August 2, 2018

Ethicon, Inc.
Joice Pappan
Regulatory Affairs Specialist II
P.O. Box 151
Route 22 West
Somerville, New Jersey 08876-0151

Re: K173923
Trade/Device Name: Temporary Cardiac Pacing Wire
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular Permanent or Temporary Pacemaker Electrode
Regulatory Class: Class II
Product Code: LDF
Dated: July 2, 2018
Received: July 3, 2018

Dear Joice Pappan:

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.

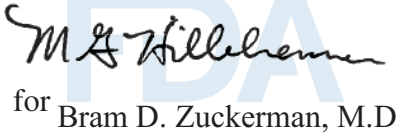
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*

K173923

Device Name

Temporary Cardiac Pacing Wire

Indications for Use *(Describe)*

Temporary Cardiac Pacing Wire is intended for use in temporary epicardial cardiac pacing or monitoring and should be removed after temporary pacing has been discontinued.

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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ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

510(k) Summary

Submitter: ETHICON Inc. a Johnson & Johnson company
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Date Prepared: December 22, 2017

Device Trade Name: Temporary Cardiac Pacing Wire

Device Common Name: Electrode, Pacemaker, Temporary

Class: II

Classification Name: Cardiovascular permanent or temporary pacemaker electrode
21 CFR 870.3680

Product Code: LDF

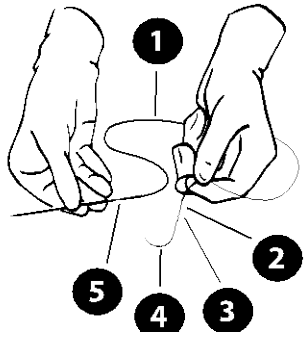
Predicate Devices:

Device	Company	Product Code	510(k) Number	Predicate for:
Temporary Cardiac Pacing Wire	ETHICON, Inc.	OMD	K980503	Fundamental Scientific Technology, Design, Materials, Construction, Performance Characteristics

Device Description:

The Temporary Cardiac Pacing Wire is a sterile single-use product. Temporary cardiac pacing wires consist of the following configurations and optional accessories:

1. The monopolar leads consist of one insulated multifilament stainless steel conductor coated with colored polyethylene.
2. The intracorporeal end of the wire has a section of exposed, uninsulated wire electrode which terminates with an attached stainless steel needle.
3. The exposed, uninsulated section of the intracorporeal end of the wire is either straight or has one or more multiple pre-formed curves (pre-formed wave).
4. The extracorporeal end of wire has a straight needle with breakaway tip attached.
5. The wire length is 60 cm.
6. Wires range in multiple diameters from 0 to 2-0, depending on the product code.



The lead consists of:

Item 1 – Insulated multifilament conductor coated with colored polyethylene

Item 2 – Uninsulated, multifilament wire (intracorporeal) electrode

Item 3 – Optional wave pre-formed into the uninsulated, intracorporeal wire end

Item 4 – Intracorporeal curved needle

Item 5 – Extracorporeal straight breakaway needle

Indications for Use:

Temporary Cardiac Pacing Wire is intended for use in temporary epicardial cardiac pacing or monitoring and should be removed after temporary pacing has been discontinued.

Summary of Technological Characteristics and Performance Testing:

Temporary Cardiac Pacing Wire is identical to the Temporary Cardiac Pacing Wire with wave (K980503) marketed device. The principle of operation and fundamental scientific technology of the modified device are equivalent to the predicate device. There are no material, construction, specification, manufacturing or sterilization process changes to the currently marketed device.

The performance modification was accomplished via testing in the MRI environment and updating the labeling per FDA guidance "Establishing Safety and compatibility of Passive implants in the Magnetic Resonance (MR) environment" dated December 11, 2014. Additionally, the change proposed in this premarket notification, modifies the indications for use statement which reinforces that the device is for short-term, temporary pacing only, as stated by the product name. The labeling (Instructions for Use) have also been modified to add clarity for the use of the device.

A comparison between the proposed and the predicate device is given in Table 1 below.

