July 14, 2022

Medos International, SARL
Michael Liao
Regulatory Affairs Manager
Chemin-Blanc 38
Le Locle, 2400
Switzerland

Re: K220040
Trade/Device Name: CEREPAK Uniform, Uniform XL, Uniform 3D, Heliform Soft, Heliform XtraSoft, Heliform XL, Heliform XtraSoft XL, Freeform, Freeform Mini, and Freeform XtraSoft Detachable Coil Systems
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: June 15, 2022
Received: June 16, 2022

Dear Michael Liao:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K220040

Device Name
CEREPAK™ Uniform, Uniform XL, Uniform 3D, Heliform Soft, Heliform XtraSoft, Heliform XL, Heliform XtraSoft XL, Freeform, Freeform Mini, and Freeform XtraSoft Detachable Coil Systems

Indications for Use *(Describe)*
The CEREPAK™ Uniform, Uniform XL, Uniform 3D, Heliform Soft, Heliform XtraSoft, Heliform XL, Heliform XtraSoft XL, Freeform, and Freeform Mini Detachable Coil Systems are indicated for embolization of intracranial aneurysms, neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and arterial and venous embolizations in the peripheral vasculature.

The CEREPAK™ Freeform XtraSoft Detachable Coil System is indicated for 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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Date Prepared: July 14, 2022

II. Device Information

Table 1: Device Information	
Device Proprietary Name	CEREPAK™ Uniform, Uniform XL, Uniform 3D, Heliform Soft, Heliform XtraSoft, Heliform XL, Heliform XtraSoft XL, Freeform, Freeform Mini, and Freeform XtraSoft Detachable Coil Systems
Common or Usual Name	Device, Neurovascular Embolization & Device, 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
Review Panel	Neurology, Cardiovascular

III. Predicate and Reference Devices

The predicate device is provided in **Table 2** below.

Table 2. Primary Predicate Device			
510(k) Number	**Date Cleared**	**Name**	**Manufacturer***
K150319	6/12/2015	MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, and GALAXY G3 XSFT Microcoil Delivery Systems (this grouping is branded as CERENOVUS SPECTRA™ Family of Coils)	Medos International, SARL
*The manufacturer at time of clearance was Codman & Shurtleff, Inc. The current manufacturer is provided above.			

In addition, the following reference device is used in this 510(k) submission to support certain design elements.

Table 3. Reference Device			
510(k) Number	**Date Cleared**	**Name**	**Manufacturer***
K171862	9/25/2017	GALAXY G3 Mini Microcoil Delivery System	Medos International, SARL
*The manufacturer at time of clearance was Codman & Shurtleff, Inc. The current manufacturer is provided above.			

There have been no prior submissions for the subject CEREPAK™ Detachable Coil Systems.

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510(k) Summary, Continued

IV. Device Description

CEREPAK™ is a platform delivery system that aids in the delivery of embolic coils (or "microcoils") using standard endovascular methods to treat hemorrhagic conditions. It consists of two main components, the CEREPAK™ Detachable Coils, and the CEREPAK™ Detacher. These components will be provided sterile and sold separately. The CEREPAK™ Detachable Coils are comprised of an embolic coil implant (microcoil) attached to a delivery system. The CEREPAK™ Detacher is a mechanical accessory that aids in the detachment of the CEREPAK™ Detachable Coils.

The delivery system of the CEREPAK™ Detachable Coils consists of a long, thin hypotube (delivery tube) shaft with an attachment interface to secure the microcoil at its distal end until deployment is required. Microcoil designs are based on the microcoils present in the predicate device. The delivery tube is advanced with the microcoil through a compatible microcatheter using standard endovascular techniques until the microcoil is placed at the target lesion.

The CEREPAK™ Detacher interacts with the delivery system to detach the microcoils. Upon finger actuation, the Detacher translates (slides) a component within the delivery tube that aided in securing the microcoil. This detaches the microcoil from the delivery tube. Once the microcoil is detached at the desired location, the delivery tube can be removed and discarded.

V. Indications for Use

The CEREPAK™ Uniform, Uniform XL, Uniform 3D, Heliform Soft, Heliform XtraSoft, Heliform XL, Heliform XtraSoft XL, Freeform, and Freeform Mini Detachable Coil Systems are indicated for embolization of intracranial aneurysms, neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and arterial and venous embolizations in the peripheral vasculature.

The CEREPAK™ Freeform XtraSoft Detachable Coil System is indicated for embolization of intracranial aneurysms.

