June 30, 2022

Abbott Vascular
Nishi Singh
Regulatory Affairs Project Manager
3200 Lakeside Drive
Santa Clara, California 95054

Re: K220634
Trade/Device Name: NC TREK NEO 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: March 3, 2022
Received: March 4, 2022

Dear Nishi Singh:

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)*
K220634

Device Name
NC TREK NEO™ Coronary Dilatation Catheter

Indications for Use *(Describe)*

The NC TREK NEO™ 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 – 5.00 mm only)

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 - K220634

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 (with Business Trade Name as Abbott Medical)
2. SUBMITTER'S ADDRESS	3200 Lakeside Drive, Santa Clara, CA 95054
3. TELEPHONE	(408) 845-3000
4. FAX	(408) 845-3743
5. CONTACT PERSON	Nishi Singh
6. DATE PREPARED	May 31, 2022
7. DEVICE TRADE NAME	NC TREK NEO™ 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 (K180040)
11. REFERENCE DEVICE NAME	Voyager NC (P810046/S226, approved August 21, 2008, P810046/S232, approved Feb 4, 2010, and downgraded to Class II- K103153, cleared December 30, 2010) and NC Emerge Monorail (K141236)

11. DEVICE DESCRIPTION

NC TREK NEO is a Non-Compliant (NC), Rapid Exchange (RX), Coronary Dilatation Catheter (CDC). 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 outside diameter (OD) of the distal end of the device, including the distal shaft, tip, and the balloon are coated with Hydrophilic Coating.

Radiopaque markers are positioned on the inner member underneath the balloon to provide accurate positioning of the balloon in the artery. The balloon 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. The Single arm on proximal end of the device provides access to the inflation lumen. It is designed with a Luer-lock fitting to facilitate connection to an inflation device.

The NC TREK NEO™ Coronary Dilatation Catheter will be available in select combinations of 1.50-6.00mm diameters and 6-25mm lengths.

12. INDICATIONS FOR USE

The NC TREK NEO™ 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 2.00mm – 5.00mm only)

13. SUBSTANTIAL EQUIVALENCE

The NC TREK NEO™ Coronary Dilatation Catheter incorporates substantially equivalent device materials and design, packaging materials and design, manufacturing processes, sterilization process, and the same indications for use and principles of operation as in the Abbott Vascular predicate device:
NC TREK™ RX Coronary Dilatation Catheter (K180040)

Comparison Items	Subject Device – NC TREK NEO™ Coronary Dilatation Catheter	Predicate Device – NC TREK™ RX Coronary Dilatation Catheter	Comparison
Indications for Use	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)	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)	Identical
Classification Name	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter 21 CFR 870.5100 (class II, special control)	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter 21 CFR 870.5100 (class II, special control)	Identical
Product Code	LOX	LOX	Identical
Sterilization method	Sterilization Method: Ethylene Oxide	Sterilization Method: Ethylene Oxide	Identical
Shelf Life	36-month (3 years)	36-month (3 years)	Identical
System Type	Rapid Exchange (RX)	Rapid Exchange (RX)	Identical
Balloon Diameter (mm)	1.5-6.0mm	1.5-5.0mm	Equivalent
Balloon Length (mm)	6-25mm	6-25mm	Identical

Comparison Items	Subject Device – NC TREK NEO™ Coronary Dilatation Catheter	Predicate Device – NC TREK™ RX Coronary Dilatation Catheter	Comparison
Balloon Material 1.50 - 5.0 mm Size	Polyether block amide	Polyether block amide	Identical
Balloon Material 5.50 - 6.00 mm Size	Polyamide	N/A	5.50 – 6.00 mm Sizes are not in the NC TREK RX Size Matrix.
Catheter Coating	Hydrophilic Coating	Hydrophilic Coating	Identical
Balloon Compliance	Non-Compliant	Non-Compliant	Identical
Balloon Rated Burst Pressure (RBP)	18 atm (Minimum)	18 atm (Minimum)	Identical
Guidewire Size (inch)	0.014”	0.014”	Identical
Total Catheter Length	145 cm	143 cm	Equivalent

14. PERFORMANCE DATA

The NC TREK NEO™ Coronary Dilatation Catheter was subjected to testing according to the requirements of *Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, 08 September 2010. Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence.
The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new questions of safety or performance issues were raised during the testing and, therefore, these devices may be considered substantially equivalent to the predicate device.

The following biocompatibility and chemical characterization tests were completed on the NC TREK NEO™ Coronary Dilatation Catheter:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic & Pyrogenicity
- Hemocompatibility

The following dimensional and *in-vitro* performance tests were completed and support the NC TREK NEO™ Coronary Dilatation Catheter

- Tip dimensions
- Crossing Profile
- Guidewire Lumen
- Shaft Dimensions
- Proximal Shaft Marker Location
- Catheter Length
- Catheter Preparation
- Balloon Inflation/Deflation Time
- Balloon Rated Burst Pressure (RBP)
- Maximum Compliance Label
- Balloon Compliance
- Balloon RBP (In-Stent)
- Proximal Seal Tensile Strength
- Outer Member to Hypotube Seal Tensile Strength (Notch-Seal Tensile Strength)
- Proximal Adaption Tensile Strength
- Catheter Tip Tensile Strength
- Inner Member Lumen Collapse
- Balloon Fatigue Resistance
- Balloon Fatigue Resistance (In-Stent)
- Hydrophilic Coating- Dry Adhesion of Coating
- Hydrophilic Coating- Coefficient of Friction
- Kink/Flex
- Torque
- Particulates
- Finished Good Sheath Removal
- Balloon Preparation, Deployment and Retraction

15. CONCLUSIONS

Given that the indications for use and the technological characteristics of the NC TREK NEO™ Coronary Dilatation Catheter are the same to the predicate device, and the results of the performance testing demonstrate no new questions of safety and effectiveness of the subject device when compared to the predicate device, Abbott concludes that the NC TREK NEO™ Coronary Dilatation Catheter is substantially equivalent to the Abbott predicate device – NC TREK RX Coronary Dilatation Catheter.