March 19, 2018

Kaneka Corporation  
% Christopher Sloan  
Principal Consultant  
Quintiles IMS  
1801 Rockville Pike, Suite 300  
Rockville, Maryland 20852  

Re: K172264  
Trade/Device Name: OTW Takeru PTCA Balloon Dilatation Catheter  
Regulation Number: 21 CFR 870.5100  
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter  
Regulatory Class: Class II  
Product Code: LOX  
Dated: March 2, 2018  
Received: March 6, 2018

Dear Christopher 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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
510(k) Number (if known)
K172264

Device Name
OTW Takeru PTCA Balloon Dilatation Catheter

Indications for Use (Describe)
The OTW Takeru PTCA Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion in the coronary artery or bypass graft stenosis for the purpose of myocardial perfusion. This product (balloon models 2.0 - 5.0 mm) is also indicated for the post-delivery expansion of balloon expandable stents.

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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5.1 510(K) SUMMARY

OTW Takeru PTCA Balloon Dilatation Catheter

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Date Prepared: February 23, 2018
Subject Device Name:

Trade Name OTW Takeru
Common or usual name Percutaneous Transluminal Coronary Angioplasty (PTCA) catheter
Classification name Percutaneous Transluminal Coronary Angioplasty (PTCA) catheter [21 CFR 870.5100; product code LOX]
Class II
Classification Panel Cardiovascular (74)

Predicate Devices:

- Primary predicate device: RX Takeru PTCA Balloon Dilatation Catheter or “RX Takeru” [K163372 (Kaneka Corporation)]
- Apex™ Over-The-Wire PTCA Dilatation Catheter or “Apex Over-The-Wire” [P860019/S208 (Boston Scientific Corporation)]

Reference Device:

- Crosstella OTW PTA Balloon Dilatation Catheter or “Crosstella OTW” [K160004 (Kaneka Corporation)]

Device Description:

OTW Takeru PTCA Balloon Dilatation Catheter (OTW Takeru) is an over-the-wire balloon dilation catheter, which consists of a distal tube, mid tube, proximal tube, balloon, guidewire transition tube, radiopaque marker(s), manifold, 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. OTW Takeru has a lumen at the distal end of the catheter through which a guidewire can be inserted. This lumen extends from the distal end of the catheter to the guidewire port on the manifold for the exit of the guidewire. The maximum compatible diameter of a guidewire used together with OTW Takeru in a PTCA procedure is 0.014 inches. Additionally, guiding catheters with a diameter of 5 or 6 Fr have been deemed to be compatible with OTW Takeru. The nominal inflated balloon
diameters range from 1.5 mm to 5.0 mm with balloon working lengths of 6 mm to 30 mm. The catheter working length is 1450 mm.

**Indications for Use**

The OTW Takeru PTCA Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion in the coronary artery or bypass graft stenosis for the purpose of myocardial perfusion.

This product (balloon models 2.0 – 5.0 mm) is also indicated for the post-delivery expansion of balloon expandable stents.

**Comparison of Indications for Use to Predicate Devices**

The OTW Takeru has the same intended use (percutaneous transluminal coronary angioplasty) as the RX Takeru and the Apex Over-The-Wire. The indications for use of the OTW Takeru are identical to that of the RX Takeru and comparable to that of Apex Over-The-Wire. Therefore, the subject device, OTW Takeru, may be considered substantially equivalent to the predicate devices.

**Comparison of Technological Characteristics to Predicate Devices**

Percutaneous Transluminal Coronary Angioplasty (PTCA) is the technological principle for both OTW Takeru and the predicate devices. PTCA is based on the use of Percutaneous Coronary Intervention (PCI) devices for the purpose of myocardial perfusion.

The OTW Takeru and predicate devices have following same technological elements:

- Operating principle – balloon dilatation of stenotic portion by pressurization of inflation medium
- Fundamental catheter design – balloon, shaft, radiopaque marker, hub or manifold, hydrophilic coating
- Shaft type – over the wire (same as the Apex Over-The-Wire)
- Concomitantly used devices – guidewire, guiding catheter, inflation device

There are following minor technological differences between OTW Takeru and the RX Takeru and/or Apex Over-The-Wire:

- Combination of balloon diameter and balloon length
- Shaft diameter
- Catheter working length
- Nominal Pressure and Rated Burst Pressure of certain balloon sizes
Performance Testing

To demonstrate substantial equivalence of OTW Takeru 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
- Coating Integrity
- Particulate Evaluation
- Balloon Rated Burst Pressure (in Stent)
- Balloon Fatigue (Repeat Balloon Inflations; in Stent)
- Shelf Life Testing

The results from these tests demonstrate that the technological characteristics and performance of the OTW Takeru are substantially equivalent to the predicate devices.

Biocompatibility:

To demonstrate the biological safety of the body-contacting materials and substantial equivalence of the OTW Takeru to the predicate devices, the following biocompatibility testing was performed in accordance with the FDA Guidance Document “Use of International Standard ISO 10993-1, “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process”; Guidance for Industry and Food and Drug Administration Staff” (dated June 16, 2016):

- Cytotoxicity
- Intracutaneous Reactivity
- Sensitization
- Material-mediated Pyrogen
- Hemocompatibility (hemolysis)
- Acute Systemic Toxicity

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

Conclusions:

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