February 1, 2020

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

Re: K200030
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: January 3, 2020
Received: January 7, 2020

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,

Xiaolin Zheng, Ph.D., M.S.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200030

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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OPTIMA EMBOLIZATION COIL SYSTEM
510(K) SUMMARY OF SUBSTANTIAL EQUIVALENCE

This 510(k) summary for the Optima Coil System is submitted in accordance with the requirements of 21 CFR 807.87(h) and 807.92 and following the recommendation outlined in FDA Guidance, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)]*, dated 28 July, 2014.

DATE PREPARED:	January 3, 2020
APPLICANT:	Balt USA, LLC 29 Parker Irvine, CA, 92653 USA
CONTACT PERSON:	Michael Peters, International Regulatory Affairs Specialist michael.peters@balt-usa.com +1.949.788.1443
TRADE NAME:	Optima Coil System
COMMON NAME:	Neurovascular embolization device
CLASSIFICATION NAME:	Device, Neurovascular Embolization Device, Vascular Embolization
DEVICE CLASSIFICATION:	Class II, 21 CFR 882.5950 (HCG) Class II, 21 CFR 870.3300 (KRD)
PRODUCT CODE:	HCG, KRD
PREDICATE DEVICE:	Optima Coil System (K172390)
PURPOSE OF SUBMISSION:	The purpose of this Special 510(k) submission is to obtain market clearance for a modified device.
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.
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/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 thermally detached from the delivery pusher in serial manner until the aneurysm is occluded.

TECHNOLOGICAL CHARACTERISTICS

The subject device has the same technological characteristics as the predicate device.

	Optima Embolization Coil System (K172390) (Predicate Device)	**Modified Optima Embolization Coil System (Subject Device)**	**Effect on substantial equivalence**
General			
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	None
Anatomical Site	Neurovasculature Peripheral Vasculature	Same	None
Delivery to site	Via delivery wire through microcatheter	Same	None
Principle of Operation	Facilitates endovascular embolization of intracranial aneurysms and other vascular abnormalities	Same	None
System Components	Coil (implant) Delivery System Detachment Controller	Same	None
Method of supply (coil/delivery system)	Sterile, single use	Same	None
Coil (Implant)			
Main Coil Material	Platinum/Tungsten alloy	Same	None
Primary Coil Wind Diameter	0.010”-0.014”	Same	None
Coil Secondary Diameter	1mm-24mm	Same	None
Coil Wire Diameter	0.00125”-0.0035”	Same	None

	Optima Embolization Coil System (K172390) (Predicate Device)	Modified Optima Embolization Coil System (Subject Device)	Effect on substantial equivalence
Secondary Shapes	Complex/Helical	Same	None
Coil Types	Framing, Filling, Finishing	Same	None
Coil length	1cm - 65cm	Same	None
Stretch resistance/attachment thread	Polyolefin Engage Thread	Same	None
Coupler/Markerband	Platinum/Iridium alloy	Same	None
No. of sizes offered	119	209	Additional models as part of line extension, all new sizes fall within existing ranges
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" Helical: .012" x .002" .011" x .0015" .010" x .00125"	All previous combinations, with addition of the following: Complex: .012" x .00125" .014" x .0015" .014" x .00175" .014" x .002" Helical: .012" x .00125" .014" x .0015" .014" x .00175" .014" x .002"	Additional combinations as part of line extension; all additions met specified criteria and were validated not to impact substantial equivalence
Delivery System (pusher)			
Construction/Design	Body coil laser welded to hypotube	Same	None
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	None

	Optima Embolization Coil System (K172390) (Predicate Device)	Modified Optima Embolization Coil System (Subject Device)	Effect on substantial equivalence
Hypotube	SSTL hypotube	Same	None
Connector	Gold plated, SSTL hypotube	Same	None
Adhesive	Dymax 1128A-M-VT	Same	None
Jacket	PET	Same	None
Fluoro safe markers	Pad Printed PET Shrink tube	Same	None
Epoxy	Epoxy 353 ND	Same	None
Lead wires	Polyimide coated silver lead wires	Same	None
Detachment Controller			
Coil detachment	Thermal via detachment controller	Same	None

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

- Addition of new sizes (coil OD, length)

Note: Some are grouped into new subfamilies for marketing purposes

PERFORMANCE DATA [807.92(b)]

All necessary verification and validation testing has been performed for the Optima Embolization Coil System to assure substantial equivalence to the predicate device and demonstrate the device performs as intended. Comparative laboratory bench testing was performed on test units representative of finished devices to ensure that the device performance is maintained for the entirety of the proposed shelf life, and that it satisfies the pre-determined design input requirements per the Design V&V Plan:

Testing Type	Acceptance Criteria	Testing Result
Visual and dimensional inspection	All samples must show no sign of visual physical damage and meet specified secondary diameter and length requirements.	Pass

Simulated Use	All samples must achieve a performance rating of 3 or greater for introduction, tracking, deployment, and repositioning.	Pass
Detachment	All samples must detach by the third attempt.	Pass
Detachment Zone tensile testing	All samples must meet a specified minimum tensile strength.	Pass
Stretch-resistance thread tensile testing	All samples must meet a specified minimum tensile strength.	Pass
Usability	All samples must meet established clinical performance metrics in the benchtop model.	Pass

The modified Optima Coil System met all specified criteria to be established as substantially equivalent to the legally marketed Predicate Optima Coil System (K1723290).

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Upon reviewing the performance data and comparing intended use, design, materials, principles of operation and overall technological characteristics, the modified Optima Coil System is determined to be substantially equivalent to the current, legally marketed Optima Coil System (K172390).