August 24, 2018

Abbott Vascular
Emily Zhao
Principal Regulatory Project Manager
3200 Lakeside Drive
Santa Clara, California 95054

Re: K180040
Trade/Device Name: NC TREK™ RX Coronary Dilatation Catheter; NC TREK™ OTW Coronary Dilatation Catheter; TREK™ RX Coronary Dilatation Catheter; TREK™ OTW Coronary Dilatation Catheter; MINI TREK™ RX Coronary Dilatation Catheter; MINI TREK™ OTW Coronary Dilatation Catheter; MINI TREK™ II OTW Coronary Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: August 5, 2018
Received: August 7, 2018

Dear Ms. Emily Zhao:

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 Gregory O'Connell
2018.08.24 11:56:50 -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)*
K180040

Device Name
NC TREK™ RX Coronary Dilatation Catheter; NC TREK™ OTW Coronary Dilatation Catheter; TREK™ RX Coronary Dilatation Catheter; TREK™ OTW and MINI TREK™ OTW Coronary Dilatation Catheter; MINI TREK™ RX Coronary Dilatation Catheter; and MINI TREK™ II OTW Coronary Dilatation Catheter

Indications for Use *(Describe)*
The NC TREK RX Coronary Dilatation Catheter is indicated for:
a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion;
b) balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction;
c) balloon dilatation of a stent after implantation (balloon models 2.0 mm – 5.0 mm only).

The NC TREK OTW Coronary Dilatation Catheter is indicated for:
a) Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion;
b) Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction;
c) Balloon dilatation of a stent after implantation (balloon models 2.00 mm – 5.00 mm only)

The TREK RX Coronary Dilatation Catheters are indicated for:
a) Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion;
b) Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction;
c) Balloon dilatation of a stent after implantation.

The TREK OTW and MINI TREK OTW Coronary Dilatation Catheter is indicated for:
a) Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion;
b) Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction;
c) Balloon dilatation of a stent after implantation (balloon models 2.00 mm –5.00 mm only).

The MINI TREK RX Coronary Dilatation Catheters are indicated for:
a) Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion;
b) Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction;
c) Balloon dilatation of a stent after implantation (balloon models 2.00 mm only);
d) Balloon dilatation of de novo chronic total coronary occlusions (CTO).

The MINI TREK II OTW Coronary Dilatation Catheter is indicated for:
a) Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion;
b) Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction (MI);
c) Balloon dilatation of a stent after implantation (balloon models 2.00 mm only);
d) Balloon dilatation of de novo chronic total coronary occlusions (CTO).

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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K180040 – 510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR 807.92 and the requirements of the Safe Medical Device Act (SMDA) of 1990.

1. SUBMITTER'S NAME Abbott Vascular

2. SUBMITTER'S ADDRESS 3200 Lakeside Drive, Santa Clara, CA 95054

3. TELEPHONE (408) 845-3000

4. FAX (408) 845-3743

5. CONTACT PERSON Emily Zhao

6. DATE PREPARED August 7, 2018

7. DEVICE TRADE NAME

NC TREK™ RX Coronary Dilatation Catheter
NC TREK™ OTW Coronary Dilatation Catheter
TREK™ RX Coronary Dilatation Catheter
TREK™ OTW Coronary Dilatation Catheter
MINI TREK™ RX Coronary Dilatation Catheter
MINI TREK™ OTW Coronary Dilatation Catheter
MINI TREK™ II OTW Coronary Dilatation Catheter

8. DEVICE COMMON NAME

- Coronary Dilatation Catheter
- Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter

9. DEVICE CLASSIFICATION NAME PTCA Catheter, LOX, Class II

10. PREDICATE DEVICE NAME

NC TREK™ RX Coronary Dilatation Catheter	K103153, K110134
NC TREK™ OTW Coronary Dilatation Catheter	K113464
TREK™ RX Coronary Dilatation Catheter	K103110, K110671, K123279
TREK™ OTW Coronary Dilatation Catheter	K103110, K110671, K121222, K123279
MINI TREK™ RX Coronary Dilatation Catheter	K103110, K110671, K123279

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MINI TREK™ OTW Coronary Dilatation Catheter	K103110, K110671, K121222, K123279
MINI TREK™ II OTW Coronary Dilatation Catheter	K121222

11. DEVICE DESCRIPTION

There are no design, materials, including colorants, manufacturing processes, or indications changes to the TREK family (TREK RX, MINI TREK RX, TREK OTW, MINI TREK OTW, MINI TREK II OTW, NC TREK RX, and NC TREK OTW) Coronary Dilatation Catheters. The intended use of the devices remains the same, as the changes are only to labeling and IFUs.

