



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 25, 2017

Medtronic, Inc
Debra Taitague
Regulatory Affairs Manager
1851 East Deere Ave
Santa Ana, California 92705

Re: K171253

Trade/Device Name: Streamline 6491 Unipolar Pediatric Temporary Pacing Lead,
Streamline 6492 Unipolar Temporary Pacing Lead,
Streamline 6495 Bipolar Temporary Myocardial Pacing Lead,
Streamline 6500 Unipolar 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: April 27, 2017

Received: April 28, 2017

Dear Debra Taitague:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light blue, semi-transparent "FDA" watermark.

for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K171253

Device Name

Streamline 6491 Unipolar Pediatric Temporary Pacing Lead, Streamline 6492 Unipolar Temporary Pacing Lead, Streamline 6495 Bipolar Temporary Myocardial Pacing Lead, Streamline 6500 Unipolar Temporary Myocardial Pacing Lead

Indications for Use (Describe)

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

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

The Model 6495 Bipolar Temporary Myocardial Pacing Lead is intended for temporary post-surgical 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 6500 Unipolar Temporary Myocardial Pacing Lead is designed for temporary post-surgical pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and 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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6.0 510(k) Summary

Date Prepared: April 27, 2017

Applicant: Medtronic
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Trade Name: Streamline¹ 6491 Unipolar Pediatric Temporary Pacing Lead
Streamline 6492 Unipolar Temporary Pacing Lead
Streamline 6495 Bipolar Temporary Myocardial Pacing Lead
Streamline 6500 Unipolar Temporary Myocardial Pacing Lead

Classification Name: Temporary Pacing Lead

Regulation Number: 21 CFR 870.3680(a)

Product Classification: Class II

Product Code: LDF

Predicate Devices	Model	Product Name
K140972	6491	Unipolar Pediatric Temporary Pacing Lead
K140972	6492	Unipolar Temporary Atrial Pacing Lead
K161249	6495	Bipolar Temporary Myocardial Pacing Lead
K140972	6500	Unipolar Temporary Myocardial Pacing Lead

¹ The trademark name Streamline™ mentioned throughout the document represents the temporary pacing lead product family Models; 6491, 6492, 6495, and 6500.

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. 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 6491 Unipolar Pediatric Temporary Pacing Lead remains in the body.

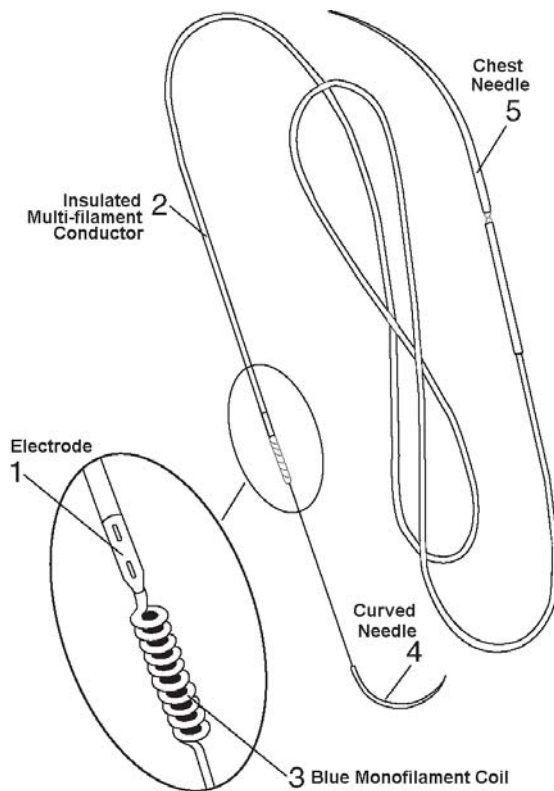


Figure 6-1: Model 6491

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.

