K110134

SECTION 2 – 510(k) SUMMARY

FEB 11 2011

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
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3. TELEPHONE	(951) 914-3243
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5. CONTACT PERSON	Suzanne Redman
6. DATE PREPARED	January 12, 2011
7. DEVICE TRADE NAME	NC TREK™ RX 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

11. DEVICE DESCRIPTION

The NC TREK RX Coronary Dilatation Catheter is a rapid exchange co-axial design with a balloon at the distal tip. **Table 1** provides a matrix of the new balloon diameters and lengths being made available via this Special 510(k). The existing predicate sizes are designated by "X" in the table below. Balloon diameters from 1.50 mm through 3.25 mm use a single layer design and balloon diameters from 3.50 mm through 5.00 mm use a co-extruded design for both predicate and new sizes.

Table 1 NC TREK RX Line Extension Balloon Sizes

Balloon Diameter (mm)	Balloon Length				
	6mm	8mm	12mm	15mm	20mm
Single Layer Balloons					
2.25	*New*	*New*	*New*	*New*	*New*
3.25	*New*	*New*	X	X	X
Co-Extruded Balloons					
3.75		*New*	X	X	X
4.50		X	X	*New*	*New*
5.00		X	X	*New*	*New*

The balloon segment expands to a known diameter and length at a specific inflation pressure and has radiopaque marker(s) under the balloon to aid in positioning the balloon in a stenosis. The coaxial shaft consists of a tubular inner and outer member. The inner member permits the use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. The outer lumen provides for inflation and deflation of the balloon with contrast fluid. The proximal shaft consists of a hypotube with a hub on the proximal end, a tapered distal section to the guide wire notch junction, along with brachial and femoral markers.

12. INDICATIONS FOR USE

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).

13. TECHNOLOGICAL CHARACTERISTICS

Comparisons of the new and predicate devices show that the technological characteristics such as product performance, design and intended use are substantially equivalent to the current marketed predicate devices.

14. PERFORMANCE DATA

The NC TREK RX Coronary Dilatation Catheters were subjected to the following *in vitro* bench tests according to the requirements of *Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September 8, 2010:

- Catheter Preparation

- Balloon Crossing Profile
- 2/3 Collapsed Balloon Profile
- Balloon Inflation / Balloon Deflation
- Balloon Fatigue
- Balloon Fatigue Within a Stent
- Balloon Rupture
- Balloon Rupture Within a Stent
- Balloon Compliance
- Kink and Flexibility
- Torque
- Catheter Coating Particulate
- Catheter Coating Integrity

Biocompatibility testing included cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemolysis, pyrogen, and complement activation.

These *in vitro* bench and biocompatibility tests demonstrated that the NC TREK RX Coronary Dilatation Catheters met all acceptance criteria and performed similarly to the predicate devices. No new safety or effectiveness issues were raised during the testing program and, therefore, these devices may be considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Abbott Vascular, Inc.
c/o Ms. Suzanne Redman
Principal Regulatory Affairs Associate
26531 Ynez Road
Temecula, CA 92591

FEB 11 2011

Re: K110134
Trade/Device Name: NC TREK™ RX Coronary Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: PTCA Catheter
Regulatory Class: Class II (two)
Product Code: LOX
Dated: January 14, 2011
Received: January 18, 2011

Dear Ms. Redman:

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. 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.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 1 – INDICATIONS FOR USE

510(k) Number (if known): K110134

Device Names: NC TREK™ RX Coronary Dilatation Catheter

Indications for Use: The NC TREK™ RX Coronary Dilatatoin 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).

Prescription Use X OR Over-The-Counter
(Per 21 CFR 801.109) (Optional Format 1-1-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110134