February 9, 2021

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Rita De Rama
Senior Regulatory Affairs Specialist
9775 Toledo Way
Irvine, California 92618

Re: K202850
Trade/Device Name: Concerto Versa™ Detachable Coil
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD,
Dated: September 25, 2020
Received: September 28, 2020

Dear Rita De Rama:

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,

Finn Donaldson
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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)*
K202850

Device Name
Concerto Versa™ Detachable Coil

Indications for Use *(Describe)*
The Concerto Versa™ Detachable Coil is indicated for arterial and venous embolization 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 K202850

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration: 2029214
Contact Person(s):	Rita De Rama Sr. Specialist, Regulatory Affairs Telephone: (949) 383-7061 Email: rita.r.derama@medtronic.com

Date Summary Prepared:	February 4, 2021
Trade Name of Device:	Concerto Versa™ Detachable Coil
Device Classification Name:	Vascular Device for Promoting Embolization
FDA Review Panel:	Cardiovascular
Classification Product Code:	KRD
Regulation Number:	870.3300
Regulation Description:	Vascular embolization device
Device Classification:	Class II
Predicate Device:	Concerto Detachable Coil System K090046

Device Description

The Concerto Versa™ Detachable Coil is an embolization coil that consists of a platinum embolization coil attached to a composite delivery pusher, and a hand-held Instant Detacher (I.D.) which, when activated, detaches the coil from the delivery pusher tip. The Instant Detacher is an accessory sold separately and was most recently cleared in K162704. The Concerto Versa™ Detachable Coil is supplied sterile and is intended for single-use only.

Indication for Use Statement

The Concerto Versa™ Detachable Coil is indicated for arterial and venous embolization in the peripheral vasculature.

Device Comparison

The Concerto Versa™ Detachable Coil is a design modification adding larger sizes, with coil loop diameters of 3-32mm and lengths of 5-65cm. The intention is to expand the Concerto Detachable Coil System family by adding thirty-two new model numbers to the currently cleared Concerto product portfolio (predicate device). These new model numbers are a line extension of the predicate device and come in a 3D platinum configuration enlaced with Nylon fibers. The first

loop of the 3mm - 14mm models are oversized to perform vessel embolization, while the first loop of 16mm - 32mm models are undersized to perform saccular embolization.
The subject Concerto Versa™ Detachable Coil and the predicate Concerto™ Detachable Coil System have many of the same technological characteristics. A comparison of the subject device and the predicate is provided below.

Technological Characteristics Comparison Table		
Design Feature	Predicate Device: Concerto Detachable Coil System (K090046)	Subject Device: Concerto Versa™ Detachable Coil
Indication for Use (IFU) Statement	The Concerto Detachable Coil System is indicated for arterial and venous embolizations in the peripheral vasculature.	The Concerto Versa™ Detachable Coil is indicated for arterial and venous embolization in the peripheral vasculature.
Dimensions		
Device Size Range	Concerto Nylon Helix: 2-10mm – Loop OD 1-30cm - Length Concerto PGLA Helix: 2 -20mm Loop OD 1-50cm – Length Concerto PGLA 3D: 2-18mm Loop OD 2-40cm - Length	3-32mm Loop OD 5-65cm Length
Coil Shape	Helical & 3D	3D
Coil Wire OD (inches)	2-3mm: 0.0015'' 4-6mm: 0.0020'' 7-10mm: 0.00225'' 12-20mm: 0.00275''	3-6mm: 0.0025'' 7-9mm: 0.00275'' 10-32mm: 0.0035''
Fiber OD/Length	0.001''/2.0mm	0.0015''/3.5mm
Distance between two fibers	2mm	Models CV-3-5 and CV-4-5: ≥3mm Other Models: ≥4mm
Delivery System (Pusher)		
Delivery System	Pusher: Composite Hypotube Stainless Steel with PTFE outer jacket and liner & PET & Pt/W alignment marker	Same
Delivery Wire/Pusher Length	188cm	Same

Technological Characteristics Comparison Table		
Design Feature	Predicate Device: Concerto Detachable Coil System (K090046)	Subject Device: Concerto Versa™ Detachable Coil
Delivery Wire/Pusher Distal OD	0.0142''	Same
Delivery Wire/Pusher Proximal OD	0.0140''	0.0200''
Introducer Sheath ID/OD/Length	ID: 0.047cm OD: 0.077cm Length: 120cm	ID: 0.071cm OD: 0.107cm Length: 130cm
Materials – Permanent Patient Contacting (Implant)		
Implant Coil Wire	Pt (92%)/ W (8%)	Same
Coil Shell/Cap Shell	Pt (92%)/ W (8%)	Stainless Steel 316L
Stretch Resistant Member	Polypropylene	Same
Fiber	PGLA or Nylon 6	Nylon 6
Detach Subassembly	Stainless Steel 316L	Same
Accessories/Product Compatibility		
Catheter Compatibility	Nylon: 2mm to 4mm, minimum micro catheter inside diameter is 0.0165" 5mm to 10mm, minimum micro catheter inside diameter is 0.021" PGLA: 12mm and above, minimum micro catheter inside diameter is 0.021"	The Concerto Versa™ Detachable Coil should only be delivered through a delivery catheter (either micro catheter or diagnostic catheter) with a minimum inner diameter of 0.027" and a maximum inner diameter of 0.041".
Method of Coil Detachment	Instant Detacher – Retraction of release cord from distal orifice of implant delivery pusher	Same
Sterilization		
Method	Ethylene Oxide (EO)	Same
Stability		
Shelf life	3 years	Same
Magnetic Resonance Imaging		
Compatibility	MR Conditional	Same