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

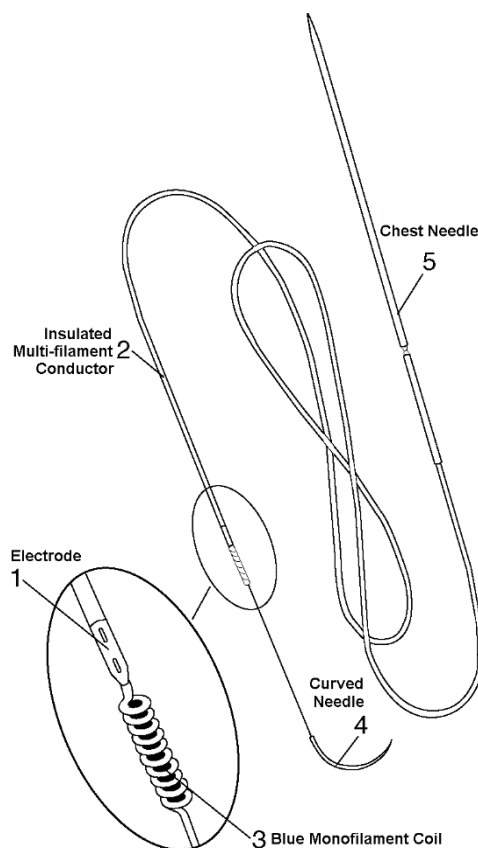


Figure 6-2: Model 6492

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 6-3](#)), 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.

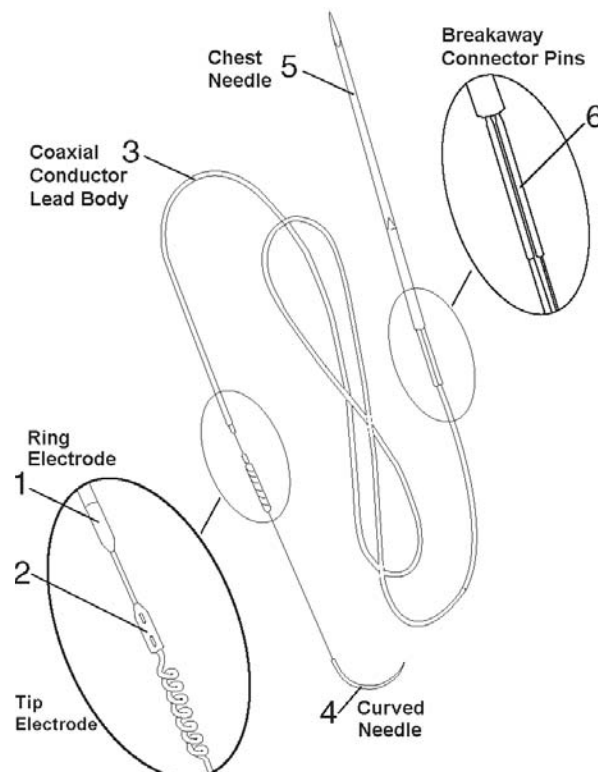


Figure 6-3: Model 6465

Model 6500 Unipolar Temporary Myocardial Pacing Lead

The Medtronic Model 6500 Unipolar Temporary Myocardial 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 6500 Unipolar Temporary Myocardial Pacing Lead (see [Figure 6-4](#)) 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 lead remains in the body, except the silicone rubber disc (6) in the case of atrial application.

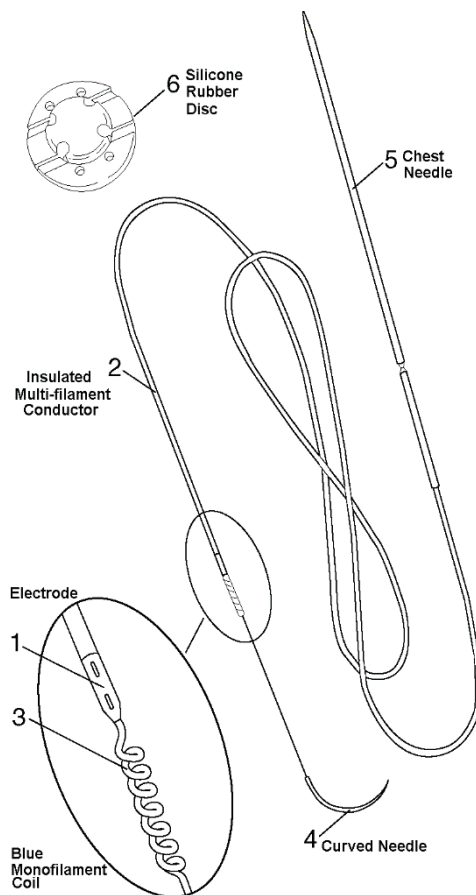


Figure 6-4: Model 6500

6.2 Intended Use

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

Model	Indication 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.
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.
6500	The Model 6500 Unipolar 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 applicable for all four (4) models presented in this special 510(k) and is not changing.

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 to the Predicate Device

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

Models 6491, 6492, and 6500 510(k) #K140972 and Model 6495 510(k) # K161249

and indicates 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 and new supplier of the blue monofilament suture.
- 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

- Biocompatibility
- Junction Strength
- Component Qualification

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.