August 14, 2026

Cerenovus, Inc.
Ryan Rivera
Senior Regulatory Affairs Program Lead
31 Technology Drive
Irvine, California 92618

Re: K262419
Trade/Device Name: Micrusframe (mfr100202); Micrusframe (mfr100253); Micrusframe (mfr100305); Micrusframe (mfr100356); Micrusframe (mfr100407); Micrusframe (mfr100412); Micrusframe (mfr100509); Micrusframe (mfr100517); Micrusframe (mfr100611); Micrusframe (mfr100626); Micrusframe (mfr100713); Micrusframe (mfr100730); Micrusframe (mfr100816); Micrusframe (mfr100829); Micrusframe (mfr140225); Micrusframe (mfr140303); Micrusframe (mfr140304); Micrusframe (mfr140306); Micrusframe (mfr140406); Micrusframe (mfr140408); Micrusframe (mfr140445); Micrusframe (mfr140507); Micrusframe (mfr140512); Micrusframe (mfr140609); Micrusframe (mfr140615); Micrusframe (mfr140711); Micrusframe (mfr140717); Micrusframe (mfr140812); Micrusframe (mfr140820); Micrusframe (mfr140914); Micrusframe (mfr140922); Micrusframe (mfr141016); Micrusframe (mfr141025); Micrusframe (mfr141118); Micrusframe (mfr141127); Micrusframe (mfr141219); Micrusframe (mfr141230); Micrusframe (mfr180510); Micrusframe (mfr180612); Micrusframe (mfr180714); Micrusframe (mfr180813); Micrusframe (mfr180830); Micrusframe (mfr180915); Micrusframe (mfr180933); Micrusframe (mfr181017); Micrusframe (mfr181034); Micrusframe (mfr181118); Micrusframe (mfr181137); Micrusframe (mfr181220); Micrusframe (mfr181240); Micrusframe (mfr181343); Micrusframe (mfr181447); Micrusframe (mfr181550); Micrusframe (mfr181647); Micrusframe (mfr181750); Micrusframe (mfr181846); Micrusframe (mfr181950); Micrusframe (mfr182050); Deltafill (dlf100154); Deltafill (dlf100208)
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: July 14, 2026
Received: July 15, 2026

Dear Ryan Rivera:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device

Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jeffrey J. Kustusch -S

Digitally signed by Jeffrey J. Kustusch -S

For Sara S. Thompson, DVM
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

# Indications for Use

| | | |
|---|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | | ? |
| Please provide the device trade name(s). | | ? |

MICRUSFRAME (MFR100202);
MICRUSFRAME (MFR100253);
MICRUSFRAME (MFR100305);
MICRUSFRAME (MFR100356);
MICRUSFRAME (MFR100407);
MICRUSFRAME (MFR100412);
MICRUSFRAME (MFR100509);
MICRUSFRAME (MFR100517);
MICRUSFRAME (MFR100611);
MICRUSFRAME (MFR100626);
MICRUSFRAME (MFR100713);
MICRUSFRAME (MFR100730);
MICRUSFRAME (MFR100816);
MICRUSFRAME (MFR100829);
MICRUSFRAME (MFR140225);
MICRUSFRAME (MFR140303);
MICRUSFRAME (MFR140304);
MICRUSFRAME (MFR140306);
MICRUSFRAME (MFR140406);
MICRUSFRAME (MFR140408);
MICRUSFRAME (MFR140445);
MICRUSFRAME (MFR140507);
MICRUSFRAME (MFR140512);
MICRUSFRAME (MFR140609);
MICRUSFRAME (MFR140615);
MICRUSFRAME (MFR140711);
MICRUSFRAME (MFR140717);
MICRUSFRAME (MFR140812);
MICRUSFRAME (MFR140820);
MICRUSFRAME (MFR140914);
MICRUSFRAME (MFR140922);
MICRUSFRAME (MFR141016);
MICRUSFRAME (MFR141025);
MICRUSFRAME (MFR141118);
MICRUSFRAME (MFR141127);
MICRUSFRAME (MFR141219);
MICRUSFRAME (MFR141230);
MICRUSFRAME (MFR180510);
MICRUSFRAME (MFR180612);
MICRUSFRAME (MFR180714);
MICRUSFRAME (MFR180813);
MICRUSFRAME (MFR180830);
MICRUSFRAME (MFR180915);
MICRUSFRAME (MFR180933);
MICRUSFRAME (MFR181017);