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VI. Predicate Comparison

Endovascular coil embolization is the technological principle for both the subject and predicate devices. A comparison of the similarities and differences between the CEREPAK™ Detachable Coil Systems and the predicate and reference devices is presented in **Table 4**.

Table 4. Subject, Predicate and Reference Device Comparison Summary

Description	Predicate Device: MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, and GALAXY G3 XSFT Microcoil Delivery Systems (K150319)	Reference Device: GALAXY G3 Mini Microcoil Delivery System (K171862)	This Submission (K220040): CEREPAK™ Uniform, Uniform XL, Uniform 3D Heliform Soft, Heliform XtraSoft, Heliform XL, Heliform XtraSoft XL, Freeform, Freeform Mini, and Freeform XtraSoft Detachable Coil 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.	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.	The CEREPAK™ Uniform, Uniform XL, Uniform 3D, Heliform Soft, Heliform XtraSoft, Heliform XL, Heliform XtraSoft XL, Freeform, and Freeform Mini Detachable Coil Systems are indicated for embolization of intracranial aneurysms, neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and arterial and venous embolizations in the peripheral vasculature. The CEREPAK™ Freeform XtraSoft Detachable Coil System is indicated for embolization of intracranial aneurysms.
Classification	Class II, 21 CFR 882.5950 & 870.3300		Same as predicate
Product Code	HCG, KRD		Same as predicate
Microcoil*			
Microcoil Material	Platinum/Tungsten	Platinum/Tungsten	Same as predicate
Microcoil Primary Wind	Triangular or Cylindrical	Cylindrical	Same as predicate
Microcoil Secondary Shape	Complex, Helical, or Spherical	Complex	Same as predicate
Microcoil Stretch-Resistant Suture	PGA= Polyglycolic Acid Suture PP= Polypropylene Suture	PP= Polypropylene Suture	PP= Polypropylene Suture
Proximal Interface	Soldered socket ring attaches to delivery system		Welded key head attaches to delivery system
Primary Coil Wind Outer Diameter	0.010” – 0.015”	0.009”	0.009” – 0.015”
Secondary Shape Outer Diameter Ranges	1.5mm – 24mm	1mm – 3mm	1mm – 24mm
Microcoil Length Ranges	1cm – 60cm	1cm – 8cm	1cm – 60cm
Microcatheter Compatibility	0.0165” to 0.021” inner lumen diameter	0.0165” to 0.017” inner lumen diameter	0.0165” to 0.021” inner lumen diameter

*CEREPAK™ includes microcoil configurations equivalent in size and shape to the predicate (K150319) and reference (K171862) devices. The predicate (K150319) includes most of the microcoil configurations that are equivalent to the CEREPAK™. The reference device (K171862) is added to complete the range of equivalent microcoil offerings in the CEREPAK™ catalog. Therefore, the range of microcoil sizes is the combination of the predicate and reference devices.

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510(k) Summary, Continued

Table 4. Subject, Predicate and Reference Device Comparison Summary, continued			
Description	**Predicate Device: MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, and GALAXY G3 XSFT Microcoil Delivery Systems (K150319)**	**Reference Device: GALAXY G3 Mini Microcoil Delivery System (K171862)**	**This Submission (K220040): CEREPAK™ Uniform, Uniform XL, Uniform 3D, Heliform Soft, Heliform XtraSoft, Heliform XL, Heliform XtraSoft XL, Freeform, Freeform Mini, and Freeform XtraSoft Detachable Coil Systems**
Delivery System (K150319 and K171862 have the same Delivery System)			
Delivery System Type	Wire Shaft with radiopaque marker		Hypotube with arrangement of wires and radiopaque marker
Radiopaque Marker Location	3cm from distal tip		Same as predicate
Introducer Sheath Material	HDPE		Same as predicate
Introducer Tip Flush Ports	3 flush ports		Same as predicate
Delivery System Length	190cm ± 5cm		Same nominal, tighter tolerances: 190 cm ± 2cm
Fluoro Saver Markers	Five Markers Located at the Proximal End		Same as predicate
Fluoro Saver Marker Microcatheter Compatibility	150cm Length		Same as predicate
Detachment Interface Material	Polyolefin Elastomer		Nitinol loop wire and 304 SS pull wire coated with PTFE
Delivery System Outer Diameter	0.0159" Max		0.0156" Max
Other Materials / Components**	Various		Various – different from predicate
Mechanism of Detachment	Connection to Microcoil System hub using Connecting Cable or EnPOWER Control Cable		Connection to accessory CEREPAK™ Detacher via slip fit with the proximal inner tube
	Detachment: Thermo-Mechanical System uses the EnPOWER Detachment Control Box (DCB) with EnPOWER Control Cable or Connecting Cable		Detachment: Mechanical finger actuation of the CEREPAK™ Detacher or manual break cause translation of the pull wire and release of the microcoil.
**Materials and components differ between subject and predicate devices however they have the same function and raise no new or different questions of safety and effectiveness. The test methods provide comparison to the predicate and are adequate to evaluate safety and effectiveness of the subject device. Additionally, biological safety is demonstrated based on applicable standards.			
Sterilization and Shelf Life			
Sterilization Method	E-Beam or Ethylene Oxide		Ethylene Oxide
Sterility Assurance Level	10^{-6}		Same as predicate
Shelf Life	3 years		1 year
Packaging	Packaged in a plastic hoop and enclosed in a pouch with Tyvek sealed to Nylon or Polyester. Placed inside carton.		Packaged in a plastic hoop and enclosed in a pouch with Tyvek sealed to Nylon. Placed inside carton.

