January 14, 2026

Medtronic, Inc.
Rishu Rathee
Sr Regulatory Affairs Specialist
2300 Berkshire Ln N
Plymouth, Minnesota 55441

Re: K253511
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: November 5, 2025
Received: November 5, 2025

Dear Rishu Rathee:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

FINN E. DONALDSON -S

Digitally signed by FINN E. DONALDSON -S
Date: 2026.01.14 14:22:27 -05'00'

For
Misti Malone
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253511

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter Information

Applicant/ Submitter Name and Address	Medtronic 2300 Berkshire Lane N Plymouth, MN 55441 USA
Contact Person	Rishu Rathee Senior Regulatory Affairs Specialist Email: rishu.rathee@medtronic.com
Date Prepared	November 4, 2025
Device Trade Name	Concerto Versa™ Detachable Coil

Subject Device

Device Classification	Regulatory Class: II
Classification Panel	Cardiovascular
Classification Name	Vascular Embolization Device
Regulation Number	21 CFR 870.3300
Product Code	KRD

Predicate Device

Device Trade name	Concerto Versa™ Detachable Coil
510(K) Number / Clearance Date	K202850 / February 4, 2021

Device Description

The Concerto Versa™ Detachable Coil is an embolization coil indicated for arterial and venous embolization in the peripheral vasculature. It consists of a platinum-tungsten embolization implant 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. The Concerto Versa™ Detachable Coil is for single use and provided sterile.

Indications for Use

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

Predicate Comparison

Attribute	Predicate Device	Subject Device
Trade Name	**Concerto Versa™ Detachable Coil**	**Concerto Versa™ Detachable Coil**
510(k) Number	K202850	K253511
Classification	Class II, KRD	Same
Regulation Number	870.3300 – Vascular Embolization Device	Same
Indications For Use	The Concerto Versa™ Detachable Coil is indicated for arterial and venous embolization in the peripheral vasculature.	Same
Sizes Available	3-32mm Loop OD 5-65cm Length	Same
Coil Shape	Spherical and Multi-Spherical	Same
Coil Wire Outer Diameter (OD)	3-6mm: 0.0025'' 7-9mm: 0.00275'' 10-32mm: 0.0035''	Same
Primary Wind OD	3-6mm: 0.0222'' 7-9mm: 0.0224'' 10-32mm: 0.0225''	Same
Fiber OD/Length	0.0015''/3.5mm	0.0015"/4.5mm
Delivery Pusher		
Delivery Wire Length (Pusher Length)	188cm	Same
Delivery Wire Distal OD (With Outer Jacket)	0.010''	0.0142"
Delivery Wire Proximal OD (Unibody)	0.0200''	Same
Pusher Taper Length	158mm	Same
Deliver Pusher Retainer Ring OD	0.0100"	0.0140"
Marker Coil OD/Wire Size	0.0096''/0.00175''	Same
General		
Biocompatibility	Per ISO 10993-1	Same
MRI Compatibility	MR Conditional	Same
Sterilization	Ethylene Oxide (EO)	Same

Summary of Non-Clinical Data

Medtronic performed design verification and validation testing to provide evidence to demonstrate substantial equivalence of the subject device to the predicate device. All data met the acceptance criteria and fell within pre-determined product specifications. The following testing was performed:

Performance Testing:

- Dimensional/Visual Inspection
- Performance/Simulated Use Testing
- Fatigue and Detachment Testing
- Tensile Testing

- Release Wire Retraction Force
- Hub compatibility
- Migration Resistance Testing
- Tip Buckling Testing
- Particulate Testing
- Direct User Testing
- Human Factors & Usability Testing

Biocompatibility Evaluation:

- Cytotoxicity Colony Assay
- Systemic Toxicity Material Mediated Rabbit Pyrogen
- ISO Intracutaneous Irritation test
- In Vitro Skin Irritation Assay
- ISO Acute Systemic Toxicity Study
- ISO Materials Mediated Pyrogenicity Test
- Hemocompatibility

Conclusion

Non-clinical testing supports substantial equivalence of the subject device, Concerto Versa™ Detachable Coil, to the predicate device, Concerto Versa™ Detachable Coil.