MICRUSFRAME (MFR181034);
MICRUSFRAME (MFR181118);
MICRUSFRAME (MFR181137);
MICRUSFRAME (MFR181220);
MICRUSFRAME (MFR181240);
MICRUSFRAME (MFR181343);
MICRUSFRAME (MFR181447);
MICRUSFRAME (MFR181550);
MICRUSFRAME (MFR181647);
MICRUSFRAME (MFR181750);
MICRUSFRAME (MFR181846);
MICRUSFRAME (MFR181950);
MICRUSFRAME (MFR182050);
DELTAFILL (DLF100154);
DELTAFILL (DLF100208);
DELTAFILL (DLF100250);
DELTAFILL (DLF100258);
DELTAFILL (DLF100308);
DELTAFILL (DLF100310);
DELTAFILL (DLF100408);
DELTAFILL (DLF100410);
DELTAFILL (DLF100510);
DELTAFILL (DLF100515);
DELTAFILL (DLF100612);
DELTAFILL (DLF100616);
DELTAFILL (DLF100716);
DELTAFILL (DLF100720);
DELTAFILL (DLF100820);
DELTAFILL (DLF100925);
DELTAFILL (DLF180312);
DELTAFILL (DLF180415);
DELTAFILL (DLF180520);
DELTAFILL (DLF180625);
DELTAFILL (DLF180733);
DELTAFILL (DLF180835);
DELTAFILL (DLF180935);
DELTAFILL (DLF181040);
DELTAFILL (DLF181242);
DELTAFILL (DLF181445);
DELTAFILL (DLF181650);
DELTAFILL (DLF181855);
DELTAFILL (DLF182060);
DELTAFILL (DLF182260);
DELTAFILL (DLF182460);
DELTAXSFT (DLX100151);
DELTAXSFT (DLX100152);
DELTAXSFT (DLX100153);
DELTAXSFT (DLX100201);
DELTAXSFT (DLX100202);
DELTAXSFT (DLX100203);
DELTAXSFT (DLX100204);
DELTAXSFT (DLX100206);

DELTAXSFT (DLX100254);
DELTAXSFT (DLX100256);
DELTAXSFT (DLX100304);
DELTAXSFT (DLX100306);
DELTAXSFT (DLX100406);
DELTAXSFT (DLX100408);
GALAXY G3 (GLY120202);
GALAXY G3 (GLY120306);
GALAXY G3 (GLY120308);
GALAXY G3 (GLY120407);
GALAXY G3 (GLY120410);
GALAXY G3 (GLY120412);
GALAXY G3 (GLY120510);
GALAXY G3 (GLY120515);
GALAXY G3 (GLY120610);
GALAXY G3 (GLY120615);
GALAXY G3 (GLY120620);
GALAXY G3 (GLY120715);
GALAXY G3 (GLY120721);
GALAXY G3 (GLY120815);
GALAXY G3 (GLY120824);
GALAXY G3 (GLY120925);
GALAXY G3 (GLY121030);
GALAXY G3 (GLY121230);
GALAXY G3 (GLY122505);
GALAXY G3 (GLY122535);
GALAXY G3 (GLY123509);
GALAXY G3 (GLY123575);
GALAXY G3 MINI (GLM910010);
GALAXY G3 MINI (GLM910015);
GALAXY G3 MINI (GLM910020);
GALAXY G3 MINI (GLM910025);
GALAXY G3 MINI (GLM910030);
GALAXY G3 MINI (GLM910040);
GALAXY G3 MINI (GLM915020);
GALAXY G3 MINI (GLM915025);
GALAXY G3 MINI (GLM915030);
GALAXY G3 MINI (GLM915040);
GALAXY G3 MINI (GLM920030);
GALAXY G3 MINI (GLM920040);
GALAXY G3 MINI (GLM920060);
GALAXY G3 MINI (GLM925035);
GALAXY G3 MINI (GLM925045);
GALAXY G3 MINI (GLM925055);
GALAXY G3 MINI (GLM930040);
GALAXY G3 MINI (GLM930060);
GALAXY G3 MINI (GLM930080)

Please provide your Indications for Use below. ?

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 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.

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 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.

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 are 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.

| | | |
|---|---|---|
| Please select the types of uses (select one or both, as applicable). | ☒ Prescription Use (21 CFR 801 Subpart D)<br>☐ Over-The-Counter Use (21 CFR 801 Subpart C) | ? |
| Please select the age group(s) for which the device(s) is to be used. | ☐ Neonates/Newborns (Birth to < 29 days old)<br>☐ Infants (29 days old to < 2 years old)<br>☐ Children (2 years old to < 12 years old)<br>☐ Adolescents (12 years old to < 22 years old)<br>☒ Adults (22 years old and greater) | ? |

