August 8, 2019

Medtronic
Joven Almazan
Regulatory Affairs Specialist
1851 East Deere Ave.
Santa Ana, California 92705

Re: K190716
Trade/Device Name: Streamline 6491 Unipolar Pediatric Temporary Pacing Lead, Streamline 6492 Unipolar Temporary Atrial Pacing Lead, Streamline 6494 Unipolar Temporary Myocardial Pacing Wire, Streamline 6495 Bipolar Temporary Myocardial Pacing Lead
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular Permanent Or Temporary Pacemaker Electrode
Regulatory Class: Class II
Product Code: LDF
Dated: July 9, 2019
Received: July 10, 2019

Dear Joven Almazan:

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,

Jessica Paulsen
Implantable Electrophysiology Devices Team
Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
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)*
K190716

Device Name
Streamline Temporary Pacing Leads

Indications for Use *(Describe)*

The Model 6491 Unipolar Pediatric Temporary Pacing Lead is intended for temporary postsurgical atrial and ventricular pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and is intended for SINGLE USE ONLY.

The Model 6492 Unipolar Temporary Atrial Pacing Lead is intended for temporary postsurgical atrial pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and is intended for SINGLE USE ONLY

The Model 6494 Unipolar Temporary Myocardial Pacing wire is intended for temporary postsurgical atrial and ventricular pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and is intended for SINGLE USE ONLY.

The Model 6495 Bipolar Temporary Myocardial Pacing Lead is intended for temporary postsurgical atrial and ventricular pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and is intended for SINGLE USE ONLY.

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

Date Prepared: April 12, 2019

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Trade Name:	Streamline™[1] Temporary Pacing Leads
Classification Name:	Temporary Pacing Lead
Regulation Number:	21 CFR 870.3680(a)
Product Classification:	Class II
Product Code:	LDF

Predicate Devices	Model	Product Name
K171253	6491	Unipolar Pediatric Temporary Pacing Lead
K171253	6492	Unipolar Temporary Atrial Pacing Lead
K140972	6494	Unipolar Temporary Myocardial Pacing Wire
K171253	6495	Bipolar Temporary Myocardial Pacing Lead

[1] The trademark name Streamline™ mentioned throughout the document represents the temporary pacing lead product family Models; 6491, 6492, 6494, and 6495.

6.1 Device Descriptions

Model 6491 Unipolar Pediatric Temporary Pacing Lead

The Medtronic Model 6491 Unipolar Pediatric Temporary Pacing Lead is designed for use in both the atrium and the ventricle. The unipolar lead is comprised of a lead body with the distal and proximal segment.

The Model 6491 Unipolar Pediatric Temporary Pacing Lead (see Figure 6-1) consists of an electrode (1) and an insulated multi-filament conductor (2) which are crimped together. A blue monofilament (3) proximally coiled for fixation of the lead is attached to the electrode and terminates distally in an atraumatic myocardial curved needle (4). A blue monofilament coil provides fixation while the lead is implanted in myocardial tissue. A curved atraumatic chest needle (5) at the proximal end of the conductor wire permits exiting the pacing lead through the chest wall. To remove the pacing lead, gentle traction should be applied.

No part of the Medtronic Model 6491 Unipolar Pediatric Temporary Pacing Lead remains in the body.

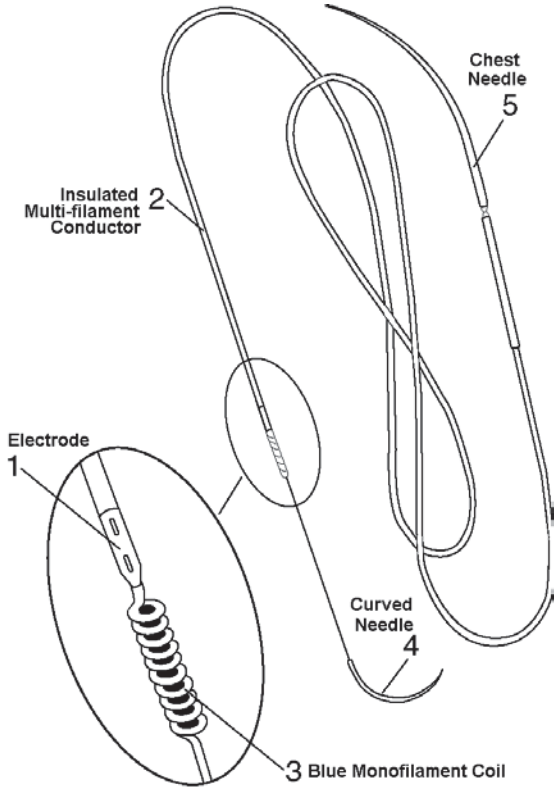

Figure 6-1: Model 6491

Model 6492 Unipolar Temporary Atrial Pacing Lead

The Medtronic Model 6492 Unipolar Temporary Atrial Pacing Lead is designed for use in the atrium. The unipolar lead is comprised of a lead body with distal and proximal segments.

