June 13, 2025

Medtronic Inc
Hillary Barasa
Principal Regulatory Affairs Specialist
710 Medtronic Parkway
Minneapolis, Minnesota 55432

Re: K250075
Trade/Device Name: Medtronic Stedi Extra Support Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: January 10, 2025
Received: January 10, 2025

Dear Hillary Barasa:

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,

LYDIA S. GLAW -S

Digitally signed by LYDIA S. GLAW -S
Date: 2025.06.13 13:49:17 -04'00'

Lydia Glaw
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)*
K250075

Device Name
Medtronic Stedi Extra Support Guidewire

Indications for Use *(Describe)*
Stedi Guidewire is intended for use to introduce and position catheters during interventional procedures within the chambers of the heart, including transcatheter aortic valve replacement (TAVR).

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 K250075

Date Prepared:	Jan 10, 2025
Applicant:	Medtronic Inc 710 Medtronic Parkway Minneapolis, MN 55432 USA **Establish Registration Number**: 2112641
Contact Person:	Hillary Barasa Principal Regulatory Affairs Specialist Email: hillary.s.barasa@medtronic.com Nisarg Shah (Alternate) Senior Manager, Regulatory Affairs Email: nisarg.g.shah@medtronic.com
Trade Name:	Medtronic Stedi™ Extra Support Guidewire
Common Name:	Guidewire
Classification Name:	Wire, Guide, Catheter
Classification:	Class II
Regulation Number:	21 CFR 870.1330
Product Code:	DQX
Name of Predicate Device:	Medtronic Confida Brecker Guidewire (K181001)
Name of Reference Devices:	Cook Lunderquist Extra Stiff Wire Guidewire (K220137)

Device Description:

The Medtronic Stedi^{TM} Extra Support Guidewire (herein after referred as Stedi Guidewire) is design for use to introduce and position catheters during interventional procedures within the chambers of the heart, including transcatheter aortic valve replacement (TAVR) procedures.

The Stedi Guidewire has a 0.035" diameter and is 275cm in length and composed of two primary components: a core, and a coil. Both components are made of stainless steel. The core wire component is a piece of stainless-steel wire which is ground on the distal end to fit into the coil and provide flexibility. The coil and the ground core are joined in two locations: a proximal bond and a distal weld. The distal end of the Stedi Guidewire is comprised of a preformed 540° curved tip is available in 2 sizes (3cm and 4cm). The Stedi Guidewire has a polytetrafluoroethylene (PTFE) coating applied to the entire length of the device in order to aid in lubricity.

The Stedi Guidewire is sterilized using ethylene oxide, nonpyrogenic, disposable, and for single use only.

Indications for Use:

Stedi Guidewire is intended for use to introduce and position catheters during interventional procedures within the chambers of the heart, including transcatheter aortic valve replacement (TAVR).

Comparison of Technological Characteristics with the Predicate Device:

The Stedi Guidewire has the same indication for use and principles of operation as the legally marketed Medtronic Confida Brecker Guidewire (K181001). In addition, the functional characteristics of the Stedi Guidewire are substantially equivalent to the Medtronic Confida Brecker Guidewire, with similar materials, dimensions, and method of construction. The design modifications to the new device include differences in coil shape, dimensional characteristics (i.e., tip sizes, proximal wire diameter, wire length), coating process, bonding type, and material used on the proximal joint. The performance and safety testing have shown that these modifications have not raised any new questions of safety or efficacy, and the device continues to meet its intended use.

Summary of Performance Data

The determination of substantial equivalence includes an assessment of non-clinical (bench) performance testing. This testing was performed in order to demonstrate that the Stedi Extra Support Guidewire met applicable design and performance requirements and to support a determination of substantial equivalence. The following testing was conducted according to established procedures and samples were analyzed according to predetermined acceptance criteria. FDA guidance *Coronary, Peripheral and Neurovascular Guidewires Performance Tests and Recommended Labeling (October 10, 2019)* was utilized.

- Design Verification and Validation Testing
    - Dimensional Verification
    - Visual Inspection
    - Simulated Use/Compatibility
    - Tensile Strength of Proximal Bond and Distal Bond
    - Torque Strength

    - Coating Integrity
    - Particulate Evaluation and Chemical Characterization
    - Lubricity/Pinch Force
    - Corrosion Resistance
    - Kink Resistance
    - Tip Flexibility/Spiral Tip Compression
    - Radiopacity
    - Flex Test
    - Fracture Test
    - Three-Point Bend Test
- Sterilization Validation per requirements of ISO 11135
- Biocompatibility Testing per the requirements of ISO 10993-1
    - Cytotoxicity
    - Sensitization
    - Irritation
    - Acute Systemic Toxicity
    - Material Mediated Pyrogenicity
    - Hemolysis
    - Complement Activation
    - Thrombogenicity
- Packaging Design Verification Testing per requirements of ISO 11607
- Shelf Life Testing

Conclusion:

The Stedi™ Extra Support Guidewire met all design input requirements based on the intended use and supports conclusion that the Stedi™ Extra Support Guidewire does not raise new questions of safety and effectiveness. The results of these tests support a determination of substantial equivalence to the predicate device Medtronic Confida™ Brecker Guidewire (K181001).