February 18, 2018

Blockade Medical, LLC (d.b.a. Balt USA)
Rebecca K. Pine
Official Correspondent
18 Technology Drive, Suite 169
Irvine, California 92618

Re: K172390
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 18, 2018
Received: January 19, 2018

Dear Rebecca K. Pine:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Carlos L. Pena -S FDA

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K172390

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 Coil System
510(k) Summary

This 510(k) summary for 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.

SUBMITTER [807.92(a)(1)]

Blockade Medical, LLC (d.b.a. Balt USA)
18 Technology Dr. Ste 169
Irvine, CA 92618

Contact person: Rebecca K Pine
Phone: (760) 809-5178
Date prepared: February 12, 2018

DEVICE [807.92(a)(2)]

Name of the device:	Optima Coil System
Common of usual name:	Neurovascular embolization device
Classification name:	Neurovascular embolization device Vascular embolization device
Regulatory Class:	Class II
Product Code:	HCG KRD
Submission Type:	Traditional 510(k)
Regulation Number:	21 CFR 882.5950
Reviewing Product Branch:	Division of Neurological and Physical Medicine Devices (Office of Device Evaluation, CDRH)

PREDICATE DEVICE [807.92(a)(31)]

Barricade Embolization Coil System (K151760)

DEVICE DESCRIPTION [807.92(a)(4)]

The Optima Coil System is a series 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.

INDICATIONS FOR USE [807.92(a)(5)]

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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE [807.92(a)(6)]

The technological characteristics of the Optima Coil System is highly analogous to the technological characteristics of the Barricade Embolization Coil System previously cleared (K151760) version of the device, as shown below:

	Barricade Embolization Coil System (K151760) (Predicate Device)	**Optima Coil System (Subject Device)**	**Effect on substantial equivalence**
Principle of Operation	Facilitates endovascular embolization of intracranial aneurysms and other vascular abnormalities	SAME	None. Identical
System components	Coil (implant) Delivery system Detachment controller	SAME	None. Identical
Coil delivery mechanism	Pusher	SAME	None. Identical
Method of supply (coil/delivery system)	Sterile, single use	SAME	None. Identical
Coil (implant)			
Main Coil Material	Platinum/Tungsten alloy	SAME	None. Identical
Primary Coil Diameter	0.010”-0.014”	SAME	None. Identical
Coil Secondary diameter	1.0mm – 15mm	1mm-24mm	None. An increase in diameter range has no effect on the intended performance of the device.
Coil Wire Diameter	0.00125”-0.003”	0.00125”-0.0035”	Minor increase (0.0005”) in diameter range has

			no effect on the intended performance of the device
Secondary Shapes	Complex/Helical	SAME	None. Identical
Coil Types	Framing, Filling, Finishing	Framing, Filling, Finishing (standard, soft, super soft, 18)	None. Identical. Nomenclature has merely been updated
Coil length	1cm – 50cm	1cm – 65cm	None. An increase in length range has no effect on the intended performance of the device.
Stretch resistance/attachment thread	.0022" Polyolefin Engage thread .0009" PET thread	.0022" Polyolefin Engage thread	None. Minor change to accommodate thermal detachment mechanism
Coupler	N/A	90%/10% Pt/Ir Markerband	None. Minor change to accommodate thermal detachment mechanism
Detachment Zone	.020" (nominal)	0.050" (nominal)	None. Minor change to accommodate thermal detachment mechanism
Delivery System			
Construction/Design	SSTL core wire	Body coil laser welded to hypotube	None. Minor change to accommodate thermal detachment mechanism. Change has no effect on the intended performance of the device.
Body coil	RO Coil (92/8 Pt/W)	4-part coil A. Heater coil (92/8 Pt/W) B. Distal Coil (SSTL) C. Radio-opaque (RO) Coil (92/8 Pt/W)	None. Minor change to accommodate thermal detachment

