

SECTION 2 – 510(k) SUMMARY – K123279

JAN 30 2013

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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5. **CONTACT PERSON** Suzanne Redman
6. **DATE PREPARED** October 19, 2012
7. **DEVICE TRADE NAME**
 - 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, 21 CFR 870.5100
10. **PREDICATE DEVICE NAME**
 - MINI TREK™ RX Coronary Dilatation Catheter
 - MINI TREK™ OTW Coronary Dilatation Catheter

11. DEVICE DESCRIPTION

11.1 MINI TREK RX Coronary Dilatation Catheter

The MINI TREK RX Coronary Dilatation Catheter is a rapid exchange co-axial design with a balloon at the distal tip. **Table 2-1** provides a matrix of the balloon diameters and lengths available for the MINI TREK RX family of devices.

Table 2-1 MINI TREK RX Size Matrix

Balloon Diameter (mm)	Balloon Length						
	6mm	8mm	12mm	15mm	20mm	25mm	30mm
1.20	X	X	X	X	X	[REDACTED]	
1.50	X	X	X	X	X		
2.00	X	X	X	X	X	X	X

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 co-axial shaft consists of a tubular inner and outer member. The inner member permits the use of a guide wire to facilitate the 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 ending distal to the guide wire notch junction, along with brachial and femoral markers.

11.2 MINI TREK OTW Coronary Dilatation Catheter

The MINI TREK OTW Coronary Dilatation Catheter is an over-the-wire (OTW) co-axial design with a balloon at the distal tip. **Table 2-2** provides a matrix of the balloon diameters and lengths available for the MINI TREK OTW family of devices.

Table 2-2 MINI TREK OTW Size Matrix

Balloon Diameter (mm)	Balloon Length						
	6mm	8mm	12mm	15mm	20mm	25mm	30mm
1.20	X	X	X	X	X	[REDACTED]	
1.50	X	X	X	X	X		
2.00	X	X	X	X	X	X	X

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 co-axial shaft consists of a tubular inner and outer member. The inner lumen 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. Along the proximal portion of the shaft are brachial and femoral markers to aid in gauging the catheter's position relative to the guiding catheter tip when introducing the

catheter through the guiding catheter. An adaption arm is located at the proximal end to provide access to the inflation lumen and guide wire lumen and allows connection with an inflation device.

11.3 MINI TREK II OTW Coronary Dilatation Catheter

The MINI TREK II OTW Coronary Dilatation Catheter is an over-the-wire (OTW) co-axial design with a balloon at the distal tip. **Table 2-3** provides a matrix of the balloon diameters and lengths available for the MINI TREK OTW family of devices.

Table 2-3 MINI TREK II OTW Size Matrix

Balloon Diameter (mm)	Balloon Length				
	6mm	8mm	12mm	15mm	20mm
1.20	X	X	X	X	X
1.50	X	X	X	X	X
2.00	X	X	X	X	X

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 co-axial shaft consists of a tubular inner and outer member. The inner lumen 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. Along the proximal portion of the shaft are brachial and femoral markers to aid in gauging the catheter's position relative to the guiding catheter tip when introducing the catheter through the guiding catheter. An adaption arm is located at the proximal end to provide access to the inflation lumen and guide wire lumen and allows connection with an inflation device.

12. INDICATIONS FOR USE

The MINI TREK RX, MINI TREK OTW and MINI TREK II OTW Coronary Dilatation Catheters (balloon models 1.50 mm – 2.00 mm) are indicated for:

- Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion
- Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction
- Balloon dilatation of a stent after implantation (balloon models 2.00 mm only)
- Balloon dilatation of *de novo* chronic total coronary occlusions (CTO)

The MINI TREK RX, MINI TREK OTW and MINI TREK II OTW Coronary Dilatation Catheters (balloon models 1.20 mm) are indicated for:

- Initial balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis ($\geq 70\%$ stenosis)

- Balloon dilatation of *de novo* chronic total coronary occlusions (CTO)

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

14.1 Summary of Biocompatibility Testing

Biocompatibility testing, previously conducted, included cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemolysis, pyrogen, and complement activation according to the recommendations of *Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September 8, 2010 and ISO 10993-1:2003, *Biological evaluation of medical devices – Part 1: Evaluation and testing*.

