April 23, 2019

Medtronic, Inc.
Breanna Hessler
Regulatory Affairs Specialist
3033 Campus Drive, Suite N550
Plymouth, MN 55441

Re: K190753
Trade/Device Name: EverCross™ 0.035" OTW PTA Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: March 22, 2019
Received: March 25, 2019

Dear Ms. Hessler:

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 Hajira F. Ahmad -S
Digitally signed by Hajira F. Ahmad -S
Date: 2019.04.23 14:25:19 -04'00'

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)*
K190753

Device Name
EverCross™ 0.035" OTW PTA Dilatation Catheter

Indications for Use *(Describe)*
The EverCross 0.889 mm (0.035 in) OTW PTA Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

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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510(k) Summary

K190753

EverCross™ 0.035" OTW PTA Dilatation Catheter

510(k) Summary	This 510(k) summary is being submitted in accordance with the requirements of 21 C.F.R § 807.92.
Applicant/ Submitter	Medtronic, Inc. 3033 Campus Drive Plymouth, MN 55441-2651 Tel: 763-398-7000
Contact Person	Breanna Hessler Regulatory Affairs Specialist Tel: 763-591-3530 Email: Breanna.Hessler@medtronic.com
Date Prepared	March 22, 2019
Device Trade Name	EverCross™ 0.035" OTW PTA Dilatation Catheter
Device Common Name	PTA Dilatation Catheter
Classification Name	Percutaneous catheter, Cardiovascular
Regulation Number	21 CFR 870.1250
Classification	Class II
Classification Panel	Cardiovascular
Product Code	LIT, DQY
Predicate Device	EverCross™ .035" OTW PTA Dilatation Catheter (K110319)

EverCross™ 0.035" OTW PTA Dilatation Catheter 510(k) Summary

Reference Device

Fortrex™ 0.035" OTW PTA Balloon Catheter (K142654)

Indications for Use

The EverCross 0.889 mm (0.035 in) OTW PTA dilatation catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

Device Description

EverCross 0.035" OTW PTA Dilatation Catheter is an over the wire (OTW) 0.035" dual lumen catheter with a distally mounted semi-compliant balloon and an atraumatic tapered tip. The distal portion of the catheter, proximal to the balloon, has a hydrophilic coating.

The manifold includes a lumen marked "THRU". This is the central lumen of the catheter, which terminates at the distal tip. This lumen is used to pass the catheter over a guidewire with a maximum diameter of 0.035". The lumen marked "BALLOON" is the balloon inflation lumen, which is used to inflate and deflate the dilatation balloon. The balloon has two radiopaque markers for positioning the balloon relative to the stenosis. The radiopaque marker bands indicate the dilating or working section of the balloon.

The EverCross 0.035" OTW PTA Dilatation Catheter is available in multiple balloon sizes and three catheter working lengths. Nominal balloon diameter and length are printed on the strain relief.

Performance data

To demonstrate substantial equivalence of the subject device, the EverCross™ 0.035" OTW PTA Dilatation Catheter to the predicate and reference devices, the technological characteristics and performance criteria were evaluated. Using FDA Guidance Documents "Deciding When to Submit a 510(k) for a Change to an Existing Device" and "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters" on non-clinical testing of medical devices and internal Risk Analysis procedures, the following in vitro tests were performed:

- Kink
- Kink Extreme
- Inflation time
- Deflation Time/ No deflate
- Trackability
- Manifold Bond Tensile
- Torque to Failure

The results from these tests demonstrate that the technological characteristics and performance criteria of the EverCross™ 0.035" OTW PTA Dilatation Catheter are comparable to the predicate and reference devices, and that the subject device performs in a manner equivalent to the predicate and reference devices currently on the market for the same intended use.

Summary of Substantial Equivalence

The subject EverCross™ 0.035" OTW PTA Dilatation Catheter has the following equivalencies to the predicate device:

- Intended use
- Indications for use
- Fundamental scientific technology
- Operating principle
- Materials of construction
- Balloon design and rated burst pressure
- Sterilization method

Conclusion

Based on the intended use, technological characteristics and performance testing included in this submission and in previously cleared submissions for this product, Medtronic concludes the EverCross 0.035" OTW PTA Dilatation Catheter to be substantially equivalent to the EverCross .035" OTW PTA Dilatation Catheter, K110319 (predicate) and Fortrex™ 0.035" OTW PTA Balloon Catheter, K142654 (reference).