DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 11, 2017

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

Re: K163479
Trade/Device Name: R2P Metacross RX PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: December 9, 2016
Received: December 12, 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.

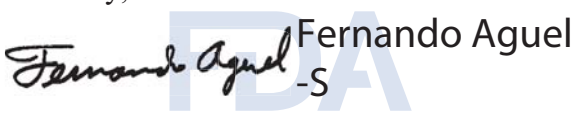
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163479

Device Name
R2P Metacross RX PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The R2P Metacross RX 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

R2P Metacross RX PTA Balloon Dilatation Catheter

510(k) Submitter

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Date Prepared: December 9, 2016

Subject Device Name:

Trade Name	R2P Metacross RX PTA Balloon Dilatation Catheter
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:

- Metacross RX PTA Balloon Dilatation Catheter [K150865 (Kaneka Corporation)]

Device Description:

R2P Metacross RX PTA Balloon Dilatation Catheter (R2P Metacross RX) is a rapid exchange balloon dilation catheter, which consists of a distal tube, proximal tube, balloon, guidewire transition tube, radiopaque markers, hub, 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 hub at the proximal end. R2P Metacross RX has a lumen (guidewire transition tube) at the distal end of the catheter through which a guidewire can be inserted, and also an opening along the balloon and distal tube to the guidewire port for the exit of a guidewire.

The maximum compatible diameter of a guidewire used together with R2P Metacross RX in a PTA procedure is 0.035 inches. Additionally, sheath introducers with a minimum diameter of 6 Fr have been deemed to be compatible with R2P Metacross RX. The nominal inflated balloon diameters range from 3.0 mm to 8.0 mm with balloon working lengths of 20 mm to 200 mm. The catheter working length is 2000 mm.

The R2P Metacross RX is provided with the following accessory device:

- Flushing Needle: provided per one catheter device for the purpose of flushing and filling of the guidewire lumen with heparinized saline before use.

Indications for Use

The R2P Metacross RX 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.

Comparison of Indications for Use to Predicate Devices

The intended use (percutaneous transluminal angioplasty) and indications for use of the R2P Metacross RX are identical to that of the Metacross RX. Therefore, the subject device's indications for use may be considered substantially equivalent to that of the predicate device.

Comparison of Technological Characteristics to Predicate Devices

Technological Comparison to Predicate Devices

The R2P Metacross RX has the following similarities to the predicate device:

- Same intended use
- Same indications for use
- Same target population
- Same operating principle
- Similar materials
- Same fundamental scientific technology
- Same sterility assurance level and method of sterilization

The principal difference between the devices is that R2P Metacross RX has a lower profile proximal tube (outer dimeter of 1.25 mm) compared to that of the Metacross RX (the outer dimeter of 1.30 mm). In addition, the R2P Metacross RX has a narrower range of balloon diameters (3.0 to 8.0 mm) compared to the Metacross RX (3.0 to 12.0 mm). The range of balloon lengths of R2P Metacross RX and Metacross RX is the same (20 mm to 200 mm). The R2P Metacross RX has only one type of catheter working length (2000 mm) unlike the Metacross RX (900, 1350 and 2000 mm). Other design or dimensional differences include the following:

- The R2P Metacross RX has three position markers (900, 1200 and 1500 mm from the distal tip of the catheter) while the Metacross RX has two (900 and 1000 mm from the distal tip of the catheter).
- The diameter of core wire was narrowed in association with the reduced profile of the proximal tube.

Performance Testing

To demonstrate substantial equivalence of R2P Metacross RX 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, Particulate Evaluation, Balloon Rated Burst Pressure (in Stent), and Balloon Fatigue (Repeat Balloon Inflations; in Stent), Transportation, and Shelf Life Testing.

The results from these tests demonstrate that the technological characteristics and performance of the R2P Metacross RX are substantially equivalent to the predicate device.

Biocompatibility:

The patient-contacting materials of the R2P Metacross RX device are identical to those of the predicate device; therefore, prior biocompatibility testing conducted on the predicate device was leveraged in support of the biological safety of the R2P Metacross RX.

Conclusions:

The R2P Metacross RX met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The R2P Metacross RX PTA Balloon Dilatation Catheter is substantially equivalent to the legally marketed predicate device.