December 6, 2022

Balt USA, LLC
Kavita Chandrashekar
Senior Regulatory Affairs Specialist
29 Parker
Irvine, California 92618

Re: K223386
Trade/Device Name: Optima Coil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: November 4, 2022
Received: November 7, 2022

Dear Kavita Chandrashekar:

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
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OHT5: Office of Neurological
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223386

Device Name
Optima Coil System

Indications for Use *(Describe)*
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.

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 K223386

Applicant:	Balt USA, LLC 29 Parker Irvine, CA 92618 Registration No.: 3014162263
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Date Summary Prepared:	December 02, 2022
Trade Name:	Optima Coil System
Common Name:	Neurovascular embolization device; Vascular embolization device
Review Panel:	Neurology; Cardiovascular
Product Code:	HCG, KRD
Regulation Number:	21 CFR 882.5950 (HCG), 21 CFR 870.3300 (KRD)
Regulation Name:	Device, Neurovascular Embolization; Device, Vascular, for Promoting Embolization
Device Classification:	Class II
Predicate Device:	Optima Coil System, 510(k): K200030

Device Description:

The Optima Coil System is a series of 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 and 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 detached from the delivery pusher in a serial manner until the aneurysm is occluded.

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.

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.

Comparison of Technological Characteristics:

Table 1 Device Comparison

Category	Optima Coil System (predicate device K200030)	Modified Optima Coil System (subject device K223386)
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.	Same
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.	Same
Risk Class	Class II	Same
Product Code	HCG, KRD	Same
Common Name	Neurovascular Embolization Device	Same
Anatomical Location	Neuro Vasculature and Peripheral Vasculature	Same
Visualization	Visible under radiographic imaging	Same
Method of Supply	Sterile; single-use	Same
Coil Delivery Mechanism	Pusher assembly	Same
System Components	Coil (implant) Delivery System Detachment Controller	Same
Main Coil Material	92/8 Platinum/Tungsten (Pt/W) Alloy	Same
Coil Length	1 cm – 65 cm	3 cm – 65 cm
Coil Secondary Diameter	1 mm – 24 mm	1 mm – 14 mm
Coil Wire Diameter	0.00125” - 0.0035”	Same
Primary Coil Wind Diameter	0.010” – 0.014”	0.012” – 0.014”

Category	Optima Coil System (predicate device K200030)		Modified Optima Coil System (subject device K223386)	
No. & Size of Helical Loops on Distalmost End (Complex only)	1.5 loops of 70% nominal diameter		3 loops of 70% nominal secondary diameter 3 loops of 100% nominal secondary diameter (with gaps of 0.0015")	
Primary Wind and Filar 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 .012" x .00125" .014" x .0015" .014" x .0020" .014" x .0025" .014" x .00275" (gap) .014" x .0030" .014" x .0030" (gap)	Helical There are no new dimensions that are subject to this submission.
No. of sizes offered	209		239 (30 additional models as part of this line extension, all new sizes fall within existing ranges)	
Detachment	Thermal via Detachment Controller		Same	
Pouch	Tyvek®		Same	
Shelf Life	5 Years		Same	
Sterilization Method, Sterility Assurance Level (SAL)	Gamma irradiation, 10^{-6}		Same	
Delivery System (pusher)				
Construction/Design	Body coil laser welded to hypotube		Same	
Body coil	4-part coil: A. Heater Coil (92/8 Pt/W) B. Distal Coil (SSTL)		Same	

	C. Radio-opaque (RO, 92/8 Pt/W) Coil D. Proximal Coil (SSTL)	
Hypotube	SSTL Hypotube	Same
Connector	Gold plated, SSTL hypotube	Same
Adhesive	Dymax 1128A-M-VT	Same
Jacket	PET	Same
Fluoro safe markers	Pad Printed PET Shrink tube	Same
Epoxy	Epoxy 353 ND	Same
Lead wires	Polyimide coated silver lead wires	Same
Detachment Controller		
Coil detachment	Thermal via detachment controller	Same

The modified Optima Coil System and the predicate Optimal Coil System differ in the following:

- Addition of new sizes of the coil implant.
- Addition of new combinations of coil OD, filar diameter, secondary shape diameter and lengths.

The differences between the subject and predicate devices do not raise new questions of safety and effectiveness.

Performance Data – Bench:

The following non-clinical bench testing was performed to evaluate the device changes and to demonstrate substantial equivalence of the modified Optima Coil System to the predicate device:

Test	Acceptance Criteria	Results
Visual Inspection, Dimensional Inspection, and Resistance Check	The test samples shall meet established test acceptance criteria for visual physical damage and secondary diameter and length.	Pass
Simulated Use	The test samples shall be prepared in accordance with the instructions for use and meet established test acceptance criteria for device performance in a clinically relevant model.	Pass
Stretch Resistance	The samples shall meet established test acceptance criteria for tensile strength.	Pass

Conclusion:

There is no change to the intended use, materials, principles of operation or performance requirements of the modified Optima Coil System in comparison to the predicate device (K200030). The successful completion of non-clinical bench testing demonstrates that the modified Optima Coil System is substantially equivalent to the predicate device.