The Model 6492 Unipolar Temporary Atrial Pacing Lead (see Figure 6-2) consists of an electrode (1) and an insulated multi-filament conductor (2) which are crimped together. A blue monofilament (3) proximally coiled for fixation of the lead is attached to the electrode and terminates distally in an atraumatic myocardial curved needle (4). A blue monofilament coil provides fixation while the lead is implanted in myocardial tissue. An atraumatic chest needle (5) at the proximal end of the conductor wire permits exiting the pacing lead through the chest wall. To remove the pacing lead, gentle traction should be applied.

No part of the Medtronic Model 6492 Unipolar Temporary Atrial Pacing Lead remains in the body.

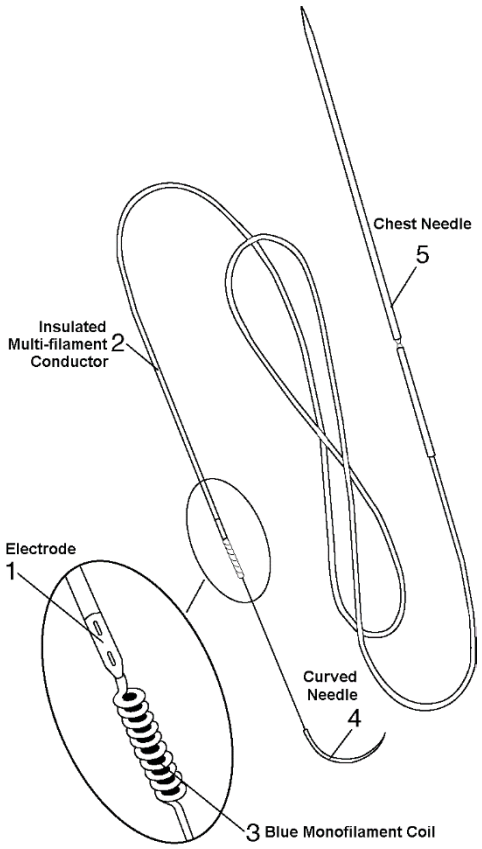

Figure 6-2: Model 6492

Model 6494 Unipolar Temporary Myocardial Pacing Wire

The Medtronic Model 6494 Unipolar Temporary Myocardial Pacing Wire is designed for use in both the atrium and the ventricle. The two leads are comprised of a lead body with distal and proximal segment.

The Model 6494 Unipolar Temporary Myocardial Pacing Wire (see Figure 6-3**)** consists of two insulated multi-filament wire (1). At one end of each wire has been stripped to have an electrode surface (2). This surface area can partly or completely be used as an electrode. The stripped end terminates distally in an atraumatic myocardial curved needle (3). An atraumatic chest needle (4) at the proximal end of the conductor wire permits running the pacing wire to exit through the chest wall. To remove the pacing wire, gentle traction should be applied.

No part of the Medtronic Model 6494 Unipolar Temporary Myocardial Pacing Wire remains in the body.

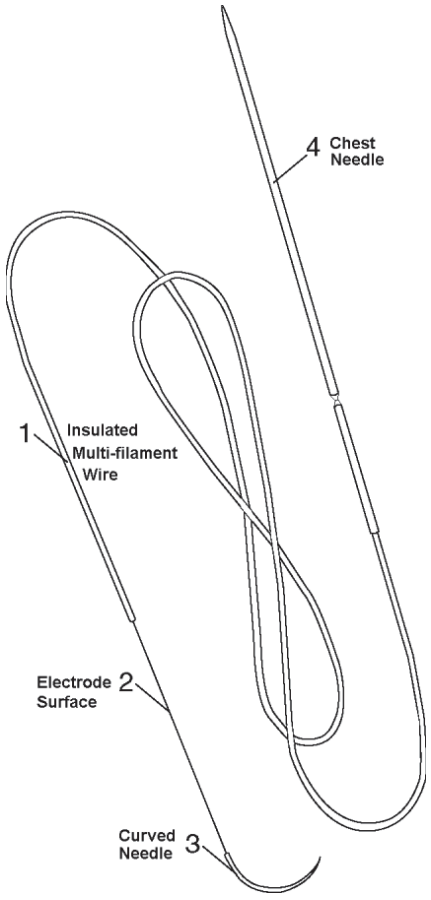

Figure 6-3: Model 6494

Model 6495 Bipolar Temporary Myocardial Pacing Lead

The Medtronic Model 6495 Bipolar Temporary Myocardial Pacing Lead is designed for use in both the atrium and the ventricle. The bipolar lead is comprised of a lead body with distal and proximal segments which includes the integrated bifurcated proximal lead connection.