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510(k) Summary, Continued

VII. Non-Clinical Testing Summary

Performance Testing - Bench

Appropriate testing was identified based on the design, risk analyses and the intended use of the CEREPAK™ Detachable Coil Systems to demonstrate that the device is substantially equivalent to the legally marketed predicate device. The following performance data are being provided in support of the substantial equivalence determination. All testing was conducted using sampling methods as required by internal procedure. The bench testing included the following tests:

Table 5. Performance Testing Summary

Test	Test Summary	Result
Design Verification: CEREPAK™ Detachable Coils		
Manual Break Joint Integrity After Transit	The objective of this test is to ensure that the manual break joint is not kinked or separated after transit.	PASS: Samples met established acceptance criteria
Crimp Integrity After Transit	The objective of this test is to ensure that the proximal inner tube does not accidentally translate prematurely after transit.	PASS: Samples met established acceptance criteria
Track Force (Delivery)	The objective of this test is to evaluate the force necessary to deliver the proposed device through a microcatheter in a simulated tortuous anatomy model.	PASS: Samples met established acceptance criteria
Microcatheter Pullback	The objective of this test is to measure the distance the microcatheter retracts comparing the tip position from prior to coil delivery to when the entire embolic coil is exposed out of the distal tip of the microcatheter.	PASS: Samples met established acceptance criteria
Microcatheter Tip Deflection	The objective of this test is to measure the deflection angle at the microcatheter tip as the device is advanced to the detachment position.	PASS: Samples met established acceptance criteria
Overall Length	The objective of this test is to measure the overall length of the delivery tube shaft of the CEREPAK™ delivery system.	PASS: Samples met established acceptance criteria
Fluorosaver Location	The objective of this test is to verify the location of the fluorosaver marker relative to the distal end of the microcoil.	PASS: Samples met established acceptance criteria
Fluorosaver Marker Durability	The objective of this test is to verify that the fluorosaver marker remains visible on the delivery system after 6 delivery and 5 withdrawal cycles.	PASS: Samples met established acceptance criteria
Delivery System Outer Diameter	The objective of this test is to measure the overall outer diameter of the CEREPAK™ delivery system.	PASS: Samples met established acceptance criteria
Marker Band Location	The objective of this test is to verify the location of the radiopaque marker relative to the distal end of the delivery tube.	PASS: Samples met established acceptance criteria
Detachment Zone Strength	The objective of this test is to measure the tensile strength of the detachment zone to prevent premature separation of the microcoil from the detachment system.	PASS: Samples met established acceptance criteria
Delivery System Weld Strength	The objective of this test is to measure the break load required to separate the overall delivery system.	PASS: Samples met established acceptance criteria
Key to Coil Weld Strength	The objective of this test is to measure the force required to separate the proximal key from the microcoil wire.	PASS: Samples met established acceptance criteria
Durability (Pull Wire Position)	The objective of this test is to verify the pull wire position relative to the proximal key shoulders after durability simulation (6 advancements and 5 withdrawals) to evaluate any movement.	PASS: Samples met established acceptance criteria
Detachment Reliability with Detacher	The objective of this test is to verify microcoil separation from the delivery tube and inner tube translation after using the Detacher to detach the microcoil.	PASS: Samples met established acceptance criteria
Inner Tube/Pull Wire Joint Strength	The objective of this test is to measure the strength of the joint between the pull wire and the proximal inner tube.	PASS: Samples met established acceptance criteria

