



September 27, 2024

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

Re: K242582
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: August 29, 2024
Received: August 30, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sara S. Thompson -S

Sara Thompson, D.V.M.
Assistant Director
DHT5A: Division of Neurosurgical,
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Enclosure

Indications for Use

510(k) Number (if known)

K242582

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.

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

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Date Summary Prepared:	09/25/2024
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): K223386

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 K223386)	Modified Optima Coil System (OptiBlock Line Extension, subject device K242582)
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
Regulation Name	Neurovascular Embolization Device	Same
Generic Name	Neurovascular Embolization Device	Same
Anatomical Location	Neuro Vasculature & 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
Sterilization Method, SAL	Gamma irradiation, 10 ⁻⁶	Same

Category	Optima Coil System (predicate device K223386)	Modified Optima Coil System (OptiBlock Line Extension, subject device K242582)
Shelf-Life	5 years	Same
Coil (Implant features)		
Main Coil Material	92/8 Platinum/Tungsten (Pt/W) Alloy	Same
Coil Length	3 cm – 65 cm	Same
Primary Coil Wind Diameter	0.012”-0.014”	0.010” - 0.014”
Coil Secondary Shape Diameter	1mm-14mm	Same
Coil Wire Diameter	0.00125” - .0030”	Same
Secondary Shapes	Complex, Helical	Same
Stretch-resistance Thread	.0022” Polyolefin Engage thread (Annealed) .0018” Polyolefin Engage thread (Annealed)	Same
Coupler	90/10 Platinum/Iridium (Pt/I) alloy Markerband	Same
Primary Wind & Filar Combinations	.012” x .00125” .014” x .0015” 0.014 x .00275” (gap) + 0.014 x 0.002” 0.014 x .00275” (gap) + 0.014 x 0.0025” 0.014” x .003” (gap) + 0.014” x .003”	.012” x .00125” .014” x .0015” .010” x .00125” .014” x .00275” (gap) + .014” x .002” .014” x .00275” (gap) + .014” x .0025” 0.014 x 0.003” (gap) + 0.014 x 0.003”
No. & Size of Distal Helical Loops (Complex Implant)	3 loops of 100% nominal diameter (with gaps of 0.0015”)	Same
Delivery System		
Construction / Design	Body coil laser welded to hypotube	Same

Category	Optima Coil System (predicate device K223386)	Modified Optima Coil System (OptiBlock Line Extension, subject device K242582)
Body Coil Components	4-part coil: 1) Heater coil (92/8 Platinum/Tungsten) 2) Distal Coil (Stainless Steel) 3) Radio-opaque (RO) Coil (92/8 Platinum/Tungsten) 4) Proximal Coil (Stainless Steel)	Same
Hypotube	Stainless Steel Hypotube	Same
Connector (to Detachment Controller)	Gold plated, stainless steel hypotube	Same
Fluorosafe Markers	Pad printed PET Shrink tube	Same
Epoxy	Epoxy 353ND	Same
Lead Wires	Polyimide coated silver lead wires	Same
Pusher Working Length	185 cm	Same
Delivery Wire Diameter	0.0125" Stainless Steel Coil 0.0125" Platinum/Tungsten Coil 0.0135" Stainless Steel hypotube	Same
PET Jacket	.016" ID x .00025" Wall PET	Same
Solder	Gold solder	Same
Bonding Adhesive	Dymax 1128A-M-VT	Same
Attachment Zone Length	0.045"	Same
Detachment Equipment		
Detachment Equipment Components	Xcel Detachment Controller	Same
User Interface	Handheld	Same
Power Source	Battery, n=3 12V, size A23	Same
Detachment Mechanism	Thermal via detachment controller	Same
Controller Sterilization	Ethylene oxide gas	Same
Method of supply	Sterile; single use	Same

The modified Optima Coil System (OptiBlock Line Extension) and the predicate Optima Coil System differ in the following:

- Addition of coil models with new combinations of diameter and length.
- Reduction of the coil's helical proximal loops by 1mm or 2mm in diameter, for coil models with nominal loop diameters of 3-5mm and 6-14mm, respectively.
- Implementation of 0.0015-inch gaps added to the primary wind of distal helical loops for secondary diameters ranging from 3 mm to 3.5 mm.
- Implementation of a smaller .010" Primary wind OD.

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 (OptiBlock Line Extension) 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, secondary diameter and length, and resistance.	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

Conclusion:

There is no change to the intended use, materials, principles of operation or performance requirements of the modified Optima Coil System (OptiBlock Line Extension) in comparison to the predicate device (K223386). The successful completion of non-clinical bench testing demonstrates that the modified Optima Coil System (OptiBlock Line Extension) is substantially equivalent to the predicate device.