August 12, 2021

C.R. Bard, Inc.
Aaron Conovaloff
Regulatory Affairs Manager
1625 West 3rd St
Tempe, Arizona 85281

Re: K203363
Trade/Device Name: Crosser iQ CTO Recanalization System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: July 2, 2021
Received: July 6, 2021

Dear Aaron Conovaloff:

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,

For

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)*
K203363

Device Name
Crosser iQ CTO Recanalization System

Indications for Use *(Describe)*
The BD Recanalization System (console and footswitch) and Crosser iQ™ Ultrasonic CTO Device are indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions.

Crosser iQ™ Ultrasonic CTO Device: The Crosser iQ™ Ultrasonic CTO Device is intended for use only with the BD Recanalization System (console and footswitch).

BD Recanalization System: The BD Recanalization System (console and footswitch) is intended for use only with the Crosser iQ™ Ultrasonic CTO Crossing Device.

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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Crosser iQ™ CTO Recanalization System

510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

Applicant:	Bard Peripheral Vascular, Inc 1625 West 3rd Street Tempe, Arizona 85281
Phone:	602-830-5453
Contact:	Aaron Conovaloff, Regulatory Affairs Manager
Date	November 13, 2020

Subject Device Name:

Device Trade Name:	**Crosser iQ™ CTO Recanalization System**
Common or Usual Name:	Catheter for Crossing Total Occlusions
Product Code:	PDU
Classification:	Class II
Review Panel:	Cardiovascular
Regulation Number:	21 CFR 870.1250

Predicate Device:

- Crosser™ CTO Recanalization Catheter (K161208; cleared May 24, 2016)

Reference Devices:

- Crosser™ CTO Recanalization System (K112308; cleared August 17, 2011)
- FlowMate™ Injector (K090621; cleared June 19, 2009)

Device Description:

BD Recanalization System (Console and Footswitch)

The BD Recanalization System (Console and Footswitch) includes a non-sterile, reusable console with an integrated roller pump and user interface, as well as a footswitch. The footswitch can be used as an alternative to the hand-controlled activation of the Crosser iQ™ Ultrasonic CTO Device. The console delivers ultrasonic energy to the Crosser iQ™ Ultrasonic CTO Device. The console is comprised of a molded outer housing and internal structural components to support and protect the electro-mechanical components, including the internal generator. The user interface includes an LCD screen to display images for guiding system preparation and use. The back of the console includes an AC power control switch and clamp assembly to allow the user to secure the console to an IV pole before the procedure and remove after, if desired. The roller pump delivers sterile saline for irrigation from a saline bag through the Crosser iQ™ Ultrasonic CTO Device saline tubing to the tip of the crossing catheter. The saline bag is not included with the BD Recanalization System. In addition to initial package labeling, labeling is present on both the front and back of the console to aid the user in identifying console interface features.

Crosser iQ™ Ultrasonic CTO Device

The Crosser iQ™ Ultrasonic CTO Device is a single use crossing catheter, consisting of a catheter assembly, handle, power cord, and saline tubing with spike set. The Crosser iQ™ Ultrasonic CTO Device is connected to the console via the power cord, through which AC power is converted into high frequency ultrasonic mechanical vibrations to the tip by a transducer within the Crosser iQ™ CTO Device handle. The Crosser iQ™ Ultrasonic CTO Device includes the GeoAlign™ Marking System along the working length of the catheter assembly, with a hydrophilic coating over the distal portion of the working length. 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 1 cm increment bands with an accuracy within ± 1 mm. The distance from the distal catheter tip is labeled in 10 cm increments. Thicker bands denote the midway point (5 cm) 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. The GeoAlign™ Marking System provides an approximation that may not be an exact representation of the actual distance traveled intravascularly and should be confirmed under fluoroscopy. The GeoAlign™ Marking System includes non-radiopaque white markings and are designed to be utilized outside the sheath

Description	Sheath Compatibility	Catheter Length	Platform
Crosser iQ™ Ultrasonic CTO Device	5 Fr	146 cm	Over the Wire, 0.014”

Indications for Use of Device:

The BD Recanalization System (Console and Footswitch) and Crosser iQ™ Ultrasonic CTO Device are indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions.

Crosser iQ™ Ultrasonic CTO Device: The Crosser iQ Ultrasonic CTO Device is intended for use only with the BD Recanalization System (Console and Footswitch).

BD Recanalization System: The BD Recanalization System (Console and Footswitch) is intended for use only with the Crosser iQ™ Ultrasonic CTO Crossing Device.

Comparison of Indications for Use to Predicate Device:

The indications for use statement for the subject device, the Crosser iQ™ CTO Recanalization System, is similar when compared to the predicate device. Therefore, the subject device, the Crosser iQ™ CTO Recanalization System, is substantially equivalent to the predicate device.