The Model 6495 Bipolar Temporary Myocardial Pacing Lead consists of an insulated multi-filament lead (see Figure 6-4), which contains a distal, discrete, ring electrode (1), a discrete, tip electrode (2), and a coaxial conductor lead body (3). Each discrete electrode is crimped onto a conductor and terminates in an atraumatic myocardial curved needle (4). The curved needle is used to create a channel in the myocardium for embedding the electrodes. A blue monofilament coil provides fixation while the lead is implanted in myocardial tissue. An atraumatic chest needle (5) at the proximal end of the conductor wire permits exiting the pacing lead through the chest wall. Terminated on the back of the chest needle are two breakaway connector pins (6), which provide an attachment to an external pulse generator.

No part of the Medtronic Model 6495 Bipolar Temporary Myocardial Pacing Lead remains in the body.

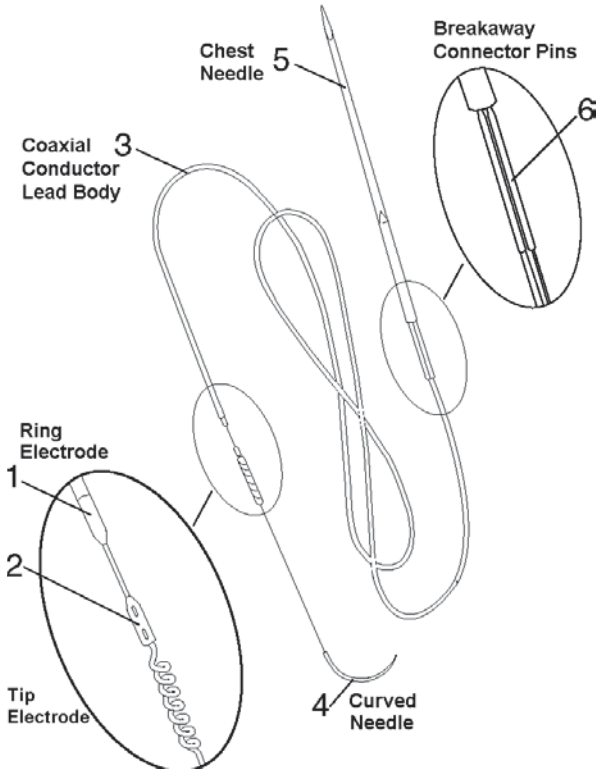

Figure 6-4: Model 6465

6.2 Intended Use

There were no changes to the intended use of the devices as related to the change proposed in the Traditional 510(k) notification. The current Indications for Use statements are noted below:

Model	Indications for Use
6491	The Model 6491 Unipolar Pediatric Temporary Pacing Lead is intended for temporary postsurgical atrial and ventricular pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and is intended for SINGLE USE ONLY.
6492	The Model 6492 Unipolar Temporary Atrial Pacing Lead is intended for temporary postsurgical atrial pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and is intended for SINGLE USE ONLY.
6494	The Model 6494 Unipolar Temporary Myocardial Pacing wire is intended for temporary postsurgical atrial and ventricular pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and is intended for SINGLE USE ONLY.
6495	The Model 6495 Bipolar Temporary Myocardial Pacing Lead is intended for temporary postsurgical atrial and ventricular pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and is intended for SINGLE USE ONLY.

6.3 Contraindications

The following contraindication statement is not changing and is applicable for all four (4) models presented in this Traditional 510(k).

There are no known general contraindications to temporary postsurgical pacing. The particular medical condition and anatomy of the patient, however, may dictate the lead system and implantation procedure to be used.

6.4 Comparison of the Predicate Device

A comparison of the Streamline family of products is being made to the currently marketed predicate devices:

Models 6491, 6492, 6495 510(k) # K171253 and 6494 510(k) #K140972 and indicate the following similarities:

- Same intended use/indications
- Same operating principle
- Same fundamental technological characteristics
- Same overall design, dimensions, and performance
- All materials are the same except for the minor formulation change of the base polyethylene (PE) material used for the insulation coating of the wire; The insulated wire comes in three different colors (yellow, purple, and blue) and no changes are being made to the supplier, chemical compositions or to the concentrations of these colorants.
- Same packaging materials
- Same sterilization requirements

6.5 Summary of Performance Data

Bench testing was used to verify the performance characteristics of these devices. Clinical testing was not required.

The following tests were conducted and the change to the PE base material successfully passed the acceptance criteria of the pre-established specifications. The new PE formulation is considered qualified for its intended use.

- Biocompatibility
- Component Qualification
- Design Verification
- Shelf Life

6.6 Conclusion

In summary, the information included in this submission demonstrates that the changes made to the Streamline family of products are substantially equivalent to the legally marketed predicate versions.