January 27, 2026

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

Re: K254221
Trade/Device Name: Optima Coil System (OptiOne Coil System)
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: December 19, 2025
Received: December 29, 2025

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,

JAIME RABEN -S

for Sara S. Thompson, DVM
Assistant 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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K254221 |

Please provide the device trade name(s).

Optima Coil System (OptiOne Coil System)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

## 510(k) Summary

| | |
|---|---|
| **Applicant:** | Balt USA, LLC<br>29 Parker<br>Irvine, CA 92618<br>Registration No.: 3014162263 |
| **Primary Contact Person:** | Kavita Chandrashekar<br>Principal Regulatory Affairs Specialist<br>Telephone: (858) 405-1276<br>Email: kavita.chandrashekar@baltgroup.com |
| **Secondary Contact** | Brandon Shepard<br>Director, Regulatory Affairs<br>Telephone: (949) 788-1443<br>Email: brandon.shepard@baltgroup.com |

| | |
|---|---|
| **Date Summary Prepared:** | 01/27/2026 |
| **Trade Name:** | Optima Coil System (OptiOne 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) |
| **Regulation Name:** | Device, Neurovascular Embolization;<br>Device, Vascular, for Promoting Embolization |
| **Device Classification:** | Class II |
| **Predicate Device:** | Optima Coil System, 510(k): K252700 |

**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 K252700) | Modified Optima Coil System (OptiOne Coil System, subject device) |
|---|---|---|
| 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)<br>Delivery System<br>Detachment Controller | Same |
| Sterilization Method, SAL | Gamma irradiation, $10^{-6}$ | Same |

| **Category** | **Optima Packing Coil System (predicate device K252700)** | **Modified Optima Coil System (OptiOne Coil System, subject device)** |
|---|---|---|
| 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 | 5 cm – 37 cm |
| Primary Coil Wind Diameter | 0.012”– 0.014” | 0.012”– 0.014” |
| Coil Secondary Shape Diameter | 2mm | 3 – 6mm[1] |
| Coil Wire Diameter | .00125" – .0015" | .00125" – .002”[2] |
| Secondary Shapes | Helical | Complex, Helical[3] |
| Coupler | 90/10 Platinum/Iridium (Pt/I) alloy Markerband | Same |
| Primary Wind & Filar Combinations | .012" x .00125"<br>.014" x .0015" | No new combinations. |
| **Delivery System** | | |
| Construction / Design | Body coil laser welded to hypotube | Same |

[1] Secondary shape diameters ranging from 1–18 mm were cleared under 510(k) **K200030**.
[2] Coil filar diameters ranging from 0.00125” to 0.0030” were cleared under 510(k) **K242582**.
[3] Complex secondary shape geometries were cleared under 510(k)s **K200030, K223386, and K242582**.

| | | |
|---|---|---|
| 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 |
| Solder | Gold solder | Same |
| Bonding Adhesive | Dymax 1128A-M-VT | Same |
| Jacket | Polyethylene Terephthalate | Same |
| **Detachment Equipment** | | |
| Detachment Equipment Components | XCEL | Same |

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

- Implementation of an updated implant design with helical loops and a series of complex boxes that will grab and anchor into the aneurysm. This update will also reduce the need for additional coiling following deployment of the OptiONE implant. 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 OptiOne 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, 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 OptiOne Coil System in comparison to the predicate device (K252700). The successful completion of non-clinical bench testing demonstrates that the subject OptiOne Coil System is substantially equivalent to the predicate device.