DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 25, 2017

Codman & Shurtleff, Inc.
Yoon Hee Beatty
Sr. Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K171862
Trade/Device Name: GALAXY G3 Mini Microcoil Delivery System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: August 21, 2017
Received: August 23, 2017

Dear Ms. Beatty:

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 (DICE) 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 (DICE) 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,

Carlos L. Pena -S

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)*
K171862

Device Name
GALAXY G3 Mini Microcoil Delivery System

Indications for Use *(Describe)*
The GALAXY G3 Mini 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.

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: Yoon Hee Beatty
Date Prepared: August 21, 2017

II. Device

Table 1. Device	
Device Proprietary Name	GALAXY G3 Mini Microcoil Delivery System
Common or Usual Name	Device, Neurovascular Embolization & Vascular, For Promoting Embolization
Classification Name	Device, Neurovascular Embolization, Class II, 21 CFR 882.5950 & 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 are applicable to the devices in this submission.

Table 2. Prior 510(k) Clearance			
510(k) Number	**Date Cleared**	**Name**	**Manufacturer**
Primary Predicate K150319	06/12/2015	Micrus Microcoil System DELTAXFT	Codman & Shurtleff, Inc.
Reference Predicate K083646	01/02/2009	Micrus Microcoil System DELTAPLUSH	Micrus Endovascular Corporation*
Reference Device K093973	05/26/2010	ORBIT GALAXY Detachable Coil System	Codman & Shurtleff, Inc.
Reference Device K021591	05/22/2002	PROWLER SELECT Infusion Catheters	Cordis Neurovascular, Inc.**
*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. ** This 510(k) was originally owned by Cordis Neurovascular, Inc., a subsidiary of Cordis Corporation. In 2008, Cordis Neurovascular, Inc., was merged with Codman and Shurtleff, Inc. This 510(k) is presently owned by Codman & Shurtleff, Inc.			

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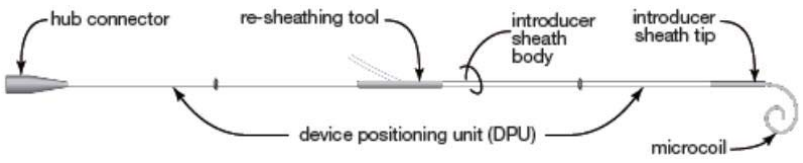
510(k) Summary, Continued

IV. Device Description

The GALAXY G3 Mini Microcoil Delivery Systems 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 a 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 microcatheter 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 contains a polypropylene suture (SR) and then formed into a secondary shape. The secondary shape is complex.

- The DPU is a variable stiffness wire and has a radiopaque marker band located three (3) cm from its distal end. The Device Positioning Unit includes five (5) fluoro saver markers on the proximal section of the shaft. The markers are intended to indicate when the tip of the microcoil is approaching the tip of the microcatheter. When the distal-most marker reaches the proximal end of the Rotating Hemostatic Valve (RHV) on the microcatheter, the tip of the coil is approaching the tip of the microcatheter and fluoroscopy should be used to guide further coil insertion.

- The introducer sheath has three main components: an introducer tip, a translucent introducer body, and a re-sheathing tool.

The EnPOWER 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 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.

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510(k) Summary, Continued

V. Indications for Use

The GALAXY G3 Mini 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.

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510(k) Summary, Continued

VI. Comparison of Technological Characteristics With Predicate Device

Endovascular coil embolization is the technological principle for both the subject and predicate devices. It is based on placing embolic coils in the neurovascular or peripheral vasculature in order to reduce or block blood flow. The subject device and predicate devices are based on the following same technological characteristics:

