May 28, 2021

Medos International SARL
℅ Ariell Joiner, Ph.D.
Senior Regulatory Affairs Program Lead
CERENOVUS
6303 Blue Lagoon Drive, Suite 315
Miami, Florida 33126

Re: K211344
Trade/Device Name: MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, GALAXY G3 XSFT, and GALAXY G3 Mini Microcoil Delivery Systems
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: April 30, 2021
Received: May 3, 2021

Dear Dr. Ariell Joiner:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Naira Muradyan, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211344

Device Name
MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, GALAXY G3 XSFT, and GALAXY G3 Mini 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 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.

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 – K211344

I. Submitter

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Date Prepared: April 30, 2021

II. Devices

Table 1. Device	
Device Proprietary Name	MICRUSFRAME , DELTAFILL, DELTAXSFT , GALAXY G3, GALAXY G3 XSFT, and GALAXY G3 Mini Microcoil Delivery Systems
Common or Usual Name	Device, Neurovascular Embolization & Vascular, for Promoting Embolization
Classification Name	Class II 21 CFR 882.5950 – Device, Neurovascular Embolization 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			
510(k) Number	**Date Cleared**	**Name**	**Manufacturer**
K171747	Jul 14, 2017	MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3 FILL, and GALAXY G3 XSFT Microcoil Delivery Systems	Medos International SARL*
K171862	Sep 25, 2017	GALAXY G3 Mini Microcoil Delivery System	
K150319	Jun 12, 2015	MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, and GALAXY G3 XSFT Microcoil Delivery Systems	
*510(k)s were previously held by Codman & Shurtleff, Inc. The 510(k)s were transferred to Medos International SARL, which is the current holder of the 510(k)s. These devices are marketed on behalf of Medos International SARL under the CERENOVUS brand.			

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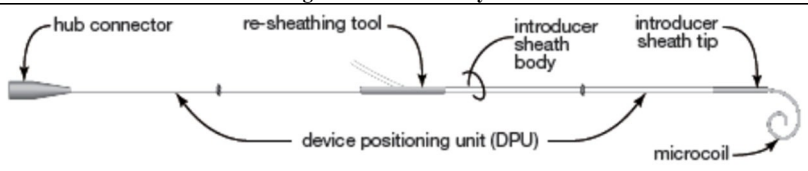
510(k) Summary, Continued

IV. Device Description

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

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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 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 arterial and venous embolizations in the peripheral vasculature.

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

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.

VI. Comparison of Technological Characteristics with Predicate Device

The devices in this submission include minor design changes (reduced distal outer diameter and taper transition) only to the Core Wire of the Device Positioning Unit. There are no modifications to the material of the Core Wire, to other elements of the Device Positioning Unit, to the components or materials of the microcoil, to the introducer, or to the ENPOWER Detachment Control System.

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 overall technological characteristics as shown in **Table 3-1** and **Table 3-2**.

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510(k) Summary, Continued

VI. Comparison of Technological Characteristics with Predicate Device, continued

Table 3-1. Technological Characteristics of the Predicate and Subject Device

Description	Predicate Devices: MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, GALAXY G3 XSFT Microcoil Delivery Systems (K150319, K171747)	This Submission: MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, GALAXY G3 XSFT Microcoil Delivery Systems
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 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 Predicate
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" – 0.015"	Same as Predicate
Secondary Shape OD Ranges	1.5mm – 24mm	Same as Predicate
Microcoil Length Ranges	1cm - 60cm	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
Introducer Tip Wall Thickness	0.0103"	Same as Predicate
Introducer Sheath Length	120cm and 81cm	Same as Predicate

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510(k) Summary, Continued

VI. Comparison of Technological Characteristics with Predicate Device, continued

Table 3-1. Technological Characteristics of the Predicate and Subject Device, *continued*		
Description	**Predicate Devices: MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, GALAXY G3 XSFT Microcoil Delivery Systems (K150319, K171747)**	**This Submission: MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, GALAXY G3 XSFT Microcoil Delivery Systems**
Delivery System, *continued*		
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 Detachment: Thermo-Mechanical System uses the ENPOWER Detachment Control Box (DCB) with ENPOWER Control Cable or Connecting Cable	Same as Predicate
Sterilization, Shelf Life, and Packaging		
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

Table 3-2. Technological Characteristics of the Predicate and Subject Device		
Description	**Predicate Device: GALAXY G3 Mini Microcoil Delivery System (K171862)**	**This Submission: GALAXY G3 Mini Microcoil Delivery System**
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.	Same as Predicate

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510(k) Summary, Continued

VI. Comparison of Technological Characteristics with Predicate Device, continued

Table 3-2. Technological Characteristics of the Predicate and Subject Device, *continued*

Description	Predicate Device: GALAXY G3 Mini Microcoil Delivery System (K171862)	This Submission: GALAXY G3 Mini Microcoil Delivery System
Microcoil		
Microcoil Material	Platinum/Tungsten	Same as Predicate
Microcoil Primary Wind	Cylindrical	Same as Predicate
Microcoil Secondary Shape	Complex	Same as Predicate
Microcoil Stretch-Resistant	PP= Polypropylene Suture	Same as Predicate
Primary Coil Wind Outer Diameter (OD)	0.009”	Same as Predicate
Secondary Shape OD Ranges	1.0mm – 3.0mm	Same as Predicate
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
Introducer Tip Wall Thickness	0.0103”	Same as Predicate
Introducer Sheath Length	81cm and 120cm	Same as Predicate
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 Detachment: Thermo-Mechanical System uses the ENPOWER Detachment Control Box (DCB) with ENPOWER Control Cable or Connecting Cable	Same as Predicate
Sterilization, Shelf Life, and Packaging		
Sterilization Method	Ethylene Oxide (EtO)	Same as Predicate
Shelf Life	3 years	Same as Predicate
Packaging	Packaged in a plastic hoop and enclosed in a pouch	Same as Predicate

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510(k) Summary, Continued

VII. Non-Clinical Performance Data

Table 4: Verification Testing		
Test	**Test Method Summary**	**Results**
Tracking Force (delivery)	The purpose of the Track Force test was to evaluate the force it takes to deliver the subject device through a microcatheter; utilizing the system Catheter Performance Simulation System (CPSS).	Pass Samples passed the established acceptance criteria

Table 5: Validation Testing		
Test	**Test Method Summary**	**Results**
Simulated Use: Tracking Force (delivery)	The purpose of the Tracking Force test was to evaluate the ease of deliverability of the coils through the microcatheter in a clinically relevant bench top model.	Pass Samples passed the established acceptance criteria
Simulated Use: Microcatheter Stability	The purpose of the Microcatheter Stability test was to evaluate the amount of movement of the microcatheter tip from its starting position in a clinically relevant bench top model.	Pass Samples passed the established acceptance criteria

Animal Testing
N/A – No animal studies were required as appropriate verification and validation of the modifications was achieved based on the 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 as appropriate verification and validation of the minor design modifications was achieved based on the bench testing.

IX. Conclusion

The minor design modifications made to the Core Wire of the Device Positioning Unit do not alter the intended use or indications for use of the subject devices. The overall technological characteristics of the subject and predicate devices remain the same. The risk assessment and successful verification and validation testing raises no new questions regarding the safety and effectiveness of the devices. Therefore, the modified devices are substantially equivalent to their respective predicate devices.

End of 510(k) Summary