



Food and Drug Administration
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April 29, 2016

Kaneka Corporation
% Mr. Christopher M. Sloan
Principal Consultant
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1801 Rockville Pike, Suite 300
Rockville, MD 20852

Re: K160013

Trade/Device Name: Crosperio OTW PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: March 29, 2016
Received: March 31, 2016

Dear Mr. Sloan:

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)

K160013

Device Name

Croserio OTW PTA Dilatation Catheter

Indications for Use (Describe)

The Croserio OTW PTA Balloon Dilatation Catheter is intended to dilate stenosis in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

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510(K) SUMMARY

Crosperio OTW PTA Balloon Dilatation Catheter

510(k) Submitter

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Date Prepared: March 22, 2016

Subject Device Name:

Trade Name	Crosperio OTW
Common or usual name	Percutaneous (peripheral) transluminal angioplasty catheter
Classification name	Percutaneous catheter [21 CFR 870.1250; product code LIT]
Class	II
Classification Panel	Cardiovascular (74)

Predicate Devices:

- Ultraverse[®] RX PTA Dilatation Catheter or “Ultraverse RX” [K131199 (Bard Peripheral Vascular Inc.)]
- Metacross OTW PTA Balloon Dilatation Catheter or “Metacross OTW” [K152080 (Kaneka Corporation)]

Device Description:

Crosperio OTW PTA Balloon Dilatation Catheter (Crosperio OTW) is an over-the-wire type of balloon dilatation catheter, which consists of an outer tube, inner tube, balloon, radiopaque markers, manifold, outer reinforcement tube and strain relief. A balloon is attached to the distal end of the catheter, and it can be inflated and deflated using the inflation device connected to the manifold at the proximal end. Crosperio OTW has a guidewire lumen at the distal end of the catheter through which a guidewire can be inserted, and also an opening along the inner tube to the guidewire port of the manifold for the introduction of a guidewire.

The maximum compatible diameter of a guidewire used together with Crosperio OTW in a PTA procedure is 0.014 inches. Additionally, the compatible size of a sheath introducer is 4 Fr. The nominal inflated balloon diameters range from 1.5 mm to 4.0 mm with balloon working lengths of 20 mm to 200 mm. Three different catheter working lengths will be provided: 650, 900 and 1500 mm.

Indications for Use

The Crosperio OTW is intended to dilate stenosis in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

Comparison of Indications for Use to Predicate Devices

The Crosperio OTW has the same intended use (percutaneous transluminal angioplasty) and comparable indications for use as the Ultraverse RX. Also, the Crosperio OTW has the identical intended use and indications for use to the Metacross OTW. Therefore, the subject device, Crosperio OTW, may be considered substantially equivalent to the predicate devices.

Comparison of Technological Characteristics to Predicate Devices

Technological Comparison to Predicate Devices

The Crosperio OTW has the following similarities to the predicate devices:

- Same intended use (same as Ultraverse RX and Metacross OTW)
- Same indications for use (similar to Ultraverse RX and same as Metacross OTW)
- Same target population (same as Ultraverse RX and Metacross OTW)
- Same operating principle (same as Ultraverse RX and Metacross OTW)
- Similar materials (similar to Ultraverse RX and Metacross OTW)
- Same fundamental scientific technology (same as Ultraverse RX and Metacross OTW)
- Same sterility assurance level and method of sterilization (same as Ultraverse RX and Metacross OTW)

Performance Testing

To demonstrate substantial equivalence of Crosperio OTW to the predicate devices, the technological characteristics and performance criteria were evaluated using the bench testing recommendations outlined in the FDA Guidance Document “Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters” dated September 8, 2010. The following *in vitro* tests were performed on the subject device:

Dimensional Verification, Balloon Preparation, Deployment and Retraction, Balloon Rated Burst Pressure, Balloon Fatigue (Repeat Balloon Inflations), Balloon Compliance, Balloon Inflation and Deflation Time, Catheter Bond Strength, Flexibility and Kink Test, Torque Strength, Radiopacity, Coating Integrity, Particulate Evaluation, Balloon Rated Burst Pressure (in Stent), and Balloon Fatigue (Repeat Balloon Inflations; in Stent), and Shelf Life Testing.

The results from these tests demonstrate that the technological characteristics and performance criteria of the Crosperio OTW are adequate for the intended use of the device

and that the device can perform in a manner equivalent to devices currently on the market with the same intended use.

Biocompatibility:

To demonstrate the biological safety of the body-contacting materials and substantial equivalence of the Crosperio OTW to the predicate devices, the following biocompatibility testing was performed in accordance with “Draft Guidance for Industry and Food and Drug Administration Staff; Use of International Standard ISO 10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing’” (dated April 23, 2013):

Cytotoxicity, Sensitization, Intracutaneous reactivity (irritation), Systemic toxicity (acute), Pyrogenicity, Hemocompatibility (thrombogenicity, hemolysis, and immunology), and Genotoxicity (bacterial gene mutation assay, *in vitro* mammalian genotoxicity assay, and *in vivo* cytogenetics assay)

The results from these tests demonstrate that the Crosperio OTW is biocompatible for its intended use similar to the predicate devices.

Conclusions:

The Crosperio OTW met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Crosperio OTW PTA Balloon Dilatation Catheter is substantially equivalent to legally marketed predicate devices.