Table 1: Device Comparison Table

	Proposed Device	**Predicate Device**
Device Name	Temporary Cardiac Pacing Wire	Temporary Cardiac Pacing Wire
510(k) Number	**TBD**	K980503
Product Code	Same	LDF
Regulation	Same	21 CFR 870.3680
Absorbable	Same	No
Intended Use	Temporary Cardiac Pacing Wire is intended for use in temporary epicardial cardiac pacing or monitoring and should be removed after temporary pacing has been discontinued	Temporary Cardiac Pacing Wire is intended for use in temporary cardiac pacing or monitoring.
Contraindication	Use of temporary cardiac pacing wires is contraindicated for permanent cardiac pacing or for monitoring.	When permanent cardiac pacing or monitoring is required, the use of the Temporary Cardiac Wire is contraindicated.
MRI Safety Information in Warnings Section	**MRI INFORMATION**  **MR Conditional** This Temporary Cardiac Pacing Wire is MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions: • Static magnetic field of 1.5-Tesla or 3-Tesla only • Maximum spatial gradient magnetic field of 1000 Gauss/cm (extrapolated).	NA

	• Transmit/receive RF head coil only. • Maximum MR system reported, transmit/receive RF head coil specific absorption rate (SAR) of 3.2 W/kg for 15 minutes of scanning (i.e. per pulse sequence). • Normal Operating Mode of operation for the MR system. In non-clinical testing and numerical modeling, the Temporary Cardiac Pacing Wire produced a temperature rise of less than 0.5°C at a maximum MR system calculated transmit/receive RF head coil SAR of 3.2-W/kg in 1.5-Tesla/64-MHz and 3-Tesla/128-MHz MR systems. **Additional MRI Safety Information** • Do not perform an MRI procedure if the Temporary Cardiac Pacing Wire is damaged or otherwise not functioning properly. • The Temporary Cardiac Pacing wire must be disconnected from the pulse generator prior to entry into the MR system room and the ends of the leads should be properly secured to prevent movement. • The use of a transmit/receive RF body coil to perform an MRI examination in a patient with the Temporary Cardiac Pacing Wire may cause patient injury due to excessive MRI-induced heating.	
Color	Same	Dyed and Undyed
Material Composition	Same	316L Stainless Steel
Sterilization	Same	Sterilized by Gamma Irradiation
Packaging	Same	Temporary Cardiac Pacing Wire is packaged in paperboard envelops, paper folders and card reels. These are then packaged in a poly-Tyvek sterile barrier

		package
U.S.P. requirements	Same	Temporary Cardiac Pacing Wire complies with the requirements of the European Pharmacopoeia for Sterile Non-Absorbable strands and the United States Pharmacopoeia U.S.P. Monograph 861, 871 and 881 for Non Absorbable Surgical Sutures.

The following tests were completed for the Temporary Cardiac Pacing Wire

Design Verification
MRI-related heating, 1.5-Tesla/64-MHz. Heating test
MRI-related heating, 3-Tesla/128-MHz. Heating test
Evaluation of Ethicon Temporal Pacing Wires Heating under MRI Conditions Using RF Coils at 64-MHz and 128 MHz

Summary of Substantial Equivalence Comparison:

Temporary Cardiac Pacing Wire is identical to the existing Temporary Cardiac Pacing Wire "with wave" (K980503) marketed device except for the following changes: (1) performance modification to test the MRI Environment, (2) modifications to the labeling (instructions for use, contraindication statements, and general updates). There are no material, construction, specification, manufacturing or sterilization process changes to the currently marketed device. The clarifications to the labeling and indications for use statement were made to add clarity for users.

Conclusion:

Based on the similarities to the predicate device identified in this submission, except for proposed modification to clarify the labeling (instructions for use), adding the MRI warning information, revision of the Indication statement and the Contraindication statement, updating the Warnings, Precautions and Interactions sections, the devices have the same fundamental technology, and the same principle of operation. There are no material, construction, specification, manufacturing or sterilization process changes to the currently marketed devices. Temporary Cardiac Pacing Wire is considered to be substantially equivalent to the predicate device (K980503).