# 510(k) Summary

## I. Submitter

Cerenovus, Inc.
31 Technology
Drive

Irvine, CA 92618, USA

Tel: +1 714 876 5048

Contact Person: Ryan Rivera
Email: rriver82@ITS.JNJ.com

## II. Devices

| Table 1. Device | |
|---|---|
| **Device Proprietary Name** | MICRUSFRAME Microcoil Delivery System, DELTAFILL Microcoil Delivery System, DELTAXSFT Microcoil Delivery System, GALAXY G3 Microcoil Delivery System, GALAXY G3 XSFT Microcoil Delivery System, and GALAXY G3 Mini Microcoil Delivery System |
| **Common or Usual Name** | Device, Neurovascular Embolization & Vascular, for Promoting Embolization |
| **Classification Name** | Class II 21 CFR 882.5950 – Device, Neurovascular Embolization<br>Class II 21 CFR 870.3300 – Device, Vascular, For Promoting Embolization |
| **Regulatory Classification** | II |
| **Product Codes** | HCG, KRD |

## III. Predicate Devices

The predicate devices are listed below in **Table 2.**

| Table 2: Predicate Devices | | | | |
|---|---|---|---|---|
| **Type** | **510(k) Number** | **Date Cleared** | **Name** | **Manufacturer** |
| Primary | K211344 | May 28, 2021 | MICRUSFRAME Microcoil Delivery System, DELTAFILL Microcoil Delivery System, DELTAXSFT Microcoil Delivery System, GALAXY G3 Microcoil Delivery System, GALAXY G3 XSFT Microcoil Delivery System, and GALAXY G3 Mini Microcoil Delivery System | Cerenovus, Inc. |
| Reference | K242582 | Sep 27, 2024 | Optima Coil System (OptiBlock Line Extension) | Balt USA |
| *510(k)s were previously held by Medos International SARL. The 510(k)s were transferred to Cerenovus, Inc., which is the current holder of the 510(k)s. | | | | |

*Continued on next page*

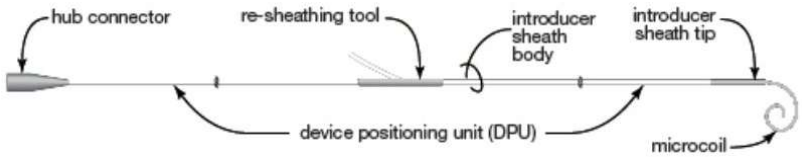
# 510(k) Summary, Continued

**IV. Device Description**

The MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, and 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).

*For the MICRUSFRAME, DELTAFILL, DELTAXSFT, and GALAXY G3 microcoils:*

- 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.

*For the GALAXY G3 Mini microcoils:*

- 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.

*For all Microcoil Delivery Systems:*

- 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.

*Continued on next page*

# 510(k) Summary, Continued

**IV. Device Description,** continued

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.

**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 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.

The 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 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.

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 are 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.

**VI. Comparison of Technological Characteristic with Predicate Device**

There are no differences in technological characteristics between the MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, and GALAXY G3 Mini Microcoil Delivery Systems and the predicate device (K211344).

*Continued on next page*

# 510(k) Summary, Continued

**VI. Comparison of Technological Characteristic with Predicate Device**

| Table 3-1. Technological Characteristics of the Predicate and Proposed Device | | | |
|---|---|---|---|
| **Description** | **Predicate Device: MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, GALAXY G3 XSFT, and GALAXY G3 Mini Microcoil Delivery System (K211344)** | **Reference Device: Optima Coil System (OptiBlock Line Extension) (K242582)** | **This Submission: MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, and GALAXY G3 Mini Microcoil Delivery System** |
| **Indications for Use** | MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, and GALAXY G3 Mini Microcoil Delivery Systems | The Optima Coil System | MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, and GALAXY G3 Mini Microcoil Delivery Systems |
| | are intended for endovascular embolization of intracranial aneurysms, | is intended for the endovascular embolization of intracranial aneurysms | are intended for endovascular embolization of intracranial aneurysms, |
| | and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and | and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae | and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and |
| | are also intended for | is also intended for | are also intended for |
| | | vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation | vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation |
| | | and for | and for |
| | arterial and venous embolizations in the peripheral vasculature. | arterial and venous embolizations in the peripheral vasculature. | arterial and venous embolizations in the peripheral vasculature. |