Table 3. Technological Characteristics of the Predicate and Proposed Devices

Description	Predicate Device: DELTAXSFT Microcoil Delivery Systems (K150319)	This Submission: GALAXY G3 Mini Microcoil Delivery Systems
Indications for Use	DELTAXSFT Microcoil Delivery Systems are intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and are also intended for arterial and venous embolizations in the peripheral vasculature.	Same as predicate GALAXY G3 Mini 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.
Microcoil		
Microcoil Material	Platinum/Tungsten	Same as predicate
Microcoil Primary Wind	Triangular	**Cylindrical***
Microcoil Secondary Shape	Helical	**Complex***
Microcoil Stretch-Resistant	PGA= Polyglycolic Acid Suture	**PP= Polypropylene Suture****
Primary Coil Wind Outer Diameter	0.0096”	**0.009”**
Secondary Shape Outer Diameter Ranges	1.5mm-4mm	**1.0mm – 3.0mm**
Microcoil Length Ranges	1cm-8cm	Same as predicate
Delivery System		
Delivery System Type	Wire Shaft with radiopaque marker	Same as predicate
Delivery System Introducer Sheath	HDPE Introducer	Same as predicate
Delivery System Resheathing Tool	Nylon 12	Same as predicate
Flush Ports	None	**Flush ports**
Introducer Sheath Tip Shape	Straight	**Tapered**
Introducer Sheath Length	120cm	**81cm and 120cm**
Device Positioning Unit (DPU3) Delivery System Length	190cm ± 5cm	Same as predicate
Device Positioning Unit Diameter	0.0159”	Same as predicate
Fluoroscopy Saver Markers	Five Markers Located on the Proximal Section of the Shaft	Same as predicate
Fluoro Saver Marker Microcatheter Compatibility	150cm Length	Same as predicate
Distal Segment of the Device Positioning Unit	Device Positioning Unit 3 (DPU3)	Same as predicate
Mechanism of Detachment	Connection to Microcoil System: Uses Connecting Cable or EnPOWER Control Cable Detachment: Thermo-Mechanical System uses the EnPOWER Detachment Control Box (DCB) with EnPOWER Control Cable or Connecting Cable	Same as predicate
Sterilization and Shelf Life		
Sterilization Method	E-Beam Radiation	**Ethylene Oxide (EtO)***
Shelf Life	3 years	Same as predicate
Packaging	Packaged in a plastic hoop and enclosed in a pouch.	**Same as predicate*****

* Same shape and sterilization method as ORBIT GALAXY DCS (K093973)
** Same material as DELTAPLUSH Microcoil (K083646)
*** Same pouch material as PROWLER SELECT Infusion Catheters (K021591)

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510(k) Summary, Continued

VII. Performance Data

Verification and Validation Testing

Verification and validation activities were conducted on the finished sterile device based on current standards and FDA Guidance Document; "*Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices"*. The following performance data were provided in support of the substantial equivalence determination. The bench testing included the following tests:

Table 4. Verification and Validation Testing

Test	Test Method Summary	Results
Spring Constant	The purpose of the Spring Constant test is to measure the softness of the coil by recording the spring constant of the primary wind.	PASS: Samples passed the established acceptance criterion
Complex Shape	The purpose of the Complex Shape test is to visually inspect the complex shape of the G3 Mini Microcoils.	PASS: Samples passed the established acceptance criterion
Particulate	The purpose of the Particulate test is to measure particulate count during simulated use per the requirements of USP788.	PASS: Samples passed the established acceptance criterion
Atraumatic Bead	The purpose of the Atraumatic Bead test is to visually verify that the bead end of the coil meets the final assembly specification.	PASS: Samples passed the established acceptance criterion
DPU 3 System Outer Diameter	The purpose of the DPU 3 System Outer Diameter test is to verify the OD is within specification to ensure microcatheter compatibility.	PASS: Samples passed the established acceptance criterion
Microcatheter Tip Deflection Force	The purpose of the Microcatheter Stability (Tip Deflection Force) test is to measure the deflection and/or stability of the microcatheter by recording the force generated at the distal tip of the microcatheter as the DPU device is advanced to the tip of the microcatheter.	PASS: Samples passed the established acceptance criterion
Detachment Zone Tensile Strength	The purpose of the Detachment Zone Tensile Strength test was to evaluate the attachment strength of the detachment fiber to prevent unintentional coil detachments	PASS: Samples passed the established acceptance criterion
Stretch Resistance Fiber Tensile Strength	The objective of test is to verify that the coil provides sufficient stretch resistance under tensile loading to ensure the coil can be retracted and repositioned without stretching.	PASS: Samples passed the established acceptance criterion

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510(k) Summary, Continued

VII. Performance Data, continued

Table 4. Verification and Validation Testing, continued		
Test	**Test Method Summary**	**Results**
Track Force (Delivery)	The purpose of the Track Force test was to evaluate the force it takes to deliver the proposed device through a microcatheter and into a clinically relevant model; utilizing the system Catheter Performance Simulation System (CPSS).	PASS: Samples passed the established acceptance criterion
Dimensional Inspection of FDL Diameter and Coil Length	The objective of test is to verify the FDL diameter and the coil length meets the specification.	PASS: Samples passed the established acceptance criterion
Coil OD Verification on Final Assembly	The purpose of the Dimensional Inspection of the Outer Diameter of the proposed device is to verify the OD is within specification.	PASS: Samples passed the established acceptance criterion
Dimensional Inspection of the Distal Fluro-saver markers	The purpose of the Dimensional Inspection of the Distal Fluoro Saver Marker was to verify that that the Fluoro Saver Markers are in the correct proximal position in order to give the physician a visual indication that the microcoil is approaching the distal tip of the microcatheter.	PASS: Samples passed the established acceptance criterion
Coil Durability	The purpose of the Coil Durability test was to evaluate the coil's ability to stay attached to the proposed device during simulated use of six insertions and withdrawals cycled into and out of a clinically relevant aneurysm model.	PASS: Samples passed the established acceptance criterion
Detachment, Coil Durability & Reliability	The purpose of the Coil Detachment Durability & Reliability test was to evaluate the reliability of the detachment mechanism of the proposed device after being cycled into and then out of a clinically relevant anatomical model six times.	PASS: Samples passed the established acceptance criterion
Resheathing Reliability	The purpose of the Re-Sheathing Reliability test was to evaluate the ability to re-insert the proposed device into the split sheath introducer after it has been unzipped after the proposed device has been inserted and withdrawal from a clinically relevant model.	PASS: Samples passed the established acceptance criterion
Fluro saver Marker Durability	The purpose of the Fluoro Saver Marker Durability test was to evaluate the ability of the Fluoro Saver Markers to stay affixed and in the correct position on the shaft of the proposed device after being cycled into and then out of a clinically relevant anatomical model six times.	PASS: Samples passed the established acceptance criterion

