July 30, 2019

Medtronic
Matthew Lobeck
Sr. Regulatory Affairs Specialist
8200 Coral Sea St NE
Mounds View, Minnesota 55112

Re: K190132
Trade/Device Name: Torqr Intracardiac Electrode Catheter, Soloist Intracardiac Electrode Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II
Product Code: DRF
Dated: July 3, 2019
Received: July 5, 2019

Dear Matthew Lobeck:

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,

Mark Fellman
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190132

Device Name

1. Torqr™ Intracardiac Electrode Catheter
2. Soloist™ Intracardiac Electrode Catheter

Indications for Use *(Describe)*

1. The Medtronic Torqr catheter is intended for use in diagnostic electrophysiologic procedures. The catheter is designed for recording intracardiac electrograms and temporary pacing associated with electrophysiology studies.
2. The Medtronic Soloist catheter is intended for use in diagnostic electrophysiologic procedures. The catheter is designed for recording intracardiac electrograms and temporary pacing associated with electrophysiology studies.

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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5.0 510(k) Summary

Date Summary Prepared: January 25, 2019

Applicant:

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Establishment Registration No. 3001504994

Official Correspondent:

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Device Trade Name:

1. Torqr™ Intracardiac Electrode Catheter
2. Soloist™ Intracardiac Electrode Catheter

Common Name: Diagnostic catheter

Classification Name: Catheter, Electrode Recording, Or Probe, Electrode Recording

Classification & Panel: Class II, 21 CFR 870.1220, Cardiovascular

Product Code: DRF

Predicate Device:

1. Torqr™ Intracardiac Electrode Catheter (K923915)
2. Soloist™ Intracardiac Electrode Catheter (K953185)

Device Description:

Medtronic diagnostic catheters are flexible radiopaque catheters constructed of extruded polymer over a stainless-steel braid. The catheters contain platinum-iridium sensing band electrodes and are designed for intracardiac recording or stimulation.

This premarket notification covers changes impacting Medtronic diagnostic catheters, including labeling updates, packaging design and packaging material changes, and product requirement updates.

Intended Use:

Medtronic diagnostic catheters are intended for use in diagnostic electrophysiologic procedures. The catheters are designed for recording intracardiac electrograms and temporary pacing associated with electrophysiology studies.

The intended use is unchanged with the proposed modifications and remains the same as that previously cleared under the respective 510(k)s.

Indications for Use:

1. The Medtronic Torqr catheter is intended for use in diagnostic electrophysiologic procedures. The catheter is designed for recording intracardiac electrograms and temporary pacing associated with electrophysiology studies.
2. The Medtronic Soloist catheter is intended for use in diagnostic electrophysiologic procedures. The catheter is designed for recording intracardiac electrograms and temporary pacing associated with electrophysiology studies.

The indications for use are unchanged with the proposed modifications and remains the same as those previously cleared under the respective 510(k)s.

Comparison of Technological Characteristics:

The following changes are being implemented as part of this premarket notification:

Labeling Changes:

- Inclusion of updated storage and transit condition information
- General symbol updates, formatting and grammatical changes
- Inclusion of contraindication and adverse event information
- Various additional changes as part of general labeling improvements

Packaging Changes:

- Relocation of labeling from shelf carton to product labels
- New label stocks for product labels and warranty document
- Addition of a protective paperboard sleeve insert
- Addition of a seal label and packaging tape to the shelf carton

Product Requirement Changes:

This premarket notification includes updates to the following Product Requirement Specifications (PRS):

PRS Attribute	Impacted Products
Product Requirements	
Biocompatibility	All
Corrosion Resistance	All
Visual – Foreign Material and Defects	All
Visual - Butt Joint Inspection	All
Visual – Band Electrodes	All
Visual – Tip Assembly	All
Visual - Lot Number	All
Catheter Outer Diameter	All
Electrode Band Spacing	All
Working Length	All
Connector to Shaft Pull Test	Torqr Intracardiac Electrode Catheter
Band and Tip DC Resistance	All
Connector Interface Requirements	All
Packaging Requirements	
Packaging configuration	Torqr Intracardiac Electrode Catheter
Traceability	All
Material Sterilization Compatibility	All
Packaging Performance	All
Sterile Barrier Integrity	All
Seal Strength	All
Shelf Life Format	All
Lot Number Identification	All
Storage and Shipping Conditions	All

While this premarket notification covers changes to labeling, packaging design and materials, and product requirement specifications, there are no changes to the finished diagnostic catheter designs or materials. The manufacturing processes and inspections related to diagnostic catheter assemblies are also remaining unchanged. Compared to the predicate, the subject device features the:

- **Same intended use**

- **Same indications for use**
- **Same fundamental scientific technology**
- **Same finished catheter design and dimensions**
- **Same user interface**
- **Same materials of construction**
- **Same manufacturing and sterilization processes**

The differences between the subject and predicate devices involve labeling, packaging, and product requirements only. The subject device design technology, performance characteristics, materials, shelf life and sterilization process are all unchanged.

The proposed changes do not constitute a change in the fundamental scientific technology for the subject devices and do not raise new or different questions of safety and effectiveness. The subject devices do not provide a new therapy, and the intended use and indications for use remain unchanged and identical to the predicates. The modified subject devices described in this 510(k) submission are substantially equivalent to the predicate devices.

Performance Data:

Performance testing (bench) was completed in support of the proposed modifications. The results of the design verification testing completed in support of the proposed changes demonstrate that all diagnostic catheters in scope of this premarket notification meet all applicable proposed product requirements.

To support the proposed product requirement changes in this premarket notification, the following tests were performed on test samples exposed to accelerated aging conditions equivalent to the product shelf life of 2 years:

Product Requirement Testing:

- Corrosion resistance testing
- Visual inspections
- Electrode band spacing measurement
- Catheter shaft dimensional measurements
- Catheter tensile testing
- Electrical resistance testing

Packaging Requirement Testing:

- Visual inspections
- Sterilization pre-conditioning

- Environmental pre-conditioning
- Label legibility testing
- Label durability testing
- Bubble leak testing

Conclusion: This premarket notification is limited to labeling, packaging design and materials, and product requirement specifications for Medtronic diagnostic catheters. There are no changes to the intended use, indications for use, performance, or fundamental scientific technology, and the subject devices are considered substantially equivalent to the legally marketed predicate devices.