14.2 Summary of *In Vitro* Bench Testing

The MINI TREK RX, MINI TREK OTW and MINI TREK II OTW Coronary Dilatation Catheters were previously 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
- Refolded Balloon Profile
- Balloon Inflation / Balloon Deflation
- Balloon Fatigue
- Balloon Fatigue Within a Stent
- Balloon Rupture
- Balloon Rupture Within a Stent
- Balloon Compliance
- Catheter Shaft Fatigue
- Catheter Shaft Rupture
- Soft Tip to Inner Member Tensile
- Proximal Balloon Seal Tensile
- Distal Catheter Tensile
- Catheter Coating Particulate
- Catheter Coating Integrity
- Catheter Coating Friction
- Kink and Flexibility
- Torque

- Radiopacity

14.3 Summary of Clinical Data

The primary objective of the EXPERT CTO clinical trial is to assess the safety and effectiveness of the XIENCE V Everolimus Eluting Coronary Stent System, XIENCE nano Everolimus Eluting Coronary Stent System and the XIENCE PRIME LL Everolimus Eluting Coronary Stent System for the treatment of chronic total coronary occlusions. Another key objective of this trial is to assess the safety and effectiveness of the MINI TREK Coronary Dilatation Catheter in pre-dilatation of chronic total occlusions.

Assessment of the MINI TREK related objective of the trial has been completed. Assessment of the MINI TREK related objective was to be performed in at least the initial 60 subjects with successful guide wire crossing, identified as confirmation of the guide wire in the distal true lumen. However, evaluable data (including core laboratory ascertained angiography data immediately following pre-dilatation with the MINI TREK Coronary Dilatation Catheter) was not available in all 60 subjects, and therefore a total analysis population of 88 subjects was reached that included 65 subjects with evaluable data for the MINI TREK related primary analysis, and 23 subjects that did not have core laboratory ascertained angiography data immediately following pre-dilatation with the MINI TREK Coronary Dilatation Catheter.¹ In both the total analysis population (N=88) and the evaluable population (N=65), the MINI TREK Coronary Dilatation Catheter was used at first attempt for pre-dilatation of the CTO. Results are presented below for the total analysis population, as this set of results best represents the performance of the MINI TREK Coronary Dilatation Catheter in the entire intended CTO study population of the EXPERT CTO trial.

Abbott Vascular notes that assessment of the MINI TREK related objective of the EXPERT CTO trial involved analysis of only the MINI TREK Coronary Dilatation Catheter cohort (subpopulation of the full EXPERT CTO study), for only data derived from the index procedure through the in-hospital visit.

Subjects with signs and/or symptoms considered typical of ischemic heart disease attributed to a CTO in a native coronary artery, who were suitable for a percutaneous revascularization, were included. Subjects with evidence of acute MI within 72 hours of the intended treatment were excluded. The target lesion was a *de novo* lesion with at least one target segment in a native coronary vessel meeting the definition of chronic total occlusion. Only one target lesion was allowed to be treated.

Primary Endpoint

The angioplasty pre-dilatation related primary endpoint was successful pre-dilatation of the CTO defined as follows: (1) successful delivery of the MINI TREK Coronary Dilatation Catheter to and across the target lesion and; (2) successful inflation and deflation of the MINI TREK Coronary Dilatation Catheter and; (3) absence (as determined by independent

¹ A total of 65 subjects with evaluable data were enrolled in the MINI TREK Coronary Dilatation Catheter cohort of the EXPERT CTO due to ongoing enrollment of the cohort that occurred in parallel with analyses to determine when at least 60 subjects with evaluable data had been enrolled.

angiographic core laboratory assessment) of clinically significant vessel perforation, flow-limiting vessel dissection, reduction in thrombolysis in myocardial infarction (TIMI) from baseline and clinically significant arrhythmias requiring medical treatment or device intervention following dilatation with MINI TREK and; (4) achievement of final TIMI flow 3 for the target lesion at the conclusion of the index procedure (i.e. after stent implantation).

