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. Peña, PhD, MS
Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

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
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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>
<thead>
<tr>
<th>Device Proprietary Name</th>
<th>Table 1. Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICRUSFRAME, DELTAFILL, DELTAXSF, GALAXY G3 FILL, and GALAXY G3 XSFT Microcoil Delivery Systems</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Common or Usual Name</th>
<th>Device, Neurovascular Embolization &amp; Vascular, for Promoting Embolization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification Name</td>
<td>Device, Neurovascular Embolization, Class II 21 CFR 882.5950 &amp; Vascular, for Promoting Embolization, Class II 21 CFR 870.3300</td>
</tr>
<tr>
<td>Regulatory Classification</td>
<td>II</td>
</tr>
<tr>
<td>Product Codes</td>
<td>HCG, KRD</td>
</tr>
</tbody>
</table>

III. Predicate Device
The predicated device is listed below in Table 2.

<table>
<thead>
<tr>
<th>510(k) Number</th>
<th>Date Cleared</th>
<th>Name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>K150319</td>
<td>06/12/2015</td>
<td>MICRUSFRAME, DELTAFILL, DELTAXSF, GALAXY G3, GALAXY G3 XSFT Microcoil Delivery Systems</td>
<td>Codman &amp; Shurtleff, Inc.</td>
</tr>
</tbody>
</table>
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).

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.
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.
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

<table>
<thead>
<tr>
<th>Description</th>
<th>Predicate Device: MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, GALAXY G3 XSFT Microcoil Delivery System (K150319)</th>
<th>This Submission: MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3 FILL, GALAXY G3 XSFT Microcoil Delivery System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for Use</td>
<td>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.</td>
<td>Same as Predicates</td>
</tr>
<tr>
<td>Microcoil Material</td>
<td>Platinum/Tungsten</td>
<td>Same as Predicate</td>
</tr>
<tr>
<td>Microcoil Primary Wind Shape</td>
<td>Triangular or Cylindrical</td>
<td>Same as Predicate</td>
</tr>
<tr>
<td>Microcoil Secondary Shape</td>
<td>Complex, Helical, or Spherical</td>
<td>Same as Predicate</td>
</tr>
<tr>
<td>Microcoil Stretch-Resistant</td>
<td>PGA= Polyglycolic Acid Suture PP= Polypropylene Suture</td>
<td>Same as Predicate</td>
</tr>
<tr>
<td>Primary Coil Wind Outer Diameter (OD)</td>
<td>0.009” – 0.016”</td>
<td>Same as Predicate</td>
</tr>
<tr>
<td>Secondary Shape OD Ranges</td>
<td>1.5mm – 24mm</td>
<td>Same as Predicate</td>
</tr>
<tr>
<td>Microcoil Length Ranges</td>
<td>1cm – 60cm</td>
<td>Same as Predicate</td>
</tr>
</tbody>
</table>
510(k) Summary, Continued

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

<table>
<thead>
<tr>
<th>Table 3. Technological Characteristics of the Predicate and Proposed Device (continued)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Delivery System Type</strong></td>
</tr>
<tr>
<td><strong>Delivery System Introducer Sheath</strong></td>
</tr>
<tr>
<td><strong>Delivery System Resheathing Tool</strong></td>
</tr>
<tr>
<td><strong>Introducer Tip Flush Ports</strong></td>
</tr>
<tr>
<td><strong>Introducer Tip Wall Thickness</strong></td>
</tr>
<tr>
<td><strong>Introducer Sheath Tip Shape</strong></td>
</tr>
<tr>
<td><strong>Introducer Sheath Length</strong></td>
</tr>
<tr>
<td><strong>Device Positioning Unit (DPU) Delivery System Length</strong></td>
</tr>
<tr>
<td><strong>Device Positioning Unit Diameter</strong></td>
</tr>
<tr>
<td><strong>Fluoroscopy Saver Markers</strong></td>
</tr>
<tr>
<td><strong>Fluoro Saver Marker Microcatheter Compatibility</strong></td>
</tr>
<tr>
<td><strong>Mechanism of Detachment</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Sterilization Method</strong></td>
</tr>
<tr>
<td><strong>Shelf Life</strong></td>
</tr>
<tr>
<td><strong>Packaging</strong></td>
</tr>
</tbody>
</table>
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>
<thead>
<tr>
<th>Test</th>
<th>Test Method Summary</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual Inspection</td>
<td>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.</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All units passed visual inspection</td>
</tr>
<tr>
<td>Tracking Force (delivery)</td>
<td>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.</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Samples passed the established acceptance criterion</td>
</tr>
<tr>
<td>Re-sheathing Reliability</td>
<td>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.</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Samples passed the established acceptance criterion</td>
</tr>
</tbody>
</table>
**510(k) Summary, Continued**

### VII. Non-Clinical Data Performance Data (continued)

<table>
<thead>
<tr>
<th>Test</th>
<th>Test Method Summary</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensional Inspection</td>
<td>The Introducer underwent dimensional inspection per approved test method.</td>
<td>Pass</td>
</tr>
<tr>
<td>Particulate Testing</td>
<td>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&quot; and repeating five times.</td>
<td>Pass</td>
</tr>
<tr>
<td>Introducer Fuse Joint Testing</td>
<td>The Introducer underwent tensile strength testing per approved test method.</td>
<td>Pass</td>
</tr>
</tbody>
</table>

Table 4: Verification and Validation Testing (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.
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.