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# 510(k) Summary, Continued

**VI. Comparison of Technological Characteristic with Predicate Device**

**Table 11-1. Technological Characteristics of the Predicate, Reference and Proposed Device,** *continued*

| Description | Predicate Device: MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, GALAXY G3 XSFT, and GALAXY G3 Mini Microcoil Delivery System (K211344) | Reference Device: Optima Coil System (OptiBlock Line Extension) (K242582) | This Submission: MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, and GALAXY G3 Mini Microcoil Delivery System |
|---|---|---|---|
| **Microcoil** | | | |
| **Microcoil Stretch-Resistant** | PGA= Polyglycolic Acid Suture<br>PP= Polypropylene Suture<br>**Galaxy G3 Mini Microcoil**<br>PP= Polypropylene Suture | .0022" Polyolefin Engage thread (Annealed)<br>.0018" Polyolefin Engage thread (Annealed) | Same as Predicate |
| **Primary Coil Wind Outer Diameter (OD)** | 0.009" – 0.015"<br>**Galaxy G3 Mini Microcoil**<br>0.009" | 0.010" - 0.014" | Same as Predicate |
| **Secondary Shape OD Ranges** | 1.5mm – 24mm<br>**Galaxy G3 Mini Microcoil**<br>1.0mm – 3.0mm | 1mm-14mm | Same as Predicate |
| **Microcoil Length Ranges** | 1cm - 60cm<br>**Galaxy G3 Mini Microcoil**<br>1cm - 8cm | 3 cm – 65 cm | Same as Predicate |
| **Delivery System** | | | |
| **Delivery System Type** | Wire Shaft with radiopaque marker | Body coil laser welded to hypotube | Same as Predicate |
| **Mechanism of Detachment** | Connection to Microcoil System: Uses Connecting Cable or EnPOWER Control Cable<br>Detachment: Thermo-Mechanical System uses the ENPOWER Detachment Control Box (DCB) with ENPOWER Control Cable or Connecting Cable | Thermal via detachment controller | Same as Predicate |

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# 510(k) Summary, Continued

**VII. Non-Clinical Data Performance Data**

No additional design verification testing is required because the proposed modification is limited to the addition of wording in the Indications for Use and does not involve any change to the device design, materials, technological characteristics, operating principles, delivery system, detachment mechanism, or performance requirements. The previously submitted verification testing, which was reviewed and cleared via K211344 remains applicable because the evaluated device configurations are representative of the currently marketed Spectra embolic coil systems and the subject change does not alter the way the device is delivered, deployed, or detached.

No additional validation testing was required because the change is limited to the addition of wording in the Indications for Use. The previous validation testing remains applicable and continues to support the clarified wording, as the change does not impact the device design, technological characteristics, principles of operation, clinical use, or user requirements.

**Table 5: Validation Testing**

| Test | Test Method Summary | Results |
|---|---|---|
| Usability: Animal Study Report | The purpose of this testing is to assess the effect of resistance heater position in the Device Position Unit of Spectra with respect to the microcatheter tip and coil mass density on the reliability of detachment of the Coil detachment system. An in vivo model with its complex nature of hemodynamics and physiologic tortuosity, allows the assessment of the acute performance of the test article to deliver an embolic coil to the target vessel. | Pass Samples passed the established acceptance criteria |
| DPU3 Design Validation In-Vivo Study Report | The study was performed to assess the efficacy of the test sample's coil insertion, radiopacity, re-sheathing and to deliver an embolic coil to the target vessel in a porcine model. There were no aneurysms created for this study the embolic coils were delivered to parent vessel target site that were suitable in diameter that allowed for multiple coil deployment while maintaining high blood flow rate | Pass Samples passed the established acceptance criteria |
| Spectra in-vivo evaluation Report | The purpose of this report is to document the in-vivo evaluation for friction in Spectra DeltaXSFT coils. | Pass Samples passed the established acceptance criteria |
| Spectra Usability Study In-Vivo | The purpose of this in-vivo usability evaluation was to assess the deliverability, deployment behaviour, microcatheter stability, and friction performance of representative Spectra-family embolic coils when delivered to suitable parent-vessel target sites. The evaluation supports the proposed indication by demonstrating that the coil systems can be delivered and deployed under physiologically relevant vessel conditions without reliance on aneurysm creation. | Pass Samples passed the established acceptance criteria |

*Continued on next page*

# 510(k) Summary, Continued

**Animal Testing**
N/A – No animal studies were required as appropriate verification and validation of the modifications were achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

**Shelf Life Testing**
N/A – Changes did not impact the shelf-life of the product.

**Biocompatibility Testing**
N/A – Changes did not impact biocompatibility.

**Sterilization**
N/A – Changes did not impact sterilization.

**VIII. Clinical Performance Data**

Clinical studies were not required because the proposed change consists only of additional wording clarification to the Indications for Use. The previously cleared verification and validation evidence remains applicable, as the modification does not alter the device design, intended use, technological characteristics, or raise new questions of safety or effectiveness.

**IX. Conclusion**

The modifications made to the additional wording to the Indications for Use does not alter the design, intended use, and technological characteristics of the proposed and predicate devices. The risk assessment of the proposed subject and the predicate device remains the same and previous verification /validation testing raised no new questions regarding the safety and effectiveness of the devices. Therefore, the modified Indications for Use are substantially equivalent to their predicate devices.

*End of 510(k) Summary*