March 23, 2023

Medtronic, Inc.
Aditi Dave
Senior Regulatory Affairs Specialist
2300 Berkshire Lane North
Plymouth, Minnesota 55441

Re: K223488
Trade/Device Name: ClosureFast™ Endovenous Radiofrequency Ablation (RFA) Catheter
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 22, 2022
Received: December 23, 2022

Dear Aditi Dave:

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 Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.03.23 10:40:48 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control 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.

510(k) Number *(if known)*
K223488

Device Name
ClosureFast™ Endovenous Radiofrequency Ablation (RFA) Catheter

Indications for Use *(Describe)*
The ClosureFast catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

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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Medtronic, Inc.
Peripheral Vascular Health
2300 Berkshire Lane North
Plymouth, MN 55441

Traditional 510(k) Summary
ClosureFast Catheter

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.
Applicant/ Submitter	Medtronic, Inc. 2300 Berkshire Lane North Plymouth, MN 55441
Contact Person	Aditi Dave Senior Regulatory Affairs Specialist Tel: 763-398-7029 Email : aditi.b.dave@medtronic.com
Secondary Contact Person	Laura Moen-Ftacek Regulatory Affairs Director Tel : 763-398-7359 Email : laura.moen-ftacek@medtronic.com
Date Prepared	March 21, 2023
Device Trade Name	ClosureFast™ Endovenous Radiofrequency Ablation Catheter
Device Common Name	Electrosurgical Device
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number	21 CFR 878.4400
Classification	Class II
Classification Panel	General & Plastic Surgery
Product Code	GEI

Medtronic, Inc.
Peripheral Vascular Health
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Predicate Device	ClosureFast™ Radiofrequency Catheter, Models CF7-7-60, CF7-7-100 and CF7-3-60
Predicate 510(k) Number	K061373 and K111887
Predicate Regulation Number	21 CFR 878.4400
Indications for Use	The ClosureFast catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.
Device Description	The ClosureFast™ Radio Frequency Ablation catheter is a sterile, single use, disposable device with an integrated connection cable. The catheter has a 6F profile with a heating element (coil) 8 cm in length and 2.00 mm in diameter. It is available in two working lengths, 60 cm and 100 cm. A single-use limiter feature is added in the Printed Circuit Board Assembly (PCBA) housed inside the handle of the device. It establishes an effective treatment window of 2 hours after the first energy cycle. The catheter's function is to provide thermal energy to the desired treatment site via radiofrequency heating of the catheter heating element. The ClosureFast catheter is designed to be used with the ClosureRFG™ Radiofrequency Generator.
Comparison of Technological Characteristics:	The proposed device has the same characteristics as the predicate devices, with the exception of the following design modifications: • Heating element dimensions (length/diameter) • Catheter Index Mark spacing • Addition of bridge tube • Addition of Single Use Limiter • Instructions for use updates **Table 1** below outlines the comparison in technological characteristics between the predicate and proposed device that are not identical but are considered substantially equivalent.

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Table 1: Comparison between proposed and predicate device

Parameters	Proposed Device	Predicate Device	
Introducer Sheath Compatibility	6F	7F	
Heating Element Length	8 cm	7 cm	3 cm
Heating Element Diameter	2.00 mm	2.3 mm	
Catheter Markings	7.5 cm	6.5 cm	2.5 cm
Bridge Tube	Yes, new component	N/A	
Single Use Limiter	Yes, new component	N/A	
Instructions for Use (IFU) (specifications)	Paper IFU (8.5" x 11" saddle stitch) and eIFU leaflet (3.5'' x 3.5'' folded)	Paper IFU (4" x 9.94" Map fold)	

Performance data

To demonstrate substantial equivalence of the proposed device to the predicate device, the following design verification and validation testing was performed:

- Mechanical
- Dimensional
- Mechanical / Tensile Strength
- Electrical
- Environmental
- Simulated Use
- Packaging Verification
- Software Verification and Validation
- Usability
- Benchtop Validation
- Sterilization Validation
- Biocompatibility

Test results demonstrate that the proposed ClosureFast catheter meets acceptance criteria and performance requirements and is acceptable for its intended use.

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Summary of Substantial Equivalence

The proposed device has the following equivalencies to the predicate device:

- Intended Use
- Indications for Use
- Principle of Operation
- Fundamental scientific technology
- Materials of construction
- Compatibility to ClosureRFG™ Radiofrequency Generator
- Packaging materials
- Sterilization method

The proposed device modifications do not impact the overall safety and effectiveness of the device. There are no new risks identified or significantly modified existing risks are identified due to these device modifications.

Conclusion

Based on the same intended use, technological characteristics, safety and performance testing included in the submission, Medtronic concludes the proposed ClosureFast Catheter to be substantially equivalent to the predicate ClosureFast Catheters.