DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

July 14, 2017

Codman & Shurtleff, Inc.
Vivian Perez
Regulatory Affairs Manager
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K171747
Trade/Device Name: MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3 FILL, and GALAXY G3 XSFT Microcoil Delivery Systems
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: June 12, 2017
Received: June 13, 2017

Dear Ms. Perez:

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,

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)*

K171747

Device Name
MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3 FILL, and GALAXY G3 XSFT Microcoil Delivery Systems

Indications for Use *(Describe)*
MICRUSFRAME, DELTAFILL, and 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.

The GALAXY G3 FILL 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 GALAXY G3 XSFT 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

Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767

Tel: (305) 265-6810
Fax: (305) 265-6889

Contact Person: Vivian Perez
Email: vperez3@its.jnj.com
Date Prepared: May 26, 2017

II. Device

Table 1. Device	
Device Proprietary Name	MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3 FILL, and GALAXY G3 XSFT Microcoil Delivery Systems
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 predicated device is listed below in **Table 2.**

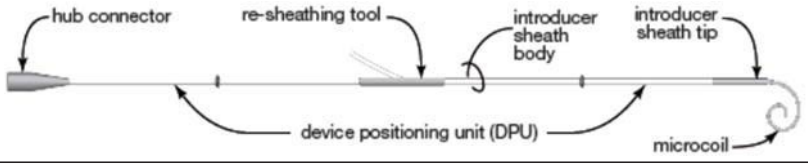
Table 2. Prior 510(k) Clearance			
510(k) Number	**Date Cleared**	**Name**	**Manufacturer**
K150319	06/12/2015	MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, GALAXY G3 XSFT Microcoil Delivery Systems	Codman & Shurtleff, Inc.

510(k) Summary, Continued

IV. Device Description

The MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3 FILL, GALAXY G3 XSFT 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 may contain either a polypropylene suture (SR) or an absorbable polymer suture and then formed into a secondary shape. The secondary shape may be 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 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, catalog no. DCB2000500, works with the ENPOWER Control Cable and with the standard connecting cable.

510(k) Summary, Continued

IV. Device Description, Continued

The devices in this submission include minor design changes only to the Device Positioning Unit's introducer sheath (introducer). There are no modifications to components or materials of the micro-coil or the ENPOWER Detachment Control System. Minor dimensional and design modifications to the introducer will help improve deliverability of the micro-coils.

510(k) Summary, Continued

V. Indications for Use

MICRUSFRAME, DELTAFILL, and 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.

The GALAXY G3 FILL 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 GALAXY G3 XSFT Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms.

510(k) Summary, Continued

VI. Comparison of Technological Characteristic with Predicate Device

Endovascular coil embolization is the technological principle for both the subject and predicate devices. This technology is based on placing embolic coils in the neurovascular or peripheral vasculature to reduce or block blood flow. The subject devices and predicate devices are based on the same technological characteristics as shown in **Table 3**. No new technological characteristics are being introduced with this change.

Table 3. Technological Characteristics of the Predicate and Proposed Device

Description	Predicate Device: MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, GALAXY G3 XSFT Microcoil Delivery System (K150319)	This Submission: MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3 FILL, GALAXY G3 XSFT Microcoil Delivery System
Indications for Use	MICRUSFRAME, DELTAFILL, and 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. GALAXY G3 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 GALAXY G3 XSFT Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms.	Same as Predicates
Microcoil		
Microcoil Material	Platinum/Tungsten	Same as Predicate
Microcoil Primary Wind	Triangular or Cylindrical	Same as Predicate
Microcoil Secondary Shape	Complex, Helical, or Spherical	Same as Predicate
Microcoil Stretch-Resistant	PGA= Polyglycolic Acid Suture PP= Polypropylene Suture	Same as Predicate
Primary Coil Wind Outer Diameter (OD)	0.009" – 0.016"	Same as Predicate
Secondary Shape OD Ranges	1.5mm – 24mm	Same as Predicate
Microcoil Length Ranges	1cm - 60cm	Same as Predicate

510(k) Summary, Continued

VI. Comparison of Technological Characteristic with Predicate Device (continued)

Table 3. Technological Characteristics of the Predicate and Proposed Device (continued)		
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
Introducer Tip Flush Ports	None	Three Flush Ports
Introducer Tip Wall Thickness	18 system: 0.005” 10 system: 0.0045	0.0103”
Introducer Sheath Tip Shape	Straight	Tapered
Introducer Sheath Length	120cm	120cm and 81cm
Device Positioning Unit (DPU) 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
Mechanism of Detachment	Connection to Microcoil System: Uses Connecting Cable or EnPOWER Control Cable	Same as Predicate
	Detachment: Thermo-Mechanical System uses the ENPOWER Detachment Control Box (DCB) with ENPOWER Control Cable or Connecting Cable	
Sterilization Method	Electron Beam Radiation	Same as Predicate
Shelf Life	3 years	Same as Predicate
Packaging	Packaged in a plastic hoop and enclosed in a pouch	Same as Predicate

