December 15, 2021

Medtronic, Inc.
Laura Hanson
Regulatory Affairs Specialist
2300 Berkshire Lane North, Suite 5
Plymouth, Minnesota 55441

Re: K213631
Trade/Device Name: Chocolate PTA Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT
Dated: November 15, 2021
Received: November 17, 2021

Dear Laura Hanson:

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,

For

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213631

Device Name

Chocolate PTA Balloon Catheter

Indications for Use *(Describe)*

The Chocolate PTA Balloon Catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, and infra-popliteal arteries.

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

Special 510(k) Summary
Chocolate PTA Balloon Catheter

510(k) Summary	This summary is being submitted in accordance with the requirements of 21 CFR § 807.92.
Applicant/ Submitter	Medtronic, Inc. 2300 Berkshire Lane North, Suite 5 Plymouth, MN 55441 Tel: 763-591-3024
Contact Person	Laura Hanson Regulatory Affairs Specialist Tel: 763-591-3024 Email: laura.r.hanson@medtronic.com
Secondary Contact Person	Brandon Casa de Calvo Regulatory Affairs Senior Manager Tel: 763-591-3024 Email: brandon.m.casa.de.calvo@medtronic.com
Date Prepared	November 9, 2021
Device Trade Name	Chocolate PTA Balloon Catheter
Submission 510(k) Number	K213631
Device Common Name	Angioplasty Catheter
Classification Name	Percutaneous catheter, Cardiovascular
Regulation Number	21 CFR 870.1250
Classification	Class II
Classification Panel	Cardiovascular
Product Code	LIT
Primary Predicate Device	Chocolate PTA Balloon Catheter
Primary Predicate 510(k) Number	K130414

Primary Predicate Regulation Number	21 CFR 870.1250
Indications for Use	The Chocolate PTA balloon catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, and infra-popliteal arteries.
Device Description	The Chocolate PTA Balloon Catheter is an "over-the-wire" balloon dilatation catheter with a braided shaft and an atraumatic tapered tip. The product family consists of 0.014" and 0.018" systems that are compatible with 0.014" and 0.018" guidewires, respectively. Overall catheter lengths range from 120-150 cm. The distal end of the catheter has a semi-compliant balloon that expands to known diameters at specific pressures. The balloon is constrained by a nitinol constraining structure (CS) which provides fast deflation and uniform re-wrap. Upon deflation, the CS is removed from the vessel along with the balloon catheter. The balloon is available in multiple sizes and contains two radiopaque markers to assist with positioning. The proximal end of the device is a common balloon catheter design of a braided shaft connected to a plastic hub and strain relief. The hub has two ports; the balloon port is used to inflate the balloon and the guidewire port connects to the guidewire lumen. The Chocolate PTA balloon catheter is intended for single-use only and is provided sterile and non-pyrogenic.
Comparison of Technological Characteristics	The subject Chocolate PTA Balloon Catheter components will have minor changes to the materials used which are equivalent to the materials used in the predicate device. These material changes are being implemented alongside supplier changes to ensure a more robust supply chain. Additionally, in order to support EU MDR requirements, Chocolate's IFU is being changed in size and stitching to accommodate additional global language requirements with a change to eliminate renal arteries from the indications for use. The subject Chocolate device shares the following technological characteristics with the predicate device. These characteristics are considered identical between the subject and predicate. • Intended Use • Principle of Operation • Balloon technical specifications including available diameters, lengths, materials, radiopaque markers, rated burst pressure, nominal pressure and constraining structure material • Catheter technical specifications including available lengths, guidewire compatibility, introducer compatibility, and all materials except for the inner member component materials listed in Table 7.1. • Packaging materials • Testing and Compliance to ISO 10993 and ISO 11135-1

- Sterilization Method

Table 7.1 below outlines the characteristics between the predicate and subject Chocolate PTA Balloon Catheters that are not identical but are considered similar and equivalent.

Table 7.1: Chocolate PTA Balloon Catheter Predicate to Subject Equivalencies

	Predicate Device	**Subject Device**
Device Name	Chocolate PTA Balloon Catheter (Primary Predicate)	Chocolate PTA Balloon Catheter
Indications for Use	The Chocolate®* PTA Balloon Catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries.	The Chocolate™* PTA balloon catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, and infra-popliteal arteries.
Inner Member component - outer layer resin	**Resin Change** Inner Member materials: Outer layer • NY-L25 Grilamid (Grilamid L25 natural) • Colorant 833125 Transblue FDA Inner layer • PE-LR734 HDPE LR7340-01 Petrothene High Density Intermediate layer (tie-layer) PE-Orevac 18300	**Resin Change** Inner Member materials: Outer layer • NY-L25 Grilamid (Grilamid L25 natural) Inner layer • PE-LR734 HDPE LR7340-02 Petrothene High Density Intermediate layer (tie-layer) PE-Orevac 18300M
IFU (specifications)	Folded & stapled 8.5” x 11.0”	Saddle stitch booklet 10” x 10”
Compliance Card	5.0” x 6.0”	4.0” x 5.0” Artwork Update
Pouch Label (dimensions)	6.25” x 8.5”	6.38” x 8.00”
Carton Label (dimensions)	6.25” x 10.40”	6.61” x 8.75”

Performance data Due to the physical differences between the subject device IFU and predicate device IFU, the subject Chocolate PTA Balloon Catheter underwent packaging validation, packaging aging, and sterilization testing with a 72-page IFU and eIFU leaflet to resemble worst-case packaging configuration. This 72-page test IFU and eIFU leaflet exceeds the size of the IFU and eIFU leaflet in the subject device. All units passed their respective testing requirements and no additional risks resulted from the changes to the IFU. Medtronic is also performing 3-year real-time aging tests to confirm the accelerated aging results. See

Section 16, Table 16.2 for a summary of completed testing for the subject Chocolate PTA Balloon Catheter IFU changes.

The proposed changes in this submission do not require a change in the sterilization process or equipment (sterilization assurance level: 10^{-6}). Due to successfully completing the testing described in section 15.3.8, it was determined that no sterilization process changes are required due to the proposed changes.

To support the safety and performance of the subject Chocolate PTA Balloon Catheter device, new biocompatibility testing was completed in report D00557778, *Biocompatibility Evaluation Report for Chocolate PTA Balloon Catheter for Supplier and Material Changes*. The subject Chocolate PTA Balloon Catheter was subjected to the following biocompatibility testing:

- Cytotoxicity
- Sensitization
- Irritation/intracutaneous reactivity
- Acute systemic toxicity
- Material mediated pyrogenicity
- Hemocompatibility testing

Based on the biocompatibility data gathered, it was concluded that the subject Chocolate PTA balloon catheter, as guided by ISO 10993-1:2018, passed the required tests and does not present a patient health hazard. As a result of this testing and the associated risk analysis, it was determined that there are no new or increased biocompatibility concerns.

The technological characteristics and performance criteria of the Chocolate PTA Balloon Catheter are equivalent to the predicate device, and the subject device performs in a manner equivalent to the predicate device currently on the market.

Conclusion Based on the intended use, technological characteristics, device design, operating principle, shelf-life testing, packaging validation and sterilization testing, Medtronic concludes the subject Chocolate PTA Balloon Catheter to be substantially equivalent to the predicate Chocolate PTA Balloon Catheter, K130414.