DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 24, 2014

Codman & Shurtleff, Inc.
Ms. Hannah Foley
Regulatory Affairs Specialist II
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K142429
Trade/Device Name: CODMAN Microcoil Delivery System, DELTAMAXX Microcoil Delivery System, ORBIT GALAXY G2 Microcoil Delivery System, EnPower Control Cable, and Connecting Cable
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: December 4, 2014
Received: December 5, 2014

Dear Ms. Hannah Foley,

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142429

Device Name
CODMAN Microcoil Delivery System
DELTAMAXX Microcoil Delivery System
ORBIT GALAXY G2 Microcoil Delivery System

Indications for Use *(Describe)*
CODMAN Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and is also intended for arterial and venous embolizations in the peripheral vasculature.

The DELTAMAXX Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and is also intended for arterial and venous embolizations in the peripheral vasculature.

The Fill ORBIT GALAXY G2 Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and is also intended for arterial and venous embolizations in the peripheral vasculature.

The Xtrasoft ORBIT GALAXY G2 Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms.

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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510(k) Summary

I. Submitter

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Contact Person: Hannah Foley
Date Prepared: December 22, 2014

II. Device

Table 1: Device	
Device Proprietary Name	CODMAN® Microcoil Delivery System, DELTAMAXX Microcoil Delivery System, ORBIT GALAXY® G2 Microcoil Delivery System, EnPower Control Cable (ECB) and Connecting Cable (CCB)
Common or Usual Name	Device, Neurovascular Embolization & Device, Vascular, For Promoting Embolization
Classification Name	Device, Neurovascular Embolization, Class II, 21 CFR 882.5950 & Device, Vascular, For Promoting Embolization, Class II 21 CFR 870.3300
Regulatory Classification	II
Product Codes	HCG, KRD

III. Predicate Device

The corresponding predicate devices that are listed in **Table 2** below pertain to the devices being bundled in this submission. Refer to **Table 3** for proprietary names of the all applicable products.

Table 2: Prior 510(k) Clearances			
510(k) Number	**Date Cleared**	**Name**	**Manufacturer**
Predicate K082739	10/17/2008	Micrus Microcoil Delivery System (Includes Cables)	Micrus Endovascular Corporation*
Predicate K083646	01/02/2009	DELTAPLUSH 10 Stretch-Resistant DPL and DELTAPLUSH 10 Cerecyte CPL (Includes Cables)	Micrus Endovascular Corporation*
Predicate K120686	04/04/2012	ORBIT GALAXY® G2 Microcoil Delivery System (Includes Cables)	Codman & Shurtleff, Inc.
Predicate K120274	03/02/2012	DELTAMAXX 18 Microcoil System (Includes Cables)	Codman & Shurtleff, Inc.
Predicate K072173	10/05/2007	Micrus Microcoil System "Cashmere"	Micrus Endovascular Corporation*
Predicate K073442	02/26/2008	Micrus Microcoil Delivery System	Micrus Endovascular Corporation*
Predicate K032872	11/28/2003	Micrus Microcoil Delivery System Long Spherical Coils	Micrus Endovascular Corporation*
Predicate K062036	08/25/2006	Micrus Microcoil Delivery System Presidio-18	Micrus Endovascular Corporation*
Predicate K053160	12/07/2005	Micrus Microcoil Delivery System Cerecyte-18	Micrus Endovascular Corporation*
*On 09/27/10, Micrus Endovascular Corporation was acquired by Johnson & Johnson and now operates as a wholly-owned subsidiary of Codman & Shurtleff, Inc within the Johnson & Johnson family of companies. Medos International SARL (Medos) will be the recognized legal manufacturer and Codman & Shurtleff, Inc. will be the subcontractor appointed by Medos.			

No reference devices were used in this submission.

