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/comination-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.


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 -S

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
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.

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
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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.
The Optima Coil System is intended for use in the peripheral and neuro-vascular to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.

### Anatomical Site
- Neurovasculature
- Peripheral Vasculature

### Delivery to site
- Via delivery wire through microcatheter

### Principle of Operation
- Facilitates endovascular embolization of intracranial aneurysms and other vascular abnormalities

### System Components
- Coil (implant)
- Delivery System
- Detachment Controller

### Method of supply (coil/delivery system)
- Sterile, single use

### Coil (Implant)
- Main Coil Material: Platinum/Tungsten alloy
- Primary Coil Wind Diameter: 0.010”-0.014”
- Coil Secondary Diameter: 1mm-24mm
- Coil Wire Diameter: 0.00125”-0.0035”

The subject device has the same technological characteristics as the predicate device.
<table>
<thead>
<tr>
<th></th>
<th>Optima Embolization Coil System (K172390) (Predicate Device)</th>
<th>Modified Optima Embolization Coil System (Subject Device)</th>
<th>Effect on substantial equivalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary Shapes</td>
<td>Complex/Helical</td>
<td>Same</td>
<td>None</td>
</tr>
<tr>
<td>Coil Types</td>
<td>Framing, Filling, Finishing</td>
<td>Same</td>
<td>None</td>
</tr>
<tr>
<td>Coil length</td>
<td>1cm - 65cm</td>
<td>Same</td>
<td>None</td>
</tr>
<tr>
<td>Stretch resistance/attachment thread</td>
<td>Polyolefin Engage Thread</td>
<td>Same</td>
<td>None</td>
</tr>
<tr>
<td>Coupler/Markerband</td>
<td>Platinum/Iridium alloy</td>
<td>Same</td>
<td>None</td>
</tr>
<tr>
<td>No. of sizes offered</td>
<td>119</td>
<td>209</td>
<td>Additional models as part of line extension, all new sizes fall within existing ranges</td>
</tr>
<tr>
<td>Primary wind (Coil OD) x Filar (Wire Diameter) combinations</td>
<td>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”</td>
<td>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”</td>
<td>Additional combinations as part of line extension; all additions met specified criteria and were validated not to impact substantial equivalence</td>
</tr>
<tr>
<td>Delivery System (pusher)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Construction/Design</td>
<td>Body coil laser welded to hypotube</td>
<td>Same</td>
<td>None</td>
</tr>
<tr>
<td>Body coil</td>
<td>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)</td>
<td>Same</td>
<td>None</td>
</tr>
</tbody>
</table>
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:

<table>
<thead>
<tr>
<th>Testing Type</th>
<th>Acceptance Criteria</th>
<th>Testing Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual and dimensional inspection</td>
<td>All samples must show no sign of visual physical damage and meet specified secondary diameter and length requirements.</td>
<td>Pass</td>
</tr>
</tbody>
</table>
### 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).