		D. Proximal Coil (SSTL)	mechanism. Change has no effect on the intended performance of the device.
Hypotube	N/A	SSTL hypotube	None. Minor change to accommodate thermal detachment mechanism. Change has no effect on the intended performance of the device.
Connector	N/A	Gold plated, SSTL hypotube	None. Minor change to accommodate thermal detachment mechanism. Change has no effect on the intended performance of the device.
Adhesive	Dymax 1128A-M	Dymax 1128A-M-VT	None. Minor change in adhesive viscosity does not affect the intended performance of the device.
Jacket	PET	Same	None. Identical
Flouro safe markers	Pad Printed PET Shrink tube	Same	None. Identical
Epoxy	N/A	Epoxy 353 ND	None. Minor change to accommodate thermal detachment mechanism. Change has no effect on the intended performance of the device.
Lead wires	N/A	Polyimide coated silver lead wires	None. Minor change to

			accommodate thermal detachment mechanism. Change has no effect on the intended performance of the device.
Heater coil coating	N/A	Polyimide coating	None. Minor change to accommodate thermal detachment mechanism. Change has no effect on the intended performance of the device.
Detachment Controller			
Coil detachment	Electrolytic via detachment controller	Thermal via detachment controlled	None. Change in detachment method does not alter the intended performance of the device

The implant segment detaches via a thermal detachment mechanism upon activation of the XCEL Detachment Controller. The predicate device, Barricade Coil System implant segment detaches via an electrolytic detachment mechanism upon activation of the detachment controller. The device is designed to be deployed and detached in the neuro and peripheral vasculature to permanently obstruct blood flow. The difference in detachment mechanism does not alter the intended performance of the device; therefore, the change in detachment mechanism does not affect the safety, effectiveness, and benefit/risk profile of the Optima Coil System.

PERFORMANCE DATA [807.92(b)]

Performance Bench Testing and Animal Testing: Results of the performance benching testing and animal testing indicate that Optima Coil System meets established performance requirements, and is substantially equivalent for its intended use.

Performance Bench Testing		
Test	**Test Method Summary**	**Results**
Corrosion Resistance	The deployed coil was placed in a sodium phosphate buffered saline solution and the resting potential (E_r) is recorded for one (1) hour in	All test samples passed testing.

	an open circuit configuration and allowed to plateau.	
Advancement and Retraction Force	The test represents the maximum force required to advance and retract the coil through the microcatheter	All test samples passed testing.
MRI Compatibility	SAR patterns and temperature rises were evaluated under MRI conditions using RF coils at 64-MHz and 128 MHz and to determine the magnetic field interactions, heating, and artifacts. for the Optima Coil System. The SEMCAD software package was used to evaluate surface heating patterns for the Optima Coil when placed inside the gel of the ASTM phamtom under 1.5T and 3-T MRI systems.	All test samples passed testing. MR Conditional.
MRI Artifact	The MRI artifact was evaluated under predetermined magnetic resonance angiography (MRA) imaging parameters.	All test samples passed testing.
Detachment Temperature Characterization	The temperature characterization of the Optima Coil System's delivery pusher during the detachment cycle was evaluated by comparing the temperature of the delivery pusher to commercially available thermal detachment coils.	All test samples passed testing.
Simulated Use testing	Simulated use testing is to demonstrate that the device will meet the requirements of the product specifications and to demonstrate that the device will meet the product specifications requirements when tested in worst case tortuosity vessel.	All test samples passed testing.
Usability – XCEL Detachment Controller	The clinical results of the usability of XCEL Detachment Controller were evaluated in accordance to IEC 60601-1-6:2010 + AMD1:2013 and IEC 62366-1:2015.	All test samples passed testing.
Particulate Characterization	Particulate matter in injections of the device were quantified after advancement/retraction procedures.	All test samples passed testing.
Design Verification and	This test is to evaluate the device	All test samples passed testing.

Packaging Validation	design and packaging design and to demonstrate that the device will meet the product specification requirements at t=0-year time-point after exposing to 1x Gamma sterilization. Bubble immersion, seal peel strength, simulated use, detachment, SR tensile test and DZ tensile strength testing were performed.	
Performance Animal Testing		
Animal Testing (GLP)	Animal testing is to evaluate the *in vivo* performance of the Optima Coil System and XCEL Detachment Controller in an acute porcine model. Performance metrics such as Introduction, Tracking, Deployment, Reposition, and Detachment within an aneurysm were rated.	All test samples passed testing.