Baseline Subject Characteristics:

The 88 subjects in the total analysis population for the angioplasty predilatation-related endpoint had a mean (\pm SD) age of 61.52 (\pm 10.37) years and 76.1% (67/88) were men and 23.9% (21/88) were women. A total of 94.3% (83/88) of the subjects were dyslipidemic; 90.8% (79/87) were hypertensive and 39.8% (35/88) were diabetics with 31.4% (11/35) of the diabetic subjects requiring insulin. Cardiac history revealed prior MI in 31.0% (26/84) of the subjects and previous percutaneous coronary intervention in 45.5% (40/88). In addition, 32.2% (28/87) of the subjects had history of smoking within the last month prior to enrollment.

Baseline Target Lesion Characteristics:

A total of 88 target lesions were treated in 88 subjects in the total analysis population. Angiographic core lab data immediately post-MINI TREK pre-dilatation were available for 65 target lesions (evaluable population subset of the total analysis population), and angiographic core lab data at the end of the index procedure (i.e. after stent implantation) were available for all 88 target lesions in the total analysis population.

Of the target lesions treated in the total analysis population, 35.2% (31/88) were located in the LAD artery, 14.8% (13/88) were located in the LCX, and 50.0% (44/88) were located in the RCA. The mean (\pm SD) lesion length was 36.68 (\pm 17.86) mm; one lesion (1.1%, (1/88)) was < 10 mm, 14.8% (13/88) of the lesions were 10-19.9 mm and 84.1% (74/88) of them were \geq 20 mm. The mean (\pm SD) occlusion length was 13.82 (\pm 8.67) mm.

Assessment of the target lesions in the total analysis population at baseline revealed moderate calcification in 20.5% (18/88) and severe calcification in 14.8% (13/88) of the lesions, and 9.2% (8/87) were eccentric and 1.1% (1/88) had thrombus.

Assessment by the angiographic core laboratory for the total analysis population included mean (\pm SD) pre-procedure reference vessel diameter (RVD) of 2.59 (\pm 0.45) mm, mean (\pm SD) pre-procedure MLD of 0.01 (\pm 0.03) mm, and mean (\pm SD) pre-procedure % diameter stenosis (DS) of 99.77 (\pm 1.04) %. Pre-procedure TIMI flow of 0 was noted in 95.5% (84/88), and pre-procedure TIMI flow of 1 was noted in 4.5% (4/88) of the lesions in the total analysis population.

Primary Endpoint Results:

In the total analysis population (N=88), the angioplasty pre-dilatation related primary endpoint was assessed using site-reported data for the third component of the endpoint where angiographic core laboratory data was not available. This analysis yielded numerically

similar primary endpoint results as the primary endpoint analysis of the evaluable population only.²

The primary endpoint, successful pre-dilatation of the CTO, was achieved in 93.2% (82/88) of the 88 subjects in the total analysis population with a 95% confidence interval (CI) of [85.7%, 97.5%]. The individual criteria for successful pre-dilatation included:

1. successful delivery of at least one MINI TREK balloon to and across the target lesion in 96.6% (85/88) of the total analysis population,
2. successful inflation and deflation with at least one MINI TREK balloon in 100.0% (85/85)³ of the total analysis population,
3. absence of clinically significant vessel perforation, flow-limiting vessel dissection, reduction in TIMI from baseline or clinically significant arrhythmias requiring medical treatment or device intervention following the dilatation with the MINI TREK balloon in 97.7% (86/88) of the total analysis population (with site-reported data if core lab data not available immediately following MINI TREK pre-dilatation), and
4. final TIMI 3 flow at the conclusion of the index procedure (i.e. after stent implantation) in 98.9% (87/88) of the total analysis population.

