December 2, 2023

Medtronic, Inc.
Karine Lortie
Sr Principal Regulatory Affairs Specialist
8200 Coreal Sea Street NE, MVS3
Mounds View, Minnesota 55112

Re: K233397
Trade/Device Name: Cosine-10™ Diagnostic Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: DRF
Dated: October 2, 2023
Received: October 3, 2023

Dear Karine Lortie:

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.

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,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K233397

Device Name

Cosine-10TM Diagnostic Catheter

Indications for Use *(Describe)*

The Cosine-10 Diagnostic Catheter is indicated for electrophysiological mapping (stimulation and recording) of cardiac structures, including in the coronary sinus.

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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15.0 510(k) Summary

Date Summary Prepared:	October 02, 2023
Applicant:	Medtronic, Inc. 8200 Coral Sea Street NE Mounds View, MN U.S.A. 55112 1.800.328.2518 Establishment Registration No. 3001504994
Official Correspondent:	Karine Lortie Senior Principal Regulatory Affairs Specialist 514.242.5882 karine.lortie@medtronic.com
Device Trade Name and Model:	Cosine-10™ Diagnostic Catheter
Common Name:	Electrophysiology Catheter
Classification Name:	Electrode Recording Catheter
Classification & Panel:	Class II, 21 CFR 870.1220, Cardiovascular
Product Code:	DRF
Predicate Device:	DECANAV Mapping Catheter (K231312)
Device Description:	The Cosine-10 Diagnostic Catheter is a sterile, single-use, steerable decapolar mapping catheter with a bidirectional deflecting tip intended for electrophysiological mapping of cardiac structures (i.e., stimulation and recording). The catheter contains 10 electrodes spaced in 5 pairs, including a distal dome electrode. Two electrode spacing configurations are available: 2-8-2 (AFR-00017) or 2-5-2 (AFR-00018). All catheter electrodes may be used for recording or stimulation. The catheter can be used with a compatible introducer sheath (7.5Fr minimum).
Intended Use:	The Cosine-10 Diagnostic Catheter is intended for electrophysiological mapping of cardiac structures
Indications for Use:	The Cosine-10 Diagnostic Catheter is indicated for electrophysiological mapping (stimulation and recording) of cardiac structures, including in the coronary sinus

Comparison of Technological Characteristics:

There are no significant differences in the fundamental scientific technology between the predicate and subject devices for the proposed intended use and indications for use. The subject and predicate devices have the same or similar underlying technological characteristics. Both devices are deflectable decapolar diagnostic catheters that utilize electrodes along a deflectable shaft section for intracardiac mapping and stimulation.

The Cosine-10 catheter features the following similarities with the predicate device:

- Same intended use
- Same fundamental scientific technology (deflectable decapolar mapping catheter)
- Same catheter outer diameter
- Similar catheter effective length

The differences in technological characteristics involve the following:

- Presence of magnetic sensor(s) in the predicate device for compatibility with 3D mapping and navigation system
- Deflection type (predicate is unidirectional and subject device is bidirectional)
- Additional electrode spacing pattern configuration available with the subject device

Differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness. The absence of magnetic sensor(s) in the subject device has no impact on safety and effectiveness of the device for its proposed intended use and indications for use (electrophysiological mapping of cardiac structures, i.e., stimulation and recording).

Safety and Performance Data:

Safety and performance testing applicable to the subject device was completed to ensure it performs as intended per product specifications and requirements/user needs. The following testing has been completed in support of the Cosine-10 Diagnostic Catheter, and all acceptance criteria were met in accordance with appropriate standards:

- Sterilization validation and adoption
- Biocompatibility
- Design verification
- Packaging validation
- Design validation

- Pre-clinical animal testing

No questions of safety or effectiveness are raised as a result of the testing. The subject device is as safe and effective as the predicate device and the subject device is considered substantially equivalent to the predicate device.

Conclusion:

The subject and predicate devices share the same intended use and have the same or similar underlying technological characteristics. Both devices are deflectable decapolar diagnostic catheters that utilize electrodes along a deflectable shaft section for intracardiac mapping and stimulation. Differences between the subject and predicate devices do not raise different questions of safety and effectiveness and safety and performance testing supports that the subject device is as safe and effective as the predicate. The subject device is considered substantially equivalent to the predicate device.