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

April 7, 2017

Kaneka Corporation
c/o Christopher M. Sloan
Quintiles Consulting
1801 Rockville Pike, Suite 300
Rockville, MD 20851

Re: K163372
Trade/Device Name: RX 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 9, 2017
Received: March 10, 2017

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.

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" (21CFR 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)*
K163372

Device Name
RX Takeru PTCA Balloon Dilatation Catheter

Indications for Use *(Describe)*

The RX 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5.0 510(K) SUMMARY

Rx Takeru PTCA Balloon Dilatation Catheter

510(k) Submitter

Kaneka Corporation
Medical Device Division
1-12-32, Akasaka, Minato-ku
Tokyo, Japan
Contact Person: Toshihiko Motomine
Telephone: +81-3-5574-8023
Email: Toshihiko.Motomine@kaneka.co.jp

Official Correspondent

Christopher M. Sloan
Principal Consultant
Quintiles Consulting
1801 Rockville Pike, Suite 300
Rockville, MD 20852
Phone: (301) 272-3114
Email: chris.sloan@quintilesims.com

Date Prepared: February 27, 2017

Subject Device Name:

Trade Name	Rx Takeru PTCA Balloon Dilatation Catheter
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: Apex™ Monorail PTCA Dilatation Catheter or "Apex" [P860019/S208 (Boston Scientific Corporation)]
- Euphora™ Rapid Exchange Balloon Dilatation Catheter or "Euphora" [K143480 (Medtronic Inc.)]

Device Description:

Rx Takeru PTCA Balloon Dilatation Catheter (Rx Takeru) is a rapid exchange type of balloon dilation catheter, which consists of a distal tube, guidewire transition tube, balloon, radiopaque marker(s), mid tube, proximal tube, core wire, 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. Rx Takeru has a guidewire lumen at the distal end of the catheter through which a guidewire can be inserted, and also an opening along the guidewire transition tube to the guidewire port for the exit of a guidewire.

The maximum compatible diameter of a guidewire used together with Rx 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 Rx 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 RX 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 RX Takeru has the same intended use (percutaneous transluminal coronary angioplasty) as the Apex and Euphora. The indications for use of the RX Takeru is similar to that of the Apex and Euphora. Therefore, the subject device, RX 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 RX Takeru and the predicate devices. PTCA is based on the use of Percutaneous Coronary Intervention (PCI) devices for the purpose of myocardial perfusion.

The RX 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, hydrophilic coating
- Shaft type – rapid exchange
- Concomitantly used devices – guidewire, guiding catheter, inflation device
- Sterilization – Ethylene oxide

There are following minor technological differences between RX Takeru and predicate devices:

- Combination of balloon diameter and balloon length
- Shaft diameter
- Catheter effective length
- Nominal Pressure and Rated Burst Pressure of certain balloon sizes

Performance Testing

To demonstrate substantial equivalence of RX 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, Radiopacity, Coating Integrity,

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 criteria of the RX Takeru 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 RX Takeru to the predicate devices, the following biocompatibility testing was performed in accordance with "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, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Pyrogen, Hemocompatibility (*in vivo* thromboresistance, hemolysis, and complement), and Genotoxicity (mouse lymphoma, bacterial reverse mutation and *in vivo* cytogenetics assay)

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

Conclusions:

The RX 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 RX Takeru PTCA Balloon Dilatation Catheter is substantially equivalent to legally marketed predicate devices.