January 17, 2025

Medtronic Inc
Cynthia Zerfass
Principal Regulatory Affairs Specialist
1851 E. Deere Avenue
Santa Ana, CA 92705

Re: K242705
Trade/Device Name: Streamline Unipolar Pediatric Temporary Pacing Lead (6491) Streamline Unipolar Temporary Atrial Pacing Lead (6492) Streamline Unipolar Temporary Myocardial Pacing Wire (6494) Streamline Bipolar Temporary Myocardial Pacing Lead (6495) Streamline Unipolar Temporary Myocardial Pacing Lead (6500)
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular Permanent Or Temporary Pacemaker Electrode
Regulatory Class: Class II
Product Code: LDF
Dated: December 18, 2024
Received: December 18, 2024

Dear Cynthia Zerfass:

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,

Sara M. Royce -S
Digitally signed by Sara M. Royce -S
Date: 2025.01.17 12:53:31 -05'00'

Sara Royce
Assistant Director
DHT2A: Division of Cardiac Electrophysiology, Diagnostics, and Monitoring 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.

Submission Number *(if known)*

K242705

Device Name

Streamline Unipolar Pediatric Temporary Pacing Lead (6491)
Streamline Unipolar Temporary Atrial Pacing Lead (6492)
Streamline Unipolar Temporary Myocardial Pacing Wire (6494)
Streamline Bipolar Temporary Myocardial Pacing Lead (6495)
Streamline Unipolar Temporary Myocardial Pacing Lead (6500)

Indications for Use *(Describe)*

Streamline temporary leads and wires treat an irregular heartbeat during or after cardiac surgery by providing electrical stimulation to the heart.
• Models 6491, 6494, 6495, and 6500 are intended for atrial and ventricular use.
• Model 6492 is intended for atrial use only.
• Model 6491 and Model 6492 have smaller chest fixation coils and are appropriate for use in thin heart tissue and, in the case of Model 6491, a smaller chest cavity (for example, in a pediatric patient).

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.

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510(k) Summary

Date Prepared: January 16, 2025

Submitter: Medtronic, Inc.

Medtronic Heart Valve Division
1851 East Deere Ave
Santa Ana, CA 92705
Establishment Registration Number: 2135394

Contact: Cindy Zerfass

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Regulatory Affairs Manager
Medtronic Heart Valve Division
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Device Name

Trade Name	Streamline™ Temporary Pacing Leads and Wire
Common Name	Heartwires

Device Classification

Classification	II
Regulation Number	21 CFR 870.3680
Classification Panel	Cardiovascular
Product Code	LDF

Predicate Device Information

Model	Description	Predicate 510(k)
6491	Unipolar Pediatric Temporary Pacing Lead	K190716
6492	Unipolar Temporary Atrial Pacing Lead	K190716
6494	Unipolar Temporary Pacing Wire	K190716
6495	Bipolar Temporary Myocardial Pacing Lead	K190716
6500	Unipolar Temporary Myocardial Pacing Lead	K171253

Device Description

Each Streamline temporary pacing lead or wire comprises a lead body with a distal and a proximal segment. The distal segment has a separate electrode. A polypropylene monofilament (PP) fixation coil (except for model 6494) extends from the distal electrode end and is attached to a small, curved needle. The curved needle creates a channel in the myocardium for embedding the electrode. The PP fixation coil provides a means of securing the electrode in place. The proximal lead body terminates into a chest needle used to penetrate the chest wall, followed by pulling the proximal portion of the lead through the chest. The device is supplied sterile and intended for single use only.

Principle of Operation

Arrhythmias can occur following cardiac surgery. When a patient's heart is not in sinus rhythm, cardiac output is not optimal, putting the patient's life at risk.

All temporary pacing leads are intended for temporary atrial and/or ventricular pacing and sensing for a contemplated implant duration of 7 days or fewer. They are designed to pace and sense the heart during and after cardiac surgery compatible with Medtronic's external pacing systems (EPG).

Description of Change

This Special 510(K) aims to notify the FDA of the language related to the Magnetic Resonance Imaging (MRI) condition added to the IFU. All models of the Streamline family products were tested in a nonclinical environment and deemed MR Conditional. Other changes were made to the IFU, which entailed rewording the Indication for Use, Contraindications, and Warnings, with no change to the intent.

Indication for Use

Streamline temporary leads and wires treat an irregular heartbeat during or after cardiac surgery by providing electrical stimulation to the heart.

- Models 6491, 6494, 6495, and 6500 are intended for atrial and ventricular use.
- Model 6492 is intended for atrial use only.
- Model 6491 and Model 6492 have smaller chest fixation coils and are appropriate for use in thin heart tissue and, in the case of Model 6491, a smaller chest cavity (for example, in a pediatric patient).

Contraindications

There are no known general contraindications to temporary postsurgical pacing. The cardiac surgeon determines the pacing system to be used based on the patient medical condition and anatomy

Comparison to Predicate Devices

Streamline Temporary Pacing Leads and wire have the following similarities to the predicate devices that have received FDA clearance: K190716 and K171253.

- Same intended use/indications for all devices in scope
- The same finished device operating principle for all devices in scope
- All Models are packaged using the same materials and sterilized via EtO.

Summary of Testing

Each Streamline Model was tested in two configurations bundled and extended and assessed as follows:

- RF Heat assessment per ASTMF2192-19e2 at 64MHz (1.5T) and at 123MHz (3T)
- Force and Torques in a 3.0 T GE Discovery MR750 whole-body MR system per test method described in ASTM F2052-15w
- Imaging artifact assessment was not tested as it was determined that only the head and lower extremities may be imaged therefore, there is limited to no risk of the lead to cause image artifacts in the scans.

Conclusion

The nonclinical MRI testing and calculations support that the Streamline family of products is MR Conditional and can be scanned safely under the following conditions:

The following table is included in the IFU.

Magnetic Resonance Imaging (MRI) safety information  A patient with a Medtronic Streamline pacing lead or wire may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.	
Name /Identification of the device	6491, 6492, 6494, 6495, 6500
Nominal value(s) of static magnetic field [T]	1.5T or 3.0T
Maximum spatial field gradient [T/m]	20 T/m
RF excitation	Circularly polarized or multichannel
RF transmit coil type	RF head transmit coil or lower extremity transmit coil. **RF body transmit coil is contraindicated.**
Operating Mode	Normal Operating Mode
Maximum head SAR	3.2 W/kg
Scan duration	There is no limit on scan duration.
Scan region	Head or lower extremity **only**
MR Image artifact	The Streamline pacing leads are not implanted in the head or lower extremity and therefore will not produce an image artifact.
Additional instructions or information essential for safe use in the MR environment	Before an MR exam, disconnect the connector pin from the pulse generator. The pulse generator is unsafe in a MR environment. **MR exams are contraindicated for patients who remain dependent on pacing.** When a patient undergoes an MR scan, the connector pins must be inserted into the pin protectors (*Chapter 6, step 6c*), with the excess lead coiled. The pin protectors and the coiled lead must be taped to an area of the patient's skin (*Chapter 6, step 7*), such as to the patient's chest.
If information about a specific parameter is not included, there are no conditions associated with the parameter.	