October 26, 2021

Kaneka Medical America LLC
% Takeaki Miyata
Manager, Regulatory Affairs Team
Kaneka Corporation
1-12-32 Akasaka
Minato-ku, Tokyo 107-6028
Japan

Re: K213166
Trade/Device Name: Thrombuster II Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEZ
Dated: September 27, 2021
Received: September 28, 2021

Dear Takeaki Miyata:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213166

Device Name
Thrombuster II Aspiration Catheter

Indications for Use *(Describe)*
The Thrombuster II Aspiration Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral system. The Thrombuster II is not intended for use in the cerebral 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

K213166

Thrombuster II Aspiration Catheter

510(k) Submitter

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Date Prepared: October 21, 2021

Subject Device Name:

Trade Name	Thrombuster II Aspiration Catheter
Common or usual name	Aspiration Thrombectomy Catheter
Classification name	Embolectomy Catheter [21 CFR 870.5150; product code is QEZ]
Class	II
Classification Panel	Cardiovascular (74)

Predicate Device:

- Xpress-Way RX [K101839 (Kaneka Corporation)]

The predicate device have not been subject to a design-related recall.

Device Description:

Thrombuster II Aspiration Catheter [Thrombuster II] is a rapid exchange type of dual lumen catheter for embolectomy. The Thrombuster II has been commercially available in EU region, Asia including Japan and China, Oceania and Middle east countries.

The main body consists of a distal shaft, proximal shaft, ring marker, hub, and strain relief. The catheter working length is 1400 mm. This product includes a core wire to resist kink during delivery in clinical usage, syringe kit (extension tube, stopcock, and lock syringe) for connecting the catheter main body and aspiration of fresh, soft emboli and thrombi, and accessories (flushing needle and filter). After insertion of the catheter into a patient body, this product aspirates and removes emboli or thrombi from a target lesion by transmitting negative pressure generated by connected lock syringe to the distal end of the catheter.

The maximum compatible diameter of a guidewire used together with Thrombuster II in a procedure is 0.014 inches. Additionally, guiding catheters with a diameter of 6 or 7 Fr have been deemed to be compatible with Thrombuster II.

Indications for Use

The Thrombuster II Aspiration Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral system. The Thrombuster II is not intended for use in the cerebral vasculature.

Comparison of Indications for Use to Predicate Device

The Thrombuster II has the same intended use (removal of thrombus form the peripheral and/or coronary vasculature through aspiration) as the predicate device. The indications for use of the Thrombsuter II is also identical to that of the predicate device.

Comparison of Technological Characteristics to Predicate Device

Embolectomy or thrombectomy by aspiration is the technological principle for both Thrombuster II and the predicate device. These devices are used in Percutaneous Coronary Intervention (PCI) or peripheral intervention for the purpose of revascularization.

The subject device and predicate device are based on the following same technological elements:

- Fundamental catheter design - rapid exchange type of dual lumen catheter
- Catheter components - proximal shaft, distal shaft, wire lumen tube with radiopaque ring marker, hub, and hydrophilic coating
- Product configuration - catheter main body, core wire, syringe kit, and accessories

- Principle of operation - aspiration of emboli and thrombi from catheter tip due to negative pressure created by connected syringe
- Dimensional specification - catheter working length, outer diameters of distal shaft and proximal shaft
- Concomitant devices - a guidewire of 0.014 inches and a guiding catheter of 6Fr or 7Fr

There are following minor technological differences between Thrombuster II and the predicate device:

- Aspiration opening shape at the distal end of catheter
- Number of lock syringes
- Filter shape

These differences do not affect common intended use, indications for use, fundamental scientific technology and performance specification in these devices.

Performance Testing

To reduce risks identified in our risk analysis of the differences, and to demonstrate substantial equivalence of Thrombuster II to the predicate device, following tests were conducted using well-established methods:

- Trackability test
- Dimensional verification
- Aspiration performance test

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

Biocompatibility:

The modifications do not affect the nature of body contact and do not change raw materials for the predicate device. Therefore, in the design control activities for the modifications, the original testing on the predicate device applies to the Thrombuster II.

Conclusions:

The Thrombuster II met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and customer inputs. The Thrombuster II is substantially equivalent to the predicate device.