicate Device (K200030)	**Prestige Coil System (Subject Device, K220069)**
Other		
Detachment	Thermal via Detachment Controller	Same as K200030
Pouch	Tyvek®	Same as K200030
Shelf Life	5 Years	Same as K200030
Method	Gamma Irradiation	Same as K200030

Evaluations Leveraged from Predicate Device

The following non-clinical device assessments were performed in support of the Predicate Device's submission and clearance and have been evaluated as still valid based on the proposed changes to the Subject Prestige Coil System.

Test	Acceptance Criteria	Results
Biocompatibility	The samples shall be biocompatible for their intended use based on the requirements of ISO 10993-1.	Pass
Shelf Life	The samples shall meet established acceptance criteria based on device specifications after simulated aging and transportation/distribution simulation.	Pass
Packaging	The samples shall meet established acceptance criteria for packaging performance.	Pass
Gamma Sterilization	The samples shall meet established acceptance criteria for sterility.	Pass
Corrosion	The samples shall meet established acceptance criteria for corrosion.	Pass
Detachment Zone Tensile	The samples shall meet established acceptance criteria for tensile strength.	Pass

In addition to the above, the Magnetic Resonance Imaging Characterization undergone by the Predicate device has also been evaluated as still applicable to the Subject device and has not been reperformed.

Performance Data – Bench:

The following non-clinical bench testing was performed to demonstrate substantial equivalence of the Prestige Coil System to the Predicate device:

Test	Acceptance Criteria	Results
Visual and Dimensional Inspection	The samples shall meet established acceptance criteria for visual physical damage and secondary diameter and length.	Pass
Simulated Use	The samples shall be prepared in accordance with the instructions for use and meet established acceptance criteria for device performance in a clinically relevant model.	Pass
Stretch-Resistance Thread Tensile Testing	The samples shall meet established acceptance criteria for tensile strength.	Pass
Usability Validation	The devices shall be prepared in accordance with their respective instructions for use and meet established acceptance criteria for device performance in a clinically relevant model. The labeling shall be clear and understandable by the intended user.	Pass

Conclusion:

There is no change to the risk profile, principles of operations or performance requirements of the Prestige Coil System in comparison to the Predicate Device (K200030). The successful completion of non-clinical bench testing demonstrates that the Prestige Coil System is substantially equivalent to the Predicate Device.