



Food and Drug Administration
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May 24, 2016

Bard Peripheral Vascular, Inc.
Ms. Melanie Hadlock
Regulatory Affairs Specialist
1625 West 3rd Street
Tempe, Arizona 85281

Re: K161208

Trade/Device Name: Crosser CTO Recanalization Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: April 27, 2016
Received: April 28, 2016

Dear Ms. Hadlock:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Kenneth J. Cavanaugh -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K161208

Device Name

CROSSER CTO Recanalization Catheter

Indications for Use (Describe)

The CROSSER CTO Recanalization System indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions via atherectomy.

The CROSSER CTO Catheter is only intended for use with the CROSSER Generator. Refer to the CROSSER Generator Manual of Operations for proper use.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
21 CFR 807.92**1. Submitter Information:**

Applicant: Bard Peripheral Vascular, Inc.
1625 West 3rd Street
Tempe, Arizona 85281

Phone: 480.350.6083

Fax: 480.449.2546

Contact: Melanie Hadlock, Regulatory Affairs Specialist

Date: April 27, 2016

2. Subject Device:

Device Trade Name: **CROSSER[®] CTO Recanalization Catheter**

Common or Usual Name: Catheter for Crossing Total Occlusions

Classification: Class II

Classification Name: Catheter for Crossing Total Occlusions

Review Panel: Cardiovascular

Regulation Number: 21 CFR 870.1250

3. Predicate Device:

CROSSER[®] CTO Recanalization Catheter (K112308)

Reference device: ULTRAVERSE[®] 035 PTA Dilatation Catheter (K142261)

4. Summary of Change:

The GEOALIGN[®] Marking System has been added to the device. The GEOALIGN[®] Marking System is a non-radiopaque ruler on the catheter shaft measured from the distal tip.

5. Device Description:

The CROSSER[®] Catheter is a high frequency mechanical recanalization system designed for recanalization of obstructed peripheral arteries. The system consists of an electronic CROSSER[®] Generator, Foot Switch, high frequency Transducer, and CROSSER[®] Catheter. The CROSSER[®] CTO Recanalization catheter, which is intended for one procedure only, is connected to the CROSSER[®] Generator through the high frequency Transducer. The Foot Switch is used to activate the CROSSER[®] Recanalization System. The CROSSER[®]

Generator and Transducer convert AC power into high frequency mechanical vibrations, which are propagated to the tip of the CROSSER[®] Catheter.

The GEOALIGN[®] Marking System is a non-radiopaque ruler on the catheter shaft measured from the distal tip. The GEOALIGN[®] Markings are designated on the catheter shaft by 1cm increment bands with an accuracy within ± 1 mm. The distance from the distal catheter tip is labeled in 10cm increments. Thicker bands denote the midway point (5cm) between the labeled distances. The GEOALIGN[®] Marking System is designed to be used as a tool to externally measure the intravascular advancement and/or retraction of the catheter. This can provide an intravascular reference regarding the location of the distal tip of the catheter or an approximate intravascular length measurement between two points. The GEOALIGN[®] Marking System may also facilitate geographic alignment of an adjunctive therapy that includes the same GEOALIGN[®] Marking System.

6. Indications for Use of Device:

The CROSSER[®] CTO Recanalization System indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions via atherectomy.

The CROSSER[®] Catheter is only intended for use with the CROSSER[®] Generator. Refer to the CROSSER[®] Generator Manual of Operations for proper use.

7. Technological Comparison to Predicate Devices:

The technological characteristics of the subject device are substantially equivalent to those of the predicate device because the two have the following similarities:

- Same intended use
- Same indications for use
- Same target population
- Same fundamental scientific technology
- Same operating principal and method of action
- Same packaging configuration
- Same sterility assurance level and method of sterilization

The subject device is a modification to the predicate device and is different as follows:

- The GEOALIGN[®] Marking System has been added to the device. The GEOALIGN[®] Marking System is a non-radiopaque ruler on the catheter shaft measured from the distal tip. The markings have the same intended purpose, use the same ink formulation, and ink application process as the previously cleared reference device of the same regulation number, the ULTRAVERSE[®] 035 PTA Dilatation Catheter (K142261, cleared September 24, 2014, Regulation Number 870.1250).

8. Performance Testing Summary:

To demonstrate substantial equivalence of the subject device to the predicate device, the technological characteristics and performance criteria were evaluated. Using the FDA guidance document, "Design Control Guidance for Medical Device Manufacturers," dated March 11, 1997, and internal risk assessment procedures, the following non-clinical tests were performed:

- GEOALIGN[®] Marking Legibility
- Dimensional Analysis:
 - GEOALIGN[®] Marking Location (Distal Position)
 - GEOALIGN[®] Marking Location (Proximal Position)
 - GEOALIGN[®] Marking Spacing
 - Catheter Outer Diameter (OD)
- GEOALIGN[®] Marking durability with Support Catheters
- GEOALIGN[®] Marking durability with Introducer Sheaths
- GEOALIGN[®] Marking compatibility with Support Catheters
- GEOALIGN[®] Marking compatibility with Introducer Sheaths

The results demonstrate that the technological characteristics and performance criteria of the CROSSER[®] CTO Recanalization Catheter is comparable to the predicate device and that it performs substantially equivalent to the legally marketed predicate device.

Biocompatibility and chemical characterization demonstrate the subject device is biocompatible and does not elicit any substances at levels of concern as result of this change.

Stability shelf life testing demonstrates the device is has the appropriate shelf life as labeled.

9. Conclusion:

The CROSSER[®] CTO Recanalization Catheter is substantially equivalent to the legally marketed predicate device, the CROSSER[®] CTO Recanalization Catheter (K112308, cleared August 17, 2011)