January 23, 2025

Shenzhen Launch Electrical Co. Ltd
Christina Zheng
Assistant of General Manager
Bldg F, Zhonggangxing Industrial Estate Zhangge Community
Guanian Street, Longhua New District
Shenzhen, 518110
China

Re: K241199
Trade/Device Name: Rotatable Connector (5944RL)
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular Permanent Or Temporary Pacemaker Electrode
Regulatory Class: Class II
Product Code: LDF
Dated: December 23, 2024
Received: December 23, 2024

Dear Christina Zheng:

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: 2025.01.23 15:22:58 -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)*

K241199

Device Name

Rotatable Connector (5944RL)

Indications for Use *(Describe)*

The rotatable connector is intended for use as part of a temporary cardiac pacing system. It connects a cardiovascular stimulating instrument to a cardiac pacing lead. It is intended for use by trained clinicians in a clinical environment.

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.

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"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

K241199

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date Prepared:	Jan 21st, 2025
Manufacturer:	Shenzhen Launch Electrical Co. Ltd Building F, Zhonggangxing Industrial Estate Zhangge Community, Guanian Street, Longhua New District, Shenzhen 518110, China
Contact Person:	Christina Zheng Assistant of General Manager Shenzhen Launch Electrical Co. Ltd Tel: +86-18825224607 email: christina.zheng@lnhmed.com

Identification of the Device:

Proprietary/Trade Name:	5944RL Rotatable Connector
Classification Name:	Electrode, Pacemaker, Temporary
Regulation Name:	Cardiovascular permanent or temporary pacemaker electrode
Regulatory Number:	21 CFR 870.3680
Product Code:	LDF
Device Class:	Class II
Review Panel:	Cardiovascular

Primary Predicate Device:

Proprietary/Trade Name:	MEDTRONIC 5833SL
Classification Name:	Electrode, Pacemaker, Temporary
Regulation Name:	Cardiovascular permanent or temporary pacemaker electrode
Regulatory Number:	21 CFR 870.3680
Product Code:	LDF
Device Class:	Class II
Review Panel:	Cardiovascular

Submitter/510(k) Holder: MEDTRONIC VASCULAR 7000 CENTRAL AVE. N.E. MINNEAPOLIS, MN 55432

Clearance: K923407 (cleared Oct 19, 1992)

Device Description:

The Model 5944RL rotatable connector is a pair of single use, disposable surgical cables with two adaptors. The cables are designed to connect a cardiovascular stimulating instrument to a cardiac pacing lead system.

Indications for Use:

The rotatable connector is intended for use as part of a temporary cardiac pacing system. It connects a cardiovascular stimulating instrument to a cardiac pacing lead. It is intended for use by trained clinicians in a clinical environment.

Comparison with Predicate Device:

The 5944RL Rotatable Connector and its predicate device the 5833SL Disposable surgical cables (K923407), have the same intended use, and similar physical characteristics.

Description	**Subject Device** 5944RL Rotatable Connector	**Predicate Device** 5833SL Disposable surgical cables
510K number	K241199	K923407
Manufacturer	Launch	Medtronic Vascular
Product code, Classification	LDF 21 CFR 870.3680 Class II	LDF 21 CFR 870.3680 Class II
Indications for use	The rotatable connector is intended for use as part of a temporary cardiac pacing system. It connects a cardiovascular stimulating instrument to a cardiac pacing lead. It is intended for use by trained clinicians in a clinical environment.	The Medtronic Model 5833SL disposable surgical cables are intended for use as part of a temporary cardiac pacing system. They connect a single chamber or dual chamber cardiovascular stimulating instrument to cardiac pacing leads or heart wires.

Description		Subject Device 5944RL Rotatable Connector	Predicate Device 5833SL Disposable surgical cables
Intended User		The Model 5944RL patient cable is intended for use by trained clinicians.	It is intended for use by trained clinicians.
Intended Use Environment		clinical environment	clinical environment
Duration of use		Limited : ≤24H	Limited : ≤24H
Single use, disposable		Yes	Yes
Provided sterile		Yes	Yes
Sterilization method		EO	Radiation
Sterility Assurance Level (SAL)		≤ 10^{-6}	≤ 10^{-6}
Sterile barrier package		Tyvek Flexible Barrier	Tyvek Flexible Barrier
Design	Product picture		
	Principles of operation	The device is used as part of a temporary cardiac pacing system based on the principle of transmitting electrical signals between the cardiovascular stimulating instrument and the cardiac pacing leads. The device allows real-time continuous and accurate pacing and sensing electrical connection during lead implantation. After the	The Medtronic Model 5833SL cable is single use, disposable surgical cables. The cables are designed to connect a cardiovascular stimulating instrument to cardiac pacing lead system.