Table 2-4 Primary Endpoint Results – Total Analysis Population

	Balloon Success	95%CI
Angioplasty predilatation-related Endpoint	93.2% (82/88)	[85.7%,97.5%]
Successful delivery of MINI TREK Coronary Dilatation Catheter to and across target lesion ¹	96.6% (85/88)	[90.4%,99.3%]
Successful inflation and deflation with MINI TREK Coronary Dilatation Catheter ²	100.0% (85/85)	[95.8%,100.0%]
Absence of clinically significant vessel perforation, flow limiting vessel dissection, reduction in TIMI flow from baseline or clinically significant arrhythmias requiring medical treatment or device intervention following dilatation with MINI TREK ³	97.7% (86/88)	[92.0%,99.7%]
Achievement of final TIMI flow 3 for the target lesion at the conclusion of the index procedure ⁴	98.9% (87/88)	[93.8%,100.0%]

² When assessed among the evaluable subjects only (N=65), the primary endpoint of successful pre-dilatation of the CTO was achieved in 93.8% (61/65) of the evaluable subjects with a 95% CI of [85.0%, 98.3%].

³ The denominator includes only subjects in whom inflation and deflation of the MINI TREK was attempted (i.e. subjects with successful delivery of the MINI TREK across the target lesion). A subject was considered successful for this component if at least one MINI TREK dilatation catheter was successfully inflated and deflated per the clinical site.

¹ Data source: site-reported. A subject was considered successful for this component if at least one MINI TREK dilatation catheter was successfully delivered to and across the target lesion per the clinical site.

² Data source: site-reported. The denominator includes only subjects in whom inflation and deflation of the MINI TREK was attempted (i.e. subjects with successful delivery of the MINI TREK across the target lesion). A subject was considered successful for this component if at least one MINI TREK dilatation catheter was successfully inflated and deflated per the clinical site

³ Data source: angiographic core laboratory for vessel perforation, flow limiting vessel dissection and reduction in TIMI from baseline (site-reported data was used if angiographic core laboratory data was not available); site-reported for clinically significant arrhythmia.

⁴ Data source: angiographic core laboratory.

Secondary Endpoint Results:

Device success, defined as attainment of < 50% residual stenosis of the target lesion using the assigned study device, was achieved in 100.0% (88/88) of the lesions in the total analysis population.

Procedure success, defined as device success and absence of in-hospital MACE (per the protocol definition), was achieved in 97.7% (86/88) of the total analysis population.

In the total analysis population (N=88), the mean (\pm SD) procedural time was 77.13 (\pm 40.17) minutes. The mean (\pm SD) contrast volume used during the procedure was 251.27 (\pm 113.14) mL, and the mean (\pm SD) fluoroscopy duration was 32.88 (\pm 21.05) minutes.

Procedural success evaluated according to crossing technique included success in:

- 98.7% (77/78) of the total analysis population using Anterograde Only crossing technique
- 100% (4/4) of the total analysis population using Retrograde Only crossing technique
- 66.7% (2/3) of the total analysis population using Combined Anterograde and Retrograde crossing technique
- 100% (3/3) of the total analysis population using multiple crossing techniques
- Other crossing methods than listed above were not used

No clinically significant perforations occurred in the total analysis population.

In the total analysis population (N=88), 2.27% (2/88) of the subjects experienced in-hospital MACE events (per WHO-based protocol MI definition), with 1.14% (1/88) experiencing clinically indicated TLR, 1.14% (1/88) experiencing MI, and no in-hospital death.