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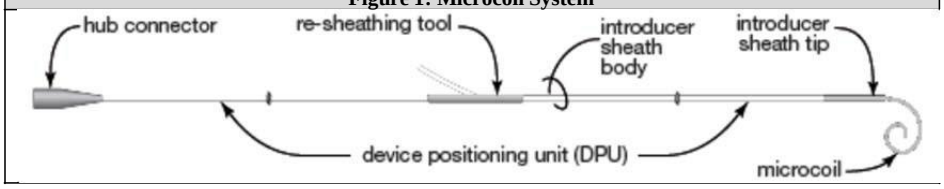
510(k) Summary Continued:

IV. Device Description

The CODMAN® Microcoil Delivery System, DELTAMAXX Microcoil Delivery System, and ORBIT GALAXY® G2 Microcoil Delivery System consist of three components, a Microcoil System, a connecting cable, and a Detachment Control Box (DCB). Each component is sold separately. As shown in **Figure 1**, the Microcoil System consists of an microcoil attached to a Device Positioning Unit (DPU).

Figure 1: Microcoil System



The Microcoil System is packaged in an introducer sheath designed to protect the coil in the packaging dispenser and to provide support for introducing the coil into the infusion catheter. The microcoil is the implantable segment of the device, and is detached from the Device Positioning Unit (DPU) using the Detachment Control System (Detachment Control Box and connecting cable).

- The microcoil is fabricated from a platinum alloy wire. The wire is wound into a primary coil which may contain either a polypropylene suture (SR) or an absorbable polymer suture (Cerecyte®) and then formed into a secondary shape. The secondary shape may be straight, spherical, complex, or helical. The DPU is a variable stiffness wire and has a radiopaque marker band located three (3) cm from its distal end. The introducer sheath has three main components: an introducer tip, a translucent introducer body, and a re-sheathing tool.

The Detachment Control Box (DCB) provides the energy necessary to allow for a thermo-mechanical detachment of the microcoil from the DPU. The connecting cable delivers the energy necessary to detach the embolic coil from the Microcoil System's detachment zone. The connecting cable is connected between the Microcoil System's hub connector on the DPU and the output connector on the DCB.

- The detachment control box may be one of two types: the blue EnPower Detachment Control Box or the black Detachment Control Box.

- The connecting cables may be one of two types: one with a remote detach button (the EnPower Control Cable) catalog no. ECB000182-00, or one without a detach button (standard connecting cable) catalog no. CCB00157-00.

- The EnPower Detachment Control Box works with the EnPower Control Cable and with the standard connecting cable. The black Detachment Control Box works only with the standard connecting cable. Both cables and Detachment Control Box are sold separately.

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510(k) Summary Continued:

IV. Device Description (Cont.)

Table 3 provides a summary of the of the Microcoil Delivery Systems and Cables, proprietary names, product model description, product catalog prefix, diameter and length, and predicate 510(k) numbers.

Table 3: CODMAN®, DELTAMAXX, and ORBIT GALAXY® G2 Microcoil Delivery Systems and Cables			
Proprietary Names / Product Model Description	**Product Catalog Prefix**	**Diameter (mm) x Length (cm) Ranges**	**510(k) No.**
CODMAN® Microcoil Delivery System:			
MICRUSPHERE 10 Platinum Coil	SPH10	2-10mm x 2.5-30cm	K082739
MICRUSPHERE 18 Platinum Coil	SPH18	2-19mm x 2.5-30cm	K082739
HELIPAQ 10 Platinum Coil	HEL10	2-10mm x 2-30cm	K082739
HELIPAQ 18 Platinum Coil	HEL18	2-20mm x 4-30cm	K082739
INTERPAQ Straight 10 Platinum Coil	STR10	2-6mm x 4-30cm	K082739
ULTIPAQ 10 Stretch Resistant Coil	FSR10	2-4mm x 1-8cm	K082739
HELIPAQ 10 Stretch Resistant Coil	HSR10	2-10mm x 1-30cm	K082739
CASHMERE 14 Stretch Resistant Coil	SRC14	2-12mm x 2.5-30cm	K072173
MICRUSPHERE XL 10 Stretch Resistance Coil	SSR10	2-8mm x 2.5-25mm	K073442, K032872
MICRUSPHERE XL 18 Stretch Resistance Coil	SSR18	8-18mm x 25-40cm	K073442, K062036, K053160
DELTAPAQ 10 Stretch Resistant Coil	DFS10	1.5-10mm x 1-25cm	K082739
DELTAPLUSH 10 Stretch Resistant Coil	DPL10	1.5-4mm x 1-8cm	K083646
PRESIDIO 10 Platinum Coil	PP410	4-8mm x 11.5-29cm	K082739
DELTAMAXX 18 Stretch Resistant Coil	DMX18	3-24mm x 12-60cm	K120274
ORBIT GALAXY® G2 Stretch Resistant Complex Coil Fill	641CF	2-20mm x 1.5-30cm	K120686
ORBIT GALAXY® G2 Stretch Resistant Complex Coil XTRASOFT	641CX	2-6mm x 1.5-20cm	K120686
ORBIT GALAXY® G2 Stretch Resistant Helical Coil XTRASOFT	641HX	2mm x 1.5-8cm	K120686
EnPower Control Cable (Microcoil Delivery Systems' Cable)	ECB	5-6ft	K082739, K083646, K120686, K120274
Connecting Cable (Microcoil Delivery Systems' Cable)	CCB	5-6ft	K082739, K083646, K120686, K120274