Description		Subject Device 5944RL Rotatable Connector	Predicate Device 5833SL Disposable surgical cables
		implantation procedure is finished, the device is disconnected and discarded.	
	Function	The Model 5944RL rotatable connector is a pair of single use, disposable surgical cables with two adaptors. The cables are designed to connect a cardiovascular stimulating instrument to a cardiac pacing lead system.	The Medtronic Model 5833SL cables are single use, disposable surgical cable. The cable is designed to connect a cardiovascular stimulating instrument to a cardiac pacing lead system.
	Construction	This device consists of a pair of connection cables, which includes a cathode cable (black wire) and an anode cable (red wire) and a pair of un-shrouded pin adaptors. The anode cable has an alligator clip at the distal end, and a 2 mm shroud pin at the proximal end. The cathode cable has a rotatable lead connector at the distal end of the cable, and a 2 mm shroud pin at the proximal end. The distal end of the respective cables consists of an alligator	The proximal end of each cable consists of a connector with 2 recessed pins that plugs into a cardiovascular stimulating instrument. The distal end of each cable consists of 2 alligator clips with color-coded boots that attach to the connector pins of cardiac leads. The red clip is positive (+). The black clip is negative (-). Plug is Type CF connection plug, which is connected to Type CF connection port.

Description		Subject Device 5944RL Rotatable Connector	Predicate Device 5833SL Disposable surgical cables
		clip and rotatable connector that attach to the electrode contacts of the cardiac pacing lead or a unipolar reference. The alligator clip with the red wire is positive (+). The rotatable connector with black wire is negative (-). Plug type is shroud pin or safety connector pin，which is connected to type of pin receptacle.	
	Method of clamp introduction	 Male to female connector, Alligator clips	 Male to female connector, Alligator clips
	Performance	Key performance -Cable segment: 22 AWG -Resistance ≤5Ω -Insulation resistance >1GΩ -Dielectric withstanding voltage: capable of 1500 volts A.C. for one minute	Key performance -Cable segment: 22 AWG -Resistance ≤5Ω -Insulation resistance >1MΩ -Dielectric withstanding voltage: capable of 1500 volts A.C. for one minute

Description	Subject Device 5944RL Rotatable Connector	Predicate Device 5833SL Disposable surgical cables
Patient Contact Materials	Cytotoxicity, Irritation, Sensitization and meet ISO 10993-1 and FDA guidance	Cytotoxicity, Irritation, Sensitization and meet ISO 10993-1 and FDA guidance
Electrical Safety and Electromagnetic compatibility	ANSI/AAMI ES60601-1 IEC60601-1-2	ANSI/AAMI ES60601-1 IEC60601-1-2
Labeling	Conforms to 21 CFR Part 801	Conforms to 21 CFR Part 801

Technology:
The 5944RL Rotatable Connector employs the same fundamental scientific technology as its predicated device.

Summary of Substantial Equivalence Comparison:
The subject devices have the same Indications for use, Intended User and use environment, same technological characteristics including Principles of operation, functions and performance, biocompatibility and general safety, only the sterilization method, construction design and Insulation resistance of performance different and they do not raise new questions of safety and effectiveness.

Summary of Non-clinical test:
5944RL Rotatable Connector was evaluated for biocompatibility, sterilization, usability as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to comply with applicable medical device safety standard, The 5944RL Rotatable Connector complies with voluntary standards:

1. ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
2. IEC 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

3. ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
4. ISO 10993-10:2021 Biological evaluation of medical devices Part 10: Tests for skin sensitization
5. ISO 11737-1:2018/A1:2021 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
6. ISO 11737-2 Third edition 2019-12 Sterilization of health care products-Microbiological methods-Part2:Tests of sterility performed in the definition,validation and maintenance of a s sterilization process
7. ASTM F88/F88M-21 Standard Test Method for Seal Strength of Flexible Barrier Materials
8. ASTM F2096-11 (Reapproved 2019) Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
9. ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems
10. IEC 60601-2-31: 2020: Medical electrical equipment – Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

Summary of Clinical Tests:
The subject of this premarket submission did not require clinical studies to support substantial equivalence.

Conclusion:
Shenzhen Launch Electrical Co. Ltd considers the 5944RL Rotatable Connector to be substantially equivalent to the predicate device.