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510(k) Summary, Continued

VII. Non-Clinical Testing Summary, continued

Table 5. Performance Testing Summary, continued

Test	Test Summary	Result
Design Verification: CEREPAK™ Detachable Coils		
Inner Tube Outer Diameter	The objective of this test is to measure the outer diameter of the proximal inner tube.	PASS: Samples met established acceptance criteria
Inner Tube Length	The objective of this test is to measure the overall length of the proximal inner tube and the length of the proximal inner tube that is exposed outside the main delivery tube.	PASS: Samples met established acceptance criteria
Detachment Reliability with Manual Break	The objective of this test is to verify microcoil separation from the delivery tube after using the manual break method to detach the microcoil.	PASS: Samples met established acceptance criteria
Manual Break Feature Buckling	The objective of this test is to measure the force required to buckle the delivery system using the manual break feature.	PASS: Samples met established acceptance criteria
Particulate Evaluation	The objective of this test is to measure particulates generated during simulated use with the CEREPAK™ Detachable Coils.	PASS: Samples met established acceptance criteria
Manual Break Markers Location	The objective of this test is to measure the spacing between the 2 manual break indicators, the distance between the manual break and each indicator, and the distance from the manual break to the proximal end of the main delivery tube.	PASS: Samples met established acceptance criteria
Detachment Kickback	The objective of this test is to measure the distance the delivery system retracts after detachment.	PASS: Samples met established acceptance criteria
Microcoil Secondary Shape	The objective of this test is to verify the secondary shape of the microcoil.	PASS: Samples met established acceptance criteria
Microcoil Secondary Diameter	The objective of this test is to measure the secondary shape diameter of the microcoil.	PASS: Samples met established acceptance criteria
Microcoil Length	The objective of this test is to measure the length of the microcoil.	PASS: Samples met established acceptance criteria
Atraumatic 2 Terminal Ends	The objective of this test is to verify that the two terminal ends of the microcoil have rounded edges and no sharp features.	PASS: Samples met established acceptance criteria
Stretch Resistance of Suture	The objective of this test is to evaluate the force at which the stretch resistant suture (SRS) fails to resist stretching.	PASS: Samples met established acceptance criteria
Introducer Secured After Transit	The objective of this test is to ensure that the introducer is within the packaging hoop in the correct location and the microcoil is not exposed out of the introducer after transit.	PASS: Samples met established acceptance criteria
Introducer Dimensions	The objective of this test is to verify the introducer length, outer diameter, taper angle and inner diameter.	PASS: Samples met established acceptance criteria
Introducer Purge Holes Dimensions	The objective of this test is to verify the introducer purge hole diameter and distance from the introducer tip to the purge hole.	PASS: Samples met established acceptance criteria
Introducer Re-Sheathing	The objective of this test is to confirm that the introducer can be re-sheathed successfully without damage to the microcoil or delivery system.	PASS: Samples met established acceptance criteria
MRI Testing	The objective of MRI testing was to determine the safety in the magnetic resonance (MR) environment and the appropriate parameters for MR conditional labeling.	PASS: Samples met established acceptance criteria

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510(k) Summary, Continued

VII. Non-Clinical Testing Summary, continued

Table 5. Performance Testing Summary, continued		
Test	**Test Summary**	**Result**
Design Verification: CEREPAK™ Detacher		
Integrity after Transit	The objective of this test is to ensure the nose cone and housing assembly of the Detacher are intact to maintain product performance.	PASS: Samples met established acceptance criteria
Max User Input Force	The objective of this test is to measure the maximum user input force required to actuate the slider on the detacher.	PASS: Samples met established acceptance criteria
Slider Travel Distance and Min Input Force	The objectives of this test are to measure the distance of slider travel and user input force required to begin the detachment motion. The test will also confirm that the spring returns the components to their initial position after use.	PASS: Samples met established acceptance criteria
Multiple Cycle Durability	The objective of this test is to measure the distance the Detacher translates the inner tube after 20 detachment cycles and to ensure the delivery system encounters a hard stop in the Detacher after 20 cycles.	PASS: Samples met established acceptance criteria
Nose Cone Insert Hard Stop and Clearance	The objective of this test is to measure the diameter of the nose cone insert proximal hole where the delivery tube will encounter a hard stop upon insertion into the Detacher.	PASS: Samples met established acceptance criteria
Insertion Max Force	The objective of this test is to measure the maximum force exerted on the Detacher during insertion of the proximal end of the delivery system.	PASS: Samples met established acceptance criteria
Printed Logo and Name Verification	The objective of this test is to ensure that the logo is printed on the CEREPAK™ Detacher.	PASS: Samples met established acceptance criteria
Design Validation: CEREPAK™ Detachable Coils and Detacher		
In-Vitro Usability Study	The in-vitro design validation was conducted with skilled users to evaluate various aspects of product performance under simulated use conditions utilizing a silicone arterial model which simulates clinically relevant anatomy.	PASS: Samples met established acceptance criteria

Animal Study
An in-vivo design validation was conducted with skilled users to demonstrate various points of product performance usability under simulated use conditions utilized in a porcine model.