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510(k) Summary, Continued

VII. Performance Data, (Cont.)

Table 4. Verification and Validation Testing, continued		
Test	**Test Method Summary**	**Results**
Distal Outer Sheath Durability	The purpose of the Distal Outer Sheath Durability test was to evaluate the durability of the distal outer sheath during the simulated use of six insertions and withdrawals of the proposed device into and then out of a clinically relevant aneurysm model.	PASS: Samples passed the established acceptance criterion
Dimensional Inspection of the Introducer	The introducer underwent dimensional inspection per approved test method.	PASS: Samples passed the established acceptance criterion
Introducer Bond Strength	The objective of the test is to verify that the bond strength of the introducer fuse joint.	PASS: Samples passed the established acceptance criterion
Coil Transfer to Microcatheter	The purpose of the test is to evaluate the introducer sheath for allowing for insertion of the embolic coil into the microcatheter through the RHV.	PASS: Samples passed the established acceptance criterion
Introducer Flushing	The purpose of the test is to visually inspect to confirm flushing.	PASS: Samples passed the established acceptance criterion
Radiopacity	The purpose of the test is to verify the ability to visualize the coil under fluoroscopy for physician to determine the location of the coil during use.	PASS: Samples passed the established acceptance criterion
Overall Coil Performance	The objective of the test is to evaluate physician's satisfaction rating on performance compared to a predicate device.	PASS: Samples passed the established acceptance criterion
MRI Testing	The purpose of the test is to demonstrate that GALAXY G3 MINI Microcoil to be "MR-conditional" according to the specific conditions used for the assessment.	PASS: Samples passed the established acceptance criterion

Shelf-Life Testing

Codman successfully completed accelerated aging testing to support a shelf life of 12 months. Finished sterile devices were subjected to environmental conditioning, simulated transportation and accelerated aging before being tested.

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510(k) Summary, Continued

VII. Performance Data (Cont.)

Packaging

The modification to the current packaging consists of a change in pouch material due to the change in sterilization method from e-beam to ethylene oxide. Utilizing previously validated pouch material used in the same sterilization cycle (K021591), the new packaging configuration was validated in accordance with applicable recommendations in International Standard ISO 11607-1 "Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems, and Packaging Systems" and ISO 11607-2 "Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing, and Assembly Processes" as recognized by FDA.

Biocompatibility Testing

Biocompatibility testing was conducted in accordance with International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation of Testing Within a Risk Management Process" (ISO 10993-1:2009/2010AC), and FDA's Guidance Document entitled "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" (June 16, 2016).

The following tests were performed:

- ISO MEM Elution
- Hemocompatibility Tests
  - *In Vitro* Hemolysis - Direct Contact (ASTM F756)
  - *In Vitro* Hemolysis - Extract
  - *In Vivo* Thromboresistance
- Chemical Characterization of Extractables (ISO 10993-18)

Sterilization

The GALAXY G3 Mini Microcoil System is ethylene oxide sterilized and was validated to assure a Sterility Assurance Level (SAL) 10^{-6} according to the requirements of International Standards ISO 11135-1 "Sterilization of Health Care Products Ethylene Oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices, and ISO 10993-7 "Biological Evaluation of medical devices – Part 7: Ethylene Oxide sterilization residual" as recognized by FDA.

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510(k) Summary, Continued

VII. Performance Data (Cont.)

Animal Study

An animal study was not required as appropriate verification and validation of the GALAXY G3 Mini Microcoil Delivery System was achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

Summary of Clinical Testing

A clinical study was not required as appropriate verification and validation of the GALAXY G3 Mini Microcoil Delivery System was achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

VIII. Conclusion

Based upon the design, materials, function, intended use, performance, manufacturing and sterilization process and the non-clinical testing performed by Codman, it is concluded that the GALAXY G3 Mini Microcoil Delivery Systems are substantially equivalent to the currently marketed CODMAN DELTAXSFT Microcoil Delivery Systems (K150319) and therefore, does not raise any new questions of safety or effectiveness.