November 18, 2020

Medtronic Vascular, Inc (formerly d.b.a ev3 Inc., Covidien llc)
Rupali Gupta
Principal Regulatory Specialist
3033 Campus Drive
Maple Grove, Minnesota 55441

Re: K202800
Trade/Device Name: Pacific Plus PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: September 21, 2020
Received: September 23, 2020

Dear Rupali Gupta:

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,

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)*
K202800

Device Name
Pacific Plus PTA Catheter

Indications for Use *(Describe)*
The Pacific Plus PTA Catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent postdilatation in the peripheral 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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510(k) Summary

Pacific™ Plus PTA Catheter

This 510(k) Summary is being submitted in accordance with the requirements of 21 C.F.R § 807.92.

1. Submitter Information

Applicant	Medtronic, Inc 710 Medtronic Parkway Minneapolis, MN 55432 Tel: 763-514-4000
Contact Person	Rupali Gupta Principal Regulatory Affairs Specialist Tel: 763-398-7000
Date Prepared	September 21, 2020

2. Subject Device

Device Trade Name	Pacific Plus PTA Catheter
Device Common Name	Catheter, Angioplasty, Peripheral, Transluminal
Classification Name	Percutaneous Catheter
Product Code	LIT
Classification	Class II
Classification Panel & Regulation Number	Cardiovascular 21 CFR§870.1250

3. Predicate Device

Device Trade Name	Pacific Plus PTA Catheter (Primary Predicate)
510(k) Number	K123358
510(k) Clearance Date	January 29, 2013

4. Reference Devices

Device Trade Name	PowerCross .018” OTW PTA Dilatation Catheter
510(k) Number	K093286
510(k) Clearance Date	November 13, 2009
Device Trade Name	Pacific Xtreme PTA Balloon Dilatation Catheter
510(k) Number	K103464

510(k) Clearance Date	December 22, 2010
Device Trade Name	Ultraverse 018 PTA Balloon Dilatation Catheter
510(k) Number	K192318
510(k) Clearance Date	October 3, 2019

5. Device Description

The Pacific Plus PTA catheter is an Over the Wire (OTW) peripheral balloon catheter, specifically designed for percutaneous transluminal angioplasty (PTA) in stenosed vessel segments. The OTW catheter is used to guide the balloon to the stenosed vessel segment. The balloon is then inflated to dilate the vessel.

The catheter is a coaxial dual lumen device. The lumen marked "WIRE" 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 outer diameter of 0.018 in (0.46 mm). The lumen marked "BALLOON" is the balloon inflation lumen, which is used to inflate and deflate the dilatation balloon with a mixture of contrast medium and saline solution.

The Pacific Plus PTA catheter is available in balloon diameters 4.0 mm - 7.0 mm, and balloon lengths from 20 mm to 300 mm, with 90 cm, 150 cm, and 200 cm catheter lengths. The distal section of the catheter includes a lubricious hydrophilic coating.

6. Indications for Use

The Pacific Plus PTA catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The device is also indicated for stent postdilatation in the peripheral arteries.

7. Comparison of Technological Characteristics with Predicate Device

The Pacific Plus PTA Catheter uses similar design and materials as the predicate device. Modifications have been made to the Pacific Plus PTA Catheter design and materials to accommodate expanded product size offerings. The overall design and fundamental scientific technology (operating principle or mechanism of action) of the subject device are the same as the predicate device. All devices are used by the physician in a similar manner typical of a PTA balloon catheter.

The proposed and predicate devices share the following technological characteristics:

- Same intended use
- Similar indications for use
- Same fundamental scientific technology

- Same principles of operation
- Similar balloon diameters
- Similar balloon lengths
- Similar rated burst pressure
- Same lubricious coating
- Similar packaging materials
- Same sterility assurance level and method of sterilization

8. Performance Data

To demonstrate substantial equivalence of the Pacific Plus PTA Catheter to the predicate and reference devices, bench testing and biocompatibility evaluation was performed. Results from these testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.

Performance Bench Testing
Using internal risk analysis procedures, the following performance tests were performed:

- Dimensional Verification
- Balloon Preparation, Deployment and Retraction
- Balloon Rated Burst Pressure
- Balloon Fatigue
- Balloon Compliance
- Balloon Inflation/Deflation Time
- Catheter Bond Strength and tip pull test
- Catheter Flexibility and Kink Test
- Catheter Torque Strength
- Catheter coating Integrity
- Particulate Evaluation

The results from these tests demonstrate that the technological characteristics and performance criteria of the Pacific Plus PTA Catheter devices are comparable to the predicate and reference devices and that the Pacific Plus PTA Catheter performs in a manner equivalent to the predicate and reference devices currently on the market with the same intended use.

Biocompatibility Testing
The biocompatibility evaluation for the Pacific Plus PTA Catheter was conducted in accordance with the principles of the ISO 10993-1:2018, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process and FDA guidance: Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, Sept 2010 and CDRH's 2016 Biocompatibility Guidance, Use of International Standard ISO 10993-1, Biological

evaluation of medical devices-Part 1: Evaluation and testing within a risk management process as recognized by FDA.

The biocompatibility testing included the following tests:

- Cytotoxicity
- Pyrogenicity
- Systemic Toxicity
- Sensitization
- Intracutaneous Reactivity (irritation)
- Haemocompatibility –Hemolysis
- Haemocompatibility –Complement Activation
- Haemocompatibility –Partial Thromboplastin Time (PTT)
- Haemocompatibility – Thromboresistance

The Pacific Plus PTA Catheter is considered biocompatible for its intended use under ISO 10993-1 category: externally communicating device, circulating blood contact with limited (<24 hour) exposure.

9. Conclusions

Based on the same intended use, similar indications for use, similar technological characteristics, and safety and performance data, Medtronic Vascular, Inc considers the Pacific Plus PTA Balloon Catheter substantially equivalent to the legally marketed predicate device (Pacific Plus, K123358) and reference devices (PowerCross, K093286, Pacific Xtreme, K103464 and Ultraverse, K192318).