11.1 NC TREK RX Device Description

The NC TREK RX Coronary Dilatation Catheter (CDC) is a medical device that is intended for use in percutaneous transluminal coronary angioplasty (PTCA) to treat patients with coronary artery disease as specified in the indications section of the instructions for use.

The catheter is a rapid exchange co-axial design with a balloon at the distal tip. The proximal lumen provides for inflation of the balloon with contrast medium. The central distal lumen permits the guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated.

The balloon has radiopaque markers to aid in positioning the balloon in the stenosis, and is designed to provide an expandable segment of known diameter and length at specified pressures.

Proximal shaft markers located on the outer shaft aid in gauging the dilatation catheter position relative to the guiding catheter tip when introducing the catheter through the guiding catheter.

An adaption arm is provided on the proximal end of the catheter to provide access to the inflation lumen. It is designed with a Luer - lock fitting for connection with an inflation device.

11.2 NC TREK OTW Device Description

The NC TREK OTW Coronary Dilatation Catheter (CDC) is a medical device that is intended for use in percutaneous transluminal coronary angioplasty (PTCA) to treat patients with coronary artery disease as specified in the indications section of the instructions for use. NC TREK OTW

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is an over-the-wire co-axial design with a balloon at the distal tip. The outer lumen provides for inflation of the balloon with contrast medium. The inner lumen permits the guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated.

The device has dual radiopaque markers to aid in positioning the balloon in the stenosis, and is designed to provide an expandable segment of known diameter and length at specified pressures.

The annular space between the outer member and the inner lumen provides a fluid path from the side arm adaptor to the balloon. The distal portion of the catheter is coated with a hydrophilic coating. The inner lumen of the inner member is coated with Microglide.

Proximal shaft markers located on the outer shaft aid in gauging the dilatation catheter position relative to the guiding catheter tip when introducing the catheter through the guiding catheter.

A side arm adaptor is provided on the proximal end of the catheter to provide access to the inflation lumen and the guide wire lumen. It is designed with a luer - lock fitting for connection with an inflation device.

11.3 TREK RX and MINI TREK RX Device Description

The TREK and MINI TREK RX (CDC) are medical devices intended for use in percutaneous transluminal coronary angioplasty (PTCA) to treat patients with coronary artery disease as specified in the indications section of the instructions for use. They are both rapid exchange coaxial designs with a balloon at the distal tip. The MINI TREK sizes range from 1.20x6mm through 2.00x30mm. The TREK sizes range from 2.25x6mm through 5.00x15mm. The proximal lumen provides for inflation of the balloon with contrast medium. The central distal lumen permits the guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated.

Balloon markers aid in positioning the balloon in the stenosis, and are designed to provide an expandable segment of known diameter and length at specified pressures. The following table describes the number of radiopaque markers by balloon diameter and length.

Balloon size	Balloon lengths	Number of markers
1.20 – 1.5mm	6mm to 20mm	One (center of balloon)
2.0mm to 4.0mm	6mm	One (center of balloon)
2.0mm to 5.0mm	8mm to 30mm	Two markers

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Proximal shaft markers located on the outer shaft aid in gauging the dilatation catheter's position relative to the guiding catheter tip when introducing the dilatation catheter through the guiding catheter.

An adaption arm is provided on the proximal end of the dilatation catheter to provide access to the inflation lumen. It is designed with a luer-lock fitting for connection with an inflation device. The annular space between the distal outer member and the central distal lumen provides a fluid path from the proximal lumen to the balloon. The shaft of the catheter, the tip, and tapers of the balloon are coated with a hydrophilic coating. The inner lumen of the inner member is coated with Microglide.

11.4 TREK OTW, MINI TREK OTW Device Description

The TREK OTW, MINI TREK OTW, and MINI TREK II OTW Coronary Dilatation Catheters (CDC) are medical devices intended for use in percutaneous transluminal coronary angioplasty (PTCA) to treat patients with coronary artery disease as specified in the indications section of the instructions for use. The TREK OTW family are over-the wire co-axial design catheters with a balloon at the distal tip. The MINI TREK OTW sizes range from 1.20x6mm through 2.00x30mm. The MINI TREK II OTW sizes range from 1.20x6mm through 2.00x20mm. The TREK™ OTW sizes range from 2.25x6mm through 5.00x15mm. The outer lumen provides for inflation of the balloon with diluted contrast medium. The inner lumen permits the guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated.