Biocompatibility

Based on minor changes in the subject device, cytotoxicity testing was conducted on the Concerto Versa ™ Detachable Coil per ISO 10993-5: 2009 and passed. All other biocompatibility testing per ISO 10993-1:2009 was leveraged for the Concerto Versa ™ Detachable Coil, as based on the predicate device described below:

Test	Test Method	Results
Biocompatibility		
Sensitization	ISO Guinea Pig Maximization Sensitization Test	Pass
Irritation	ISO Intracutaneous Reactivity Test	Pass
Acute Systemic Toxicity	ISO Acute Systemic Injection Test	Pass
Pyrogenicity	Materials Mediated Pyrogen	Pass
Sub-Chronic/ Sub-Acute Toxicity	Sub-Acute /Sub-Chronic Toxicity	Pass
Genotoxicity	Bacterial Reverse Mutation (Ames Assay)	Pass
	In Vitro Mouse Lymphoma	Pass
Implantation	Intramuscular Implantation (13 wk)	Pass
	Intramuscular Implantation (1 wk)	Pass
	Intramuscular Implantation (4 wk)	Pass
Hemocompatibility	Complement Activation (SC5b-9)	Pass
	In-Vivo Thrombogenicity Assay (Porcine, 4-hr)	Pass
	Partial Thromboplastin Time (PTT)	Pass
	Platelet & Leukocyte Count (P&L)	Pass
	Hemolysis Assay (Direct Contact and Extract Method)	Pass

Performance Data

Non-clinical bench testing was performed and leveraged to evaluate the performance of the Concerto Versa ™ Detachable Coil. A subset of design verification testing was conducted based on the FDA Guidance for Vascular and Neurovascular Embolization Devices to evaluate the physical and mechanical properties of the subject device and demonstrate substantial equivalence to the predicate. The following tests were performed shown in the table below, and all passed. Verification and validation testing was performed using a clinically relevant tortuosity model of the splenic and gastroduodenal arteries. All other bench testing was leveraged, as based on the similarities with the predicate device. GLP acute animal data was also leveraged from the predicate device.

Additionally, the following clinically relevant endpoints were addressed as follows:

- Device migration, occlusion effectiveness and recanalization were evaluated through design verification testing with passing results, which are similar to the predicate device.
- Acute complications were addressed based upon the materials, delivery of the device to the target location and clinical applications which are similar to that of the predicate device.
- Local foreign-body reaction was addressed through the product specifications requiring the device to be biocompatible per ISO10993-1 and to be provided sterile.

Test	Specification	Results
Friction in Catheter	Friction force shall meet specification when delivered in a clinically relevant model with a catheter.	Pass
Coil Force Transfer Ratio	Force transfer of delivery system and implant meet specification when delivered into a catheter.	Pass
Pusher Length	The delivery system (pusher) length measurement shall meet specification.	Pass
Coil Visual Inspection	The coil shall have no damage and kinks. The 1st loop shall be a full loop.	Pass
Friction in Sheath	Friction force shall meet specification when delivered through a sheath.	Pass
Fatigue	The coil shall be able to be re-sheathed and re-deployed in a clinically relevant model with a catheter 6 times minimum, without breaking or prematurely detaching.	Pass
PP Tensile	Stretch resistance tensile strength must meet specification.	Pass
Kink resistance	The distal end of 27cm pusher shall be able to track through a 0.027" catheter that is wrapped around a 3.8mm pin gage without kinking.	Pass
Detachment	The coil must detach when detachment is attempted.	Pass
Tip Buckling	Tip buckling force shall meet minimum and maximum specifications.	Pass
Tinius Olsen	The distal 25cm of the pusher shall meet specification when deflected 60º in a Tinius-Olsen with a 1/8" span, at room temperature.	Pass
Loop Deformation	The loop deformation force shall meet specifications.	Pass
Anchor Flow Rate	Anchor flow rate shall meet specifications based on size vessel model size and coil size.	Pass
1st Loop OD Measurement	1st Loop OD must meet specifications based on size.	Pass
Flow Occlusion	For each size coil: The reduction flow of specified coil shall meet specification in the appropriate vessel model.	Pass
Primary Wind OD Measurement	Primary wind OD shall meet specification.	Pass
Coil Length	Coil length shall meet specification based on coil model.	Pass
Pusher Elongation	Elongation force on the pusher to cause release cord actuation must meet specification.	Pass
Pusher Skive Tensile	Tensile strength of pusher must meet specification.	Pass

Test	Specification	Results
Primary wind weld tensile strength	Primary implant weld tensile strengths must meet specification.	Pass
Couple Tube Tensile	Coupler Weld tensile strength must meet specification.	Pass
Shield Coil Tensile	Shield Coil weld tensile strength shall meet specification.	Pass
Detachment	Detachment times will be less than 5s. The coil should be able to be manually detached by the back-up method at the secondary detachment break location.	Pass
Fiber Amount Counting	Fiber amount shall meet specification based on coil model.	Pass
Fiber Pull Out Force	Fiber pull out force shall meet specification.	Pass
Distribution Simulation	Device shall keep integrity with packaging throughout shipping.	Pass

Conclusion:
The subject Concerto Versa™ Detachable Coil and Instant Detacher is substantially equivalent to the predicate Concerto Detachable Coil System. There is no change to the Indication for Use (IFU) Statement for the subject device in comparison to the predicate device. The subject and the predicate devices differ slightly in regard to minor technological characteristics, while maintaining the same fundamental scientific technology. The information provided in this submission supports a determination of substantial equivalence for the subject Concerto Versa™ Detachable Coil and Instant Detacher.