Immediately following pre-dilatation of the target lesion with the MINI TREK balloon, the evaluable population (N=65) had mean MLD (\pm SD) of 0.44 (\pm 0.37) mm with mean (\pm SD) change in MLD of 0.39 (\pm 0.35) mm. In addition, 21.5% (14/65) of the lesions had TIMI flow of 0, 20.0% (13/65) of the lesions had TIMI flow of 1, 6.2% (4/65) of the lesions had TIMI flow of 2, and 52.3% (34/65) of the lesions had TIMI flow of 3 following pre-dilatation. The mean (\pm SD) change in TIMI flow was 1.72 (\pm 1.28). Assessment of these parameters for the entire total analysis population could not be performed, since angiography immediately following MINI TREK pre-dilatation was not available for angiographic core lab assessment for the remaining subjects in the total analysis population.

Conclusions:

One of the main objectives of the EXPERT CTO trial was to assess the safety and effectiveness of the MINI TREK Coronary Dilatation Catheter in pre-dilatation of chronic total occlusions. In the total analysis population, with site-reported data where angiography core laboratory data immediately following MINI TREK pre-dilatation were not available, the primary endpoint of successful pre-dilatation of the CTO was achieved in 93.2% (82/88) of the subjects with a 95% CI of [85.7%, 97.5%].

These success rates compare favorably with historical averages for this complex lesion class, and are in accordance with the recent trend towards significantly higher success rates among experienced operators utilizing advanced device technology and procedural techniques. These favorable outcome data demonstrate the MINI TREK to be both effective and safe in pre-dilatation of chronic total occlusions.

The effectiveness profile of the MINI TREK is further supported by the increase in TIMI flow and MLD observed immediately following pre-dilatation with the MINI TREK as well as at the conclusion of the procedure.

The low rates of procedural complications associated with the use of the MINI TREK, including low in-hospital MACE (per WHO-based protocol MI definition) and low in-hospital TLR rates in the total analysis population, further support the safety profile of the MINI TREK Coronary Dilatation Catheter.

The data emerging from the EXPERT CTO study compare favorably to published rates of procedural success and in-hospital complications for the recanalization of CTOs, a notoriously difficult lesion class. These data support the safety and effectiveness of the MINI TREK Coronary Dilatation Catheter for the treatment of chronic total occlusions.

14.4 Performance Testing - Conclusion

The previously conducted biocompatibility testing, previously conducted *in vitro* bench testing and new clinical study results demonstrated that the MINI TREK RX, MINI TREK OTW, and MINI TREK II OTW 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.



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

Abbott Vascular, Inc.
C/O Ms. Suzanne Redman
26531 Ynez Road
Temecula, CA 92589

JAN 30 2013

Re: K123279

Trade/Device Name: MINI TREK™ RX, MINI TREK™ OTW, and MINI TREK™ II OTW
Coronary Dilatation Catheters

Regulation Number: 21 CFR 870.5100

Regulation Name: Percutaneous Transluminal Coronary Angioplasty Catheter

Regulatory Class: Class II

Product Code: LOX

Dated: December 20, 2012

Received: December 21, 2012

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. 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); 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" (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 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 (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Matthew G. Hillebrenner

for
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): K123279

Device Names: MINI TREK™ RX Coronary Dilatation Catheter
MINI TREK™ OTW Coronary Dilatation Catheter
MINI TREK™ II OTW Coronary Dilatation Catheter

Indications for Use: The MINI TREK RX, MINI TREK OTW and MINI TREK II OTW Coronary Dilatation Catheters (balloon models 1.50 mm – 2.00 mm) are indicated for:

- Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion
- Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction
- Balloon dilatation of a stent after implantation (balloon models 2.00 mm only)
- Balloon dilatation of *de novo* chronic total coronary occlusions (CTO)

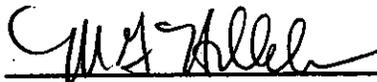
The MINI TREK RX, MINI TREK OTW and MINI TREK II OTW Coronary Dilatation Catheters (balloon models 1.20 mm) are indicated for:

- Initial balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis)
- Balloon dilatation of *de novo* chronic total coronary occlusions (CTO)

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 K123279