



July 7, 2017

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

Kaneka Corporation
c/o Christopher M. Sloan
Quintiles Consulting
1801 Rockville Pike, Suite 300,
Rockville, MD 20852 US

Re: K170941

Trade/Device Name: RX NC Takeru
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: June 19, 2017
Received: June 20, 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,

 Fernando Aguel
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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)

K170941

Device Name

RX NC Takeru PTCA Balloon Dilatation Catheter

Indications for Use (Describe)

The RX NC 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 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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5.0 510(K) SUMMARY

RX NC Takeru PTCA Balloon Dilatation Catheter

510(k) Submitter

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Date Prepared: June 9, 2017

Subject Device Name:

Trade Name	RX NC 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 Device:

- NC Quantum Apex™ Monorail PTCA Dilatation Catheter or “NC Quantum Apex” [P860019/S241 (Boston Scientific Corporation)]

Reference Device:

- RX Takeru PTCA Balloon Dilatation Catheter or “RX Takeru” [K163372 (Kaneka Corporation)]

Device Description:

RX NC Takeru PTCA Balloon Dilatation Catheter (RX NC Takeru) is a rapid exchange type of balloon dilation catheter, which consists of a distal tube, guidewire transition tube, balloon, radiopaque markers, 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 NC 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 NC 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 NC Takeru. The nominal inflated balloon diameters range from 2.0 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 NC 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 is also indicated for the post-delivery expansion of balloon expandable stents.

Comparison of Indications for Use to Predicate Device

The RX NC Takeru has the same intended use (percutaneous transluminal coronary angioplasty) as the NC Quantum Apex. The indications for use of the RX NC Takeru is similar to those of the NC Quantum Apex. Therefore, the subject device, RX NC Takeru, may be considered substantially equivalent to the predicate device.

Comparison of Technological Characteristics to Predicate Device

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

The RX NC Takeru and predicate device 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 NC Takeru and predicate device:

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

Performance Testing

To demonstrate substantial equivalence of RX NC Takeru to the predicate device, 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 NC 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 NC Takeru to the predicate device, the following biocompatibility testing, which was performed on the reference device (RX Takeru) 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), was leveraged:

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 NC Takeru is biocompatible for its intended use similar to the predicate device.

Conclusions:

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