Biocompatibility:

Biocompatibility Test	Results	Conclusion
Optima Coil Implant		
Cytotoxicity - MEM Elution (GLP) - 72 hour extract ISO 10993-5	The test article scored '0' at 24, 48 and 72±4 hours	Non-cytotoxic
Sensitization - ISO Guinea Pig Maximization Sensitization Test (GLP-2 extract) ISO 10993-10	None of the extracts of the test article exhibited a sensitization response greater than '0'.	Did not elicit sensitization response
Irritation or Intracutaneous irritation reactivity - ISO Intracutaneous Irritation Test (GLP-2 Extracts) ISO 10993-10	The difference in the mean test and control scores of the extract dermal observations were less than 1.0.	Non-irritant
Acute systemic toxicity - ISO Acute Systemic Injection Test (GLP-2 Extracts) ISO 10993-11	None of the test article treated animals were observed with clinical signs consistent with toxicity at any of the observation periods.	No signs of toxicity
Acute systemic toxicity - ISO Material Mediated Rabbit pyrogen (GLP)	None of the test article extracts had a temperature rise > 0.5 °C at the required observation time points.	Non-pyrogenic

ISO 10993-11		
Hemocompatibility - ASTM Hemolysis Assay – Direct Contact and Extract Method (GLP) ISO 10993-4	Based on the validity of the assay, the test article is considered non-hemolytic under the test conditions employed.	Non-hemolytic
Hemocompatibility - Prothrombin Time (PT) -GLP ISO 10993-4	No statistically significant difference was observed between the plasma exposed to the test article, predicate and control.	No adverse effect on prothrombin coagulation
Hemocompatibility - Complement Activation SC5b-9 Assay with Sponsor-Supplied Comparison Article (GLP) ISO 10993-4	When compared to the reference control data the test article and comparison article results for the SC5b9 assay showed no statistically significant difference between the results ($p<0.05$).	Exhibited activation not significant/Passed
Genotoxicity - ISO In Vitro Mouse Lymphoma with Extended Treatment (GLP) ISO 10993-3	No test article mutant frequency was found to be significantly different than concurrent negative controls according to statistical analysis. No test article result exceeded the GEF in any treatment. The test article is considered to be non-mutagenic and non-clastogenic in the test system.	Non-mutagenic and non-clastogenic
Genotoxicity ISO Bacterial Mutagenicity Test – Ames assay (GLP-4 Salmonella Strains and 1 E. Coli Strain – 2 Extracts) ISO 10993-3	The test article did not induce substantial increases in reversion rates of the type that are associated with mutagenesis. Furthermore, no substantial test article toxicity was noted that may have interfered with the ability of the test system to detect mutagens.	Non-mutagenic
Genotoxicity - ISO In Vivo Mouse Micronucleus Assay (GLP-2 Extracts) ISO 10993-3	There were no apparent gross manifestations of toxicity nor biologically significant erythropoietic disturbances resulting in delayed mutagenesis. Furthermore, there were no biologically significant increases in mPCE production in the test article treated groups as compared to the concurrent negative controls.	Non-mutagenic

Implantation - ISO Intramuscular Implantation Test with Histopathology – 4 Week – 3 Rabbits (GLP) ISO 10993-6	The average irritation score of the test article is 6.7 whereas the average irritation score of the control article is 6.3.	When comparing the irritation score of the test article to the control article, the irritation scores are found to be comparable. Pass
Implantation - ISO Intramuscular Implantation with Histopathology – 13 Week – 4 Rabbits ISO 10993-6	The average irritation score of the test article is 8.8 whereas the average irritation score of the control article is 9.3.	When comparing the score of the test article to the control article, the irritation scores are found to be comparable. Pass
Carcinogenicity ISO 10993-18 ISO 10993-17	Toxicological Risk Assessment	Non-carcinogenic
Subacute/Subchronic Tooxicity ISO 10993-11	Toxicological Risk Assessment	Pass
ChronicToxicity ISO 10993-11	Toxicological Risk Assessment	Pass
Delivery Pusher		
Cytotoxicity - ISO MEM Elution Using L-929 Mouse Fibroblast Cells (GLP) ISO 10993-5	The test article scored '0' at 24, 48, and 72 + 4 hours	Non-cytotoxic
Sensitization - ISO Guinea Pig Maximization Sensitization Test (GLP-2 extract) ISO 10993-10	None of the animals challenged with the test article extracts were observed with a sensitization response greater than '0'.	Did not elicit sensitization response
Irritation or Intracutaneous irritation reactivity - ISO Intracutaneous Irritation Test (GLP-2 Extracts) ISO 10993-10	The differences in the mean test and control scores of the extract dermal observations were less than 1.0	Non-irritant
Acute systemic toxicity - ISO Acute Systemic Injection Test (GLP-2 Extracts) ISO 10993-11	None of the test article treated animals were observed with clinical signs consistent with toxicity at any of the observation periods.	No signs of toxicity
Acute systemic toxicity - ISO Materials Mediated Rabbit pyrogen (GLP)	None of the e test article extracts had a temperature rise > 0.5 0C at the required observation time points.	Non-pyrogenic