Balloon markers aid in positioning the balloon in the stenosis, and are designed to provide an expandable segment of known diameter and length at specified pressures. The following table describes the number of radiopaque markers by balloon diameter and length.

Balloon size	Balloon lengths	Number of markers
1.20 – 1.5mm	6mm to 20mm	One (center of balloon)
2.0mm to 4.0mm	6mm	One (center of balloon)
2.0mm to 5.0mm	8mm to 30mm	Two markers (distal and proximal balloon shoulders)

Proximal shaft markers located on the outer shaft aid in gauging the dilatation catheter's position relative to the guiding catheter tip when introducing the dilatation catheter through the guiding catheter.

An adaption arm is provided on the proximal end of the dilatation catheter to provide access to the inflation lumen and the guide wire lumen. It is designed with a luer-lock fitting for connection with an inflation device.

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The annular space between the outer member and the inner lumen provides a fluid path from the side arm adaptor to the balloon. The outer shaft of the catheter, the tip, and tapers of the balloon are coated with a hydrophilic coating. The inner lumen of the inner member is coated with Microglide.

12. INDICATIONS FOR USE

The MINI TREK II OTW Coronary Dilatation Catheter is indicated for:
a) Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion;
b) Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction (MI);
c) Balloon dilatation of a stent after implantation (balloon models 2.00 mm only);
d) Balloon dilatation of de novo chronic total coronary occlusions (CTO).

The MINI TREK RX Coronary Dilatation Catheters are indicated for:
a) Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion;
b) Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction;
c) Balloon dilatation of a stent after implantation (balloon models 2.00 mm only);
d) Balloon dilatation of de novo chronic total coronary occlusions (CTO).

The NC TREK OTW Coronary Dilatation Catheter is indicated for:
a) Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion;
b) Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction;
c) Balloon dilatation of a stent after implantation (balloon models 2.00 mm – 5.00 mm only)

The NC TREK RX Coronary Dilatation Catheter is indicated for:
a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion;
b) balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction;
c) balloon dilatation of a stent after implantation (balloon models 2.0 mm – 5.0 mm only).

The TREK OTW and MINI TREK OTW Coronary Dilatation Catheter is indicated for:
a) Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion;
b) Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction;
c) Balloon dilatation of a stent after implantation (balloon models 2.00 mm –5.00 mm only).

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The TREK RX Coronary Dilatation Catheters are indicated for:
a) Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion;
b) Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction;
c) Balloon dilatation of a stent after implantation.

13. SUBSTANTIAL EQUIVALENCE

The changes proposed in this special 510(k) submission only affect the IFU and the labels. The TREK family devices (TREK RX, MINI TREK RX, TREK OTW, MINI TREK OTW, MINI TREK II OTW, NC TREK RX, and NC TREK OTW) have not been changed. The devices are identical to their relevant predicate devices, with the exception of the updates to the labels and IFUs. The changes to the IFU and labels are being made for consistency across the various balloons and to align with bare metal stent (BMS) and drug eluting stent (DES) instructions for use, as appropriate. Therefore, there is substantial equivalence to the predicate devices.

14. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the device are not affected by the proposed changes. Therefore, technological characteristics remain the same. The predicate device has identical indications, design, materials and manufacturing processes as the devices affected by the IFU changes. The current versions of these products are the predicate devices.

Changes are being made to align IFUs and labels for consistency across all the CDCs and to align, as appropriate, with Abbott Vascular bare metal stent (BMS) and drug eluting stent (DES) system IFUs. Changes will include alignment of clinician instructions, warnings, precautions, contraindications and adverse events sections of the IFUs across all the CDCs and, as appropriate, to align with AV bare metal stent (BMS) and drug eluting stent (DES) system IFUs. Updates are also being made to align with the latest review of the Risk Master List (RML) for CDC products. A review of literature supports that the unprotected left main coronary artery is no longer a contraindication. However, considering the limitation of the available data and the risk associated with the device use in an unprotected left main coronary artery, the following statement has been added in the Warnings section: The safety and effectiveness of the device has not been established in patients with lesions located in an unprotected left main coronary artery. In addition, information required to meet certain EU MDR requirements are also included in the updated IFU and label.

There are no manufacturing, materials, or design changes associated with the updates to the IFU and labels for the TREK family of coronary dilatation catheters.

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Because the changes proposed in this Special 510(k) submission do not present any device changes, the predicate device has identical indications, design, materials and manufacturing processes as the devices affected by the IFU changes. The current versions of these products are the predicate devices.

14. PERFORMANCE DATA

No safety or effectiveness issues were raised by this change, as the change modifies and adds content to the IFU. The performance data that supports the predicate devices remains the same.