October 24, 2023

Medtronic Vascular
Amy Sanders
Principal Regulatory Affairs Specialist
3850 Brickway Blvd.
Santa Rosa, California 95403

Re: K232570
Trade/Device Name: Steerant Super Stiff Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: August 24, 2023
Received: August 24, 2023

Dear Amy Sanders:

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.

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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2023.10.24 15:35:57 -04'00'

Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
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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)*
K232570

Device Name
Steerant Super Stiff Guidewire

Indications for Use *(Describe)*
The Medtronic Steerant Super Stiff Guidewire is intended to be used to facilitate catheter placement and exchange during diagnostic or interventional procedures in the aorta. The guidewire is not indicated for coronary or neuro 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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Submitter:	Medtronic Vascular, Inc. 3850 Brickway Blvd Santa Rosa, CA 95403 (707) 591-2091 (707) 566-1432
Contact Person:	Amy Sanders Sr. Regulatory Affairs Specialist 3850 Brickway Blvd Santa Rosa, CA 95403 Amy.Sanders@medtronic.com
Date Prepared:	August 25, 2023
Device Trade Name:	Steerant™ Super Stiff Guidewire
Device Classification:	Class II
Classification Name:	Guidewire
Regulation Number:	21 CFR 870.1330
Classification Product Code:	DQX
Classification Panel:	Cardiovascular
Predicate Device:	Archer Super Stiff Guidewire (K101339)
Reference Device:	Cook Lunderquist Extra Stiff Wire Guide (K220137)

Device Description:

Steerant™ Super Stiff Guidewire (herein after referred to as Steerant) is a 0.035" diameter PTFE coated stainless steel guidewire. The Steerant guidewire is offered in 200 cm and 260 cm lengths and incorporates a flexible tip section and inner 8 cm radiopaque tungsten coil for enhanced visibility. The Steerant guidewire is offered in single and double curve tip configurations. The Steerant guidewire is sterile, non-pyrogenic, disposable and for single use only.

Indications for Use:

The Medtronic Steerant Super Stiff Guidewire is intended to be used to facilitate catheter placement and exchange during diagnostic or interventional procedures in the aorta. The guidewire is not indicated for coronary or neuro vasculature.

Device Modifications:

The purpose of this submission is to introduce the Steerant guidewire that includes modifications from the cleared Archer guidewire (K101339).

Comparison of Technical Characteristics:

The subject device, Steerant Guidewire predicate device Archer Guidewire (K101339), and reference device Lunderquist (K220137) all have a similar design and materials of construction.

There is no change of intended use or fundamental scientific technology between the proposed, predicate, and reference devices. The proximal core wire is designed to provide support to aid the interventional device placement. The distal section is designed to be flexible, atraumatic, and radiopaque. The coating is designed to reduce friction between the guidewire and lumen of the catheter.

Table 6-1: Predicate, Reference, and Subject Device Comparison

Description	Predicate Device (K101339)	Reference Device (K220137)	Subject Device
Manufacturer	Medtronic	Cook Medical	Medtronic
Name	Archer Super Stiff Guidewire	Lunderquist Extra-Stiff Wire Guide	Steerant Super Stiff Guidewire
Diameter	0.035"	0.035"	0.035"
Length	200 cm or 260 cm	260 cm or 300 cm	200 cm or 260 cm
Tip Configurations	Single or Double curve	Single or Double curve	Single or Double curve
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

Table 6-1: Predicate, Reference, and Subject Device Comparison

Description	Predicate Device (K101339)	Reference Device (K220137)	Subject Device
Indications for Use	The Medtronic Archer 0.035 in (0.89 mm) super stiff guidewire is intended to facilitate catheter placement and exchange during diagnostic or interventional procedures in the aorta, where increased support, distal flexibility, and low surface friction of the guide wire is needed.	The Lunderquist Extra Stiff Wire Guides are intended to facilitate catheterization and/or placement of devices during vascular diagnostic procedures and vascular interventional procedures. The Lunderquist Extra Stiff Wire Guides are intended for use in the major vessels, the aorta and vena cava, including their access vessels and adjacent vessels.	The Medtronic Steerant Super Stiff Guidewire is intended to be used to facilitate catheter placement and exchange during diagnostic or interventional procedures in the aorta. The guidewire is not indicated for coronary or neuro vasculature.
Outer Coil Coating	PTFE (with PFOA)	PTFE	PTFE (Zero-PFOA)
Core Wire	Stainless Steel	Stainless Steel	Stainless Steel
Outer Coil	Stainless Steel	Stainless Steel	Stainless Steel
Inner Coil	Gold Plated Tungsten	Gold	Tungsten
Tip Joint	Plasma Weld	Weld	Plasma Weld
Proximal Joint	Laser Weld	Weld	Epoxy Bond

Substantial Equivalence to K101339:

The assessment of non-clinical performance data demonstrates that the Steerant guidewire is substantially equivalent to the Archer guidewire.

Non-Clinical Performance Data:

The following tests were performed on the subject device to demonstrate that the device meets performance requirements for its intended use. All the predetermined acceptance criteria were met and results passed to support a determination of substantial equivalence. Steerant met all of the Archer performance requirements that were carried over.

- Design Verification Testing
- Design Validation Testing
- Sterilization Validation per requirements of ISO 11135
- Biocompatibility Testing per the requirements of ISO 10993-1
- Packaging Design Verification Testing per requirements of ISO 11607
- Shelf Life Testing

Conclusion:

The Steerant guidewire is substantially equivalent in intended use, function, materials, method of operation, and performance to the previously cleared Archer guidewire (K101339). Steerant has the same fundamental technological characteristics, principles of operation, and applications as the predicate and reference devices.