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510(k) Summary Continued:

V. Indications for Use

CODMAN® Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and is also intended for arterial and venous embolizations in the peripheral vasculature.

The DELTAMAXX Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and is also intended for arterial and venous embolizations in the peripheral vasculature.

The Fill ORBIT GALAXY® G2 Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and is also intended for arterial and venous embolizations in the peripheral vasculature.

The Xtrasoft ORBIT GALAXY® G2 Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms.

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510(k) Summary Continued:

VI. Comparison of Technological Characteristics With Predicate Device

There are no new technological characteristics being introduced with the proposed packaging change to the CODMAN®, DELTAMAXX, ORBIT GALAXY® G2 Microcoil Delivery Systems and Cables. The CODMAN®, DELTAMAXX, ORBIT GALAXY® G2 Microcoil Delivery Systems and Cables were shown to be substantially equivalent to the predicate devices through comparison of indications for use, function, operating principle, bench testing, sterilization, biocompatibility, and materials.

The modifications proposed in this submission are for packaging only. Therefore the summary table provided below is a comparison of technological characteristics focused on the CODMAN®, DELTAMAXX, ORBIT GALAXY® G2 Microcoil Delivery Systems and Cables' packaging.

Table 4: Product Packaging Comparison Information

Characteristics	Predicate Devices: CODMAN® Microcoil Delivery System (K082739, K073442. K072173, K083646) DELTAMAXX Microcoil Delivery System (K120274) ORBIT GALAXY® G2 Microcoil Delivery System (K120686)	This Submission: CODMAN® Microcoil Delivery System DELTAMAXX Microcoil Delivery System ORBIT GALAXY® G2 Microcoil Delivery System
Dimensions		
Pouch Size	11" x 10"	**14" x 10"**
Carton Size	10.125" x 11" x 0.703"	Same as Predicates
Dispenser Hoop	Length: 260cm & Diameter: 8.75"	Same as Predicates
Material		
Pouch Material	TPF-0521 PET/adhesive/LDPE/w/heat seal coating sealed to TPF-0501A PET/ LDPE	**TPS-4050 Nylon/LDPE Film w/ heat seal coating sealed to TPS-4050 Nylon/LDPE Film**
Dispenser Hoop Material	Tubing: Medical Grade Polyethylene Clip: Medical Grade MDPE	Same as Predicates
EnPower Control(ECB)/Connecting (CCB) Cable Mounting Card Material	0.024" Clay Coated Solid Bleached Sulfate	Same as Predicates
Carton Material	0.024" Clay Coated Solid Bleached Sulfate	Same as Predicates
Source		
Pouch Vendor	Tolas Health Care Packaging	Same as Predicates
Carton Vendor	Royal Paper Box &Constellation Anderson DDB Health & Lifestyles	Same as Predicates
Dispenser Hoops	Contech Packaging, Inc.	Same as Predicates
Pouch Sealing Method		
Sealer	Sencorp Model 12-PV/2	Same as Predicates
Sterilization		
Sterilization Method	E-Beam Radiation	Same as Predicates
Microcoil Delivery Systems' Target Surface Dose	37kGy	Same as Predicates
EnPower Control (ECB) / Connecting (CCB) Cables Target Surface Dose	42kGy	Same as Predicates
Shelf-Life		
Microcoil Delivery Systems' Product Shelf Life	5 years	Same as Predicates
EnPower Control (ECB) / Connecting (CCB) Cables Product Shelf Life	3 years	Same as Predicate

Note: The EnPower Control (ECB) and Connecting (CCB) Cables are part of all Microcoil Delivery Systems Listed.