510(k) Summary, Continued

VII. Non-Clinical Data Performance Data

Verification and Validation Testing

The modifications proposed in this submission affect only the introducer sheath component of the delivery system's device positioning unit. Consequently, the verification and validation activities were focused around the introducer portion of the Device Positioning Unit (DPU). There were no changes made that affect the intended use, operational principle, design principle, manufacturing or sterilization processes of the devices. Appropriate testing was identified based on the modifications made, review of the products' risk analysis and previous use of the predicate device which was cleared under K150319. All testing conducted for the modification of the DPU's introducer was based on current standards and FDA Guidance Document; "Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices" issued on December 29, 2004. All testing was performed on final sterile product following the same test methods used to test the predicate device. The following performance data were provided in support of the substantial equivalence determination.

Table 4: Verification and Validation Testing

Test	Test Method Summary	Results
Visual Inspection	Visual inspection of the test units to check for cosmetic defects to ensure the units are prepared for verification testing as per established test method.	Pass All units passed visual inspection
Tracking 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). Test samples were delivered through a compatible microcatheter to verify track forces per approved test method.	Pass Samples passed the established acceptance criterion
Re-sheathing 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. The introducer sheath underwent 1 re-sheathing cycle to verify reliability per approved test method.	Pass Samples passed the established acceptance criterion

510(k) Summary, Continued

VII. Non-Clinical Data Performance Data (continued)

Table 4: Verification and Validation Testing (continued)		
Test	**Test Method Summary**	**Results**
Dimensional Inspection	The Introducer underwent dimensional inspection per approved test method.	Pass Samples passed the established acceptance criterion
Particulate Testing	The full assembly underwent particulate testing per approved test method. Simulated use consisted of pushing forward to the tip of the microcatheter and then pulling back 8" and repeating five times.	Pass Samples passed the established acceptance criterion
Introducer Fuse Joint Testing	The Introducer underwent tensile strength testing per approved test method.	Pass Samples passed the established acceptance criterion

510(k) Summary, Continued

VII. Non-Clinical Data Performance Data

Animal Testing
The modified introducer was validated by performing an acute *in-vivo* animal study. An *in-vivo* model allowed the assessment of the acute performance of the test article to deliver an embolic coil to the target parent vessel in swine. The new introducer design demonstrated acceptable overall performance in all attributes evaluated.

Shelf Life Testing
This change does not impact the shelf-life of the device. The introducer assembly is made of the same base materials and by the same vendors as the predicate devices. The minor design changes to the device positioning unit's introducer do not impact the packaging of the device. The shelf-life testing conducted on the predicate device is applicable to the proposed device.

Biocompatibility Testing
The modified device will be manufactured using many of the same components and manufacturing processes as the predicate device. Previous biocompatibility testing conducted covered all the tests required by ISO 10993-1:2009, FDA Bluebook Memorandum G95-1, and FDA's Draft Guidance Document entitled "Use of International Standard ISO10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" issued April 23, 2013. Additional biocompatibility testing was conducted as part of the modifications to the introducer. A limited subset of the recommended biocompatibility tests, including *in vitro* cytotoxicity and *in vitro* hemolysis were successfully conducted on the modified introducer. In addition, chemical characterization of extractables of the Introducers manufactured with the current heat shrink polymer and the Introducers manufactured with a new heat shrink polymer were successfully conducted per ISO 10993-18.

Sterilization
The minor design changes to the device positioning unit introducer account for a negligible change in density (less than 0.024%). These changes did not impact the packaging, packaging process, sterilization configuration or sterilization process of the predicate device, the existing sterilization validation remains applicable for the proposed device.

Summary of Clinical Testing
Clinical studies were not required as appropriate verification and validation of the minor design modifications to the delivery system's device positioning unit's introducer were achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing. All testing was conducted using statistical sampling methods as required by the Codman & Shurtleff, Inc. Design Control procedures.

510(k) Summary, Continued

VIII. Conclusion

The minor design modifications made to the introducer do not alter the intended use or indications for use of the predicate devices, or the fundamental scientific technology of the predicate devices. Risk assessment of the modifications and successful verification/validation testing raised no new questions regarding the safety and effectiveness of the predicate devices, Codman has determined that the modified devices are substantially equivalent to the predicate devices.