Clinical Testing
A clinical study was not required, because appropriate verification and validation of the subject device was achieved considering the similarities of the proposed device to the predicate device and based on the results of the bench testing.

Shelf-Life Testing
One year accelerated aging was successfully performed on the CEREPAK™ Detachable Coils and Detacher. Through review of package integrity testing and previous testing with sterile packages made of the same material combinations, the sterile pouches are confirmed to have a shelf life of three years. However, based on the lesser shelf life currently validated for the product and packaging, the shelf life of the CEREPAK™ Detachable Coil Systems, including both the Detachable Coils and Detacher components, is established as one year.

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510(k) Summary, Continued

VII. Non-Clinical Testing Summary, continued

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*," and FDA Guidance for Industry and FDA Staff, "*Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process'*." Since the duration of contact is classified differently for the microcoil and the delivery system, biocompatibility testing was performed separately. The following testing was performed:

Table 6. Biocompatibility Test Summary

Test		Results	Conclusion
CEREPAK™ Detachable Coils – microcoil component			
Cytotoxicity		Non-cytotoxic	PASS
Sensitization		Non-sensitizing	PASS
Irritation or Intracutaneous Reactivity		Non-irritating	PASS
(Acute) Systemic Toxicity		Negative	PASS
Genotoxicity		Non-genotoxic	PASS
Hemocompatibility	ASTM Hemolysis	Non-hemolytic	PASS
	SC5b-9 Complement Activation Assay	Not a potential activator of complement system	PASS
CEREPAK™ Detachable Coils – delivery system component			
Cytotoxicity		Non-cytotoxic	PASS
Sensitization		Non-sensitizing	PASS
Irritation or Intracutaneous Reactivity		Non-irritating	PASS
(Acute) Systemic Toxicity		Negative	PASS
Hemocompatibility	ASTM Hemolysis	Non-hemolytic	PASS
	SC5b-9 Complement Activation Assay	Not a potential activator of complement system	PASS
	In Vivo Thromboresistance Study	Thromboresistant	PASS

The embolic coils are implants with permanent (> 30 days) contact with blood. The Delivery System (within introducer component) is an externally communicating device with limited (≤ 24 hours) contact with circulating blood. Based on the passing results of the aforementioned tests, the CEREPAK™ Detachable Coils (embolic coils and delivery system) have demonstrated acceptable biocompatibility in compliance with ISO 10993-1 and applicable regulatory requirements and are considered biologically safe for their intended use.

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510(k) Summary, Continued

VII. Non-Clinical Testing Summary, continued

Sterilization

The CEREPAK™ Detachable Coils and CEREPAK™ Detacher are sterilized using a validated 100% ethylene oxide (EO) sterilization process by means of the overkill approach to ensure sterility assurance level (SAL) of 10^{-6} in accordance with 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*." The CEREPAK™ Detachable Coils (embolic coils and delivery system) meet EO and ethylene chlorohydrin (ECH) residual limits per EN ISO 10993-7. The CEREPAK™ Detachable Coils and CEREPAK™ Detacher are for single use only.

VIII. Conclusion

Based upon the intended use, design, materials, function, side-by-side in-vitro testing and animal testing, it is concluded that the subject device, CEREPAK™ Uniform, Uniform XL, Uniform 3D, Heliform Soft, Heliform XtraSoft, Heliform XL, Heliform XtraSoft XL, Freeform, Freeform Mini, and Freeform XtraSoft Detachable Coil Systems, are substantially equivalent to the predicate device, MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, and GALAXY G3 XSFT Microcoil Delivery Systems (branded as the CERENOVUS SPECTRA™ Family of Coils), K150319, cleared on June 12, 2015. Risk assessment and verification and validation testing confirmed that the technological differences do not raise new questions of safety and effectiveness for the subject device. The subject device, as designed, manufactured, packaged and sterilized, is substantially equivalent to the predicate device.