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510(k) Summary Continued:

VII. Performance Data

There were no changes made that affect the CODMAN®, DELTAMAXX, ORBIT GALAXY® G2 Microcoil Delivery Systems and Cables' intended use, operational principle, design principle, product materials, manufacturing or sterilization processes. The modifications proposed in this submission are for the packaging only. Therefore, design verification and validation of the product was not warranted.

Verification and validation activities were focused on demonstrating package integrity of the proposed pouches. Appropriate testing was identified based on a review of the products' risk analyses and previous use of the Nylon/LDPE Film pouch. Testing was conducted as appropriate for the inclusion of the proposed pouches based on current standards, and all testing was performed on final sterile product, unless otherwise specified. The following performance data were provided in support of the substantial equivalence determination.

Packaging Integrity Testing
Packaging Integrity testing demonstrated that the sterile barrier system of the proposed pouch maintains packaging integrity after exposure to sterilization, simulated handling and distribution. The validation also demonstrates that the packaging design and materials are acceptable for the CODMAN®, DELTAMAXX, ORBIT GALAXY® G2 Microcoils Delivery System. The following tests were performed:

- Visual Inspection
- Dye Leak
- Seal Strength
- Product Functional Testing on EnPower Control Cable

Characterization Testing: Moisture and Humidity Creep

Sterile Pouch Shelf-Life Testing
Pouch Shelf Life visual inspection demonstrated that the proposed pouch's integrity was maintained. The inspected seals were complete and uniform throughout the entire seal area of the proposed pouch for each time interval (Accelerated Aging: time-zero, 1yr, 3yr, 5yr, 10yr) (Real-Time Aging: time-zero, 1yr, 3yr) in the sterilized test groups. There were no detected negative trends in seal strength. These results demonstrate that the seals maintain their strength over time. Testing confirmed that the device will remain sterile through the proposed shelf life and integrity of its packaging are not compromised during transportation and distribution. The following tests were performed:

- Visual Inspection
- Seal Strength

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510(k) Summary Continued:

VII. Performance Data (Cont.)

Biocompatibility Testing

The biocompatibility evaluation for the CODMAN®, DELTAMAXX, ORBIT GALAXY® G2 Microcoil Delivery Systems and Cables' was conducted in accordance with FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices - Part 1: Evaluation and testing included the following test ASTM F2475, Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials, recommends that in vitro cytotoxicity be conducted for packaging materials that contact the device directly, but do not come into direct contact with the patient. Packaging Material only comes in contact with parts of the device that are Transient Device/ Circulating Blood, Contact with Heart & Central Circulatory System/ Exposure (<24 hours).
The following tests were performed:

- In vitro Cytotoxicity

Sterilization

Sterilization method validation in accordance with ISO 11137: 2006. Only the material and size of the pouch are changing. There are no changes to the product. All of the bioburden related test results met the acceptance criteria for the representative products as packaged in the new pouch, and the full shipper weights and densities remain within the acceptable dose mapped results. Therefore, the packaging change to the CODMAN®, DELTAMAXX, ORBIT GAXALY® G2 Microcoil Delivery Systems, EnPower Control and Connecting Cables are considered acceptable. The following tests were performed:

- Bioburden measurement
- Identification of top three organisms
- Bacteriostasis/Fungistasis (B/F)
- Bioburden recovery study (Extraction efficiency)

Animal Testing

No animal studies were required as appropriate verification and validation of the packaging modifications were achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

Summary of Clinical Testing

No clinical studies were required as appropriate verification and validation of the packaging modifications were achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

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510(k) Summary Continued:

VIII. Conclusion

Based upon the design, materials, function, intended use, and the non-clinical testing performed by Codman, it is concluded that the proposed packaging for CODMAN®, DELTAMAXX, ORBIT GALAXY® G2 Microcoil Delivery Systems and Cables is substantially equivalent to the currently marketed CODMAN®, DELTAMAXX, ORBIT GALAXY® G2 Microcoil Delivery Systems and Cables and therefore, does not raise any new questions of safety and effectiveness.