ISO 10993-11		
Hemocompatibility Hemolysis Assay – Direct Contact and Extract Method (GLP) ISO 10993-4	Based on the validity of the assay, the test article is considered non-hemolytic under the test conditions employed.	Non-hemolytic
Hemocompatibility Complement Activation - SC5b-9 Assay with Sponsor-Supplied Comparison Article (GLP) ISO 10993-4	The SC5b-9 assay results for the reference control and the results of test article were not statistically significant ($p>0.05$) and is considered satisfactory under the test conditions employed. The SC5b-9 assay results for the comparison article were statistically significantly ($p<0.05$) lower than the reference control data.	Exhibited activation not significant
Hemocompatibility - Prothrombin Time (PT) – GLP ISO 10993-4	No statistically significant difference was observed between the plasma exposed to the test article, predicate and control.	No adverse effect on prothrombin coagulation
Hemocompatibility - Thromboresistance Evaluation (GLP -4 Hour – 2 Dog) ISO 10993-4	Implantation of the test and control devices in the jugular veins of two canines resulted in no adverse effects or clinical signs.	Thrombus formation not significant/Passed
Hemocompatibility - ISO in Vitro Mouse Lymphoma with Extended Treatment (GLP) ISO 10993-3	No test article mutant frequency exceeded the GEF or was significantly different from concurrent negative control results at a 95% confidence interval.	Non-mutagenic and non-clastogenic
Genotoxicity - ISO Bacterial Mutagenicity Test – Ames assay (GLP-4 Salmonella Strains and 1 E. Coli Strain – 2 Extracts) ISO 10993-3	The test article did not induce substantial increases in reversion rates of the type that are associated with mutagenesis.	Non-mutagenic

Sterilization:

Test	**Test Method Summary**	**Results**
Sterilization – Optima Coil System	To establish the sterilization dose and a routine sterilization process and to validate the sterilization process to achieve an SAL of 10^{-6} for the Optima	All test samples passed testing.

	Coil System. Bioburden, dose verification, Sterility, and B&F testing were performed.	
Sterilization – XCEL Detachment Controller	To establish the sterilization cycle and a routine sterilization process and to validate the sterilization process to achieve an SAL of 10^{-6} for the XCEL Detachment Controller. Bioburden, EO and ECH residual, and sterility testing were performed.	All test samples passed testing.
Bacterial Endotoxin (LAL)	Fully packaged devices were assembled and packaged using approved materials defined for the finished product and sterilized per the documented sterilization process. Samples were tested for Inhibition/Enhancement Assay and Kinetic chromogenic LAL Bacterial Endotoxin testing.	All test samples passed testing.

Shelf Life and Packaging:

Test	**Test Method Summary**	**Results**
Shelf Life- Optima Coil System	Test samples were subjected to one (1) time Gamma sterilization cycle at the maximum dose range, accelerated aged for the equivalent of 2 years, environmentally conditioned per ASTM F1980-16 and subjected to transportation simulation per ASTM 4169-16.	All test samples passed testing.
Shelf Life-XCEL Detachment Controller	Test samples were subjected to EO sterilization, environmentally conditioned and subjected to transportation simulation per ASTM 4169. Subsequent to the transport simulation, packaging tests were performed to evaluate the integrity and seal strength of the sterile barrier system.	All test samples passed testing.

CONCLUSIONS

The Optima Coil System met all specified criteria and did not raise new safety or performance questions. Based on the 510(k) summary and information provided herein, we conclude the subject device, Optima Coil System, is substantially equivalent in its intended use, design, material, performance, and the underlying fundamental scientific technology used, to the predicate device, Barricade Coil System (K151760).