Technological Comparison to Predicate Devices:

The subject Crosser iQ™ CTO Recanalization System has the following similarities to the Crosser™ CTO Recanalization System predicate device (K161208 - cleared on May 24, 2016):

- Same intended use
- Same indications for use
- Same target population/conditions of use (anatomical location of use, how device interacts with other devices, interaction with patient)
- Same principles of operation/mechanism of action
- Same fundamental scientific technology
- Same sterility assurance level

The subject device, the Crosser iQ™ CTO Recanalization System, has the following differences when compared to the predicate device:

- Incorporation of power injector functionality (i.e. FlowMate) into Console
- Increase in frequency range
- Decrease in device stroke/displacement
- Addition of frequency and displacement control loop systems
- Energy ramp up upon device activation
- Disposable transducer
- Inclusion of instructional user interface in Console
- Multiple activation options (i.e. hand switch or foot switch)
- Various usability enhancements
- Sterilization via ethylene oxide

Performance Data:

To demonstrate substantial equivalence of the subject device to the predicate device, its technological characteristics and performance criteria were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Assessment procedures, the following *in vitro* tests were performed on the subject device:

- Simulated Use – Track Interventional Device Testing Equipment (IDTE)
- Simulated Use Crossing Consistency SFA 50% / Lumen Diameter
- Simulated Use – Catheter Durability (5-Minute)
- Simulated Use – Withdrawal
- Maximum Temperature
- Crossing Device Minimum Joint Tensile Strength
- Radiopacity
- Leakage
- Luer Positive Pressure Leak
- Luer Stress Cracking
- Luer Sub-Atmospheric Pressure Leak
- Luer Resistance to Axial Separation
- Luer Resistance to Unscrewing Torque
- Luer Resistance to Thread Override
- Particulate
- Burst Strength
- Corrosion Resistance
- Flow Rate
- Worst Case Guiding Sheath Compatibility
- Packaging and Visual Defects – Console and Footswitch
- Functional Measurement of Capital Equipment
- Packaging and Visual Defects – Catheter
- Bubble Emission Leak
- Packaging Seal Strength, Tensile
- Heat Seal Visual Inspection
- Cytotoxicity
- Intracutaneous Reactivity
- Sensitization
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemolysis
- Complement Activation
- Partial Thromboplastin Time
- In Vivo Thrombogenicity
- Chemical Characterization
- Sterilization adoption testing

Summative Usability Study
A summative human factors evaluation using a total of 15 physicians and 15 technologists for tasks associated with operating the Crosser iQ™ CTO Ultrasonic CTO Device and BD Recanalization System was conducted. The methods and tasks outlined in the evaluation instructed participants to use the device following the steps outlined in the IFU. The study assessed how physicians and technologists use the Crosser iQ™ Ultrasonic CTO Device and the BD Recanalization System during a simulated CTO procedure to obtain evidence of substantially equivalent safety outcomes for the subject device. Acceptance criteria for the study were met, and the results demonstrate substantially equivalent safety outcomes for the subject device when used by the intended users in the intended use environment.

Animal Study
A GLP animal study was conducted to demonstrate substantially equivalent safety outcomes for the Crosser iQ™ CTO Recanalization System, including both the Crosser iQ™ Ultrasonic CTO Device and the BD Recanalization Capital Equipment. This study was conducted in non-diseased porcine peripheral arteries. The study evaluated the subject Crosser iQ™ Ultrasonic CTO Device against the predicate Crosser™ 14S OTW catheter.

Nine animals were treated in this tissue safety study using the right and left iliofemoral arteries. On the day of treatment, the animals were anesthetized and prepped for the treatment procedure. Each animal received six individual/non-overlapping treatments in the internal and external right and left femoral arteries and the right and left external iliac arteries. Device usability was assessed by the operator. After the procedure, 3 animals were terminated and sent to necropsy for gross examination and tissue procurement, and the remaining 6 animals were survived for 14 - 15 days prior to termination. On the day of termination, animals had pre-terminal angiography performed, and then were humanely euthanized and sent to necropsy for gross examination and tissue procurement. A full gross assessment was performed on all animals and downstream tissues, and any abnormal tissues from major organs was sent for histological analysis.

All endpoints were evaluated per protocol for this study. Success criteria were met for animal health, tissue response, and device usability. Overall, based on the procedures performed and data collected on this study, the subject Crosser iQ™ Ultrasonic CTO Device performed comparably to the predicate Crosser™ 14S OTW with regards to animal health, tissue response, and device usability in this acute and chronic in vivo swine model.

Conclusions:

The results from both in vitro and animal studies demonstrate that the technological characteristics and performance criteria of the Crosser iQ™ CTO Recanalization System are substantially equivalent to the predicate device, and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

The subject device, the Crosser iQ™ CTO Recanalization System, met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Crosser iQ™ CTO Recanalization System is substantially equivalent to the legally marketed predicate device, Crosser CTO Recanalization System.