May 4, 2020

Control Medical Technology
Shawn Fojtik
President
2757 South 300 West Suite F
Salt Lake City, Utah 84115

Re: K200871
Trade/Device Name: Aspire MAX 7 - 11F Mechanical Thrombectomy System and Aspire Mechanical Aspirator
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEZ
Dated: March 25, 2020
Received: April 1, 2020

Dear Mr. Fojtik:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200871

Device Name
Aspire MAX 7 - 11F Mechanical Thrombectomy System and Aspire Mechanical Aspirator

Indications for Use *(Describe)*
The Aspire MAX 7 - 11F Mechanical Thrombectomy System and Aspire Mechanical Aspirator is indicated for the removal of fresh soft emboli and thrombi from vessels 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K200871

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary is provided.

Date Summary was Prepared

April 29, 2020

Submitter

Control Medical Technology ("Submitter")
2757 South 300 West
Salt Lake City, Utah 84115 USA
Phone (383) 444-2666

FDA Establishment Registration Number

3007282893

Contact

Control Medical Technology
2757 South 300 West
Salt Lake City, Utah 84115 USA
Shawn Fojtik
Phone (383) 444-2666

Device Information

Trade Names:	Aspire MAX 7 - 11F Mechanical Thrombectomy System and Aspire Mechanical Aspirator
Common Name:	Thrombectomy catheter and/or embolectomy catheter
Classification Name:	Embolectomy catheter
Product Code:	QEZ
Regulation:	Class II, 21 CFR 870.5150

Predicate Device

The Subject Device is substantially equivalent to the legally marketed Aspire MAX 5 – 6F Mechanical Thrombectomy System ("Predicate Device(s)").

Trade Names:	Aspire MAX 5 – 6F Mechanical Thrombectomy System™ K113757 February 22, 2012.
Common Name:	Thrombectomy catheter and/or embolectomy catheter
Classification Name:	Embolectomy catheter
Product Code:	DXE
Regulation:	Class II, 21 CFR 870.5150

Reference Devices

The Subject Device references the Vascular Solutions Pronto XL 8 – 14F Thrombectomy System ("Reference K112571") and the Heraeus DuraSheath K181463 ("Reference K181463"). Reference K112571 is referenced because it is available with 8F – 14F outer diameter catheter components and used for thrombectomy in peripheral vasculature same as the Subject Devices. Reference K181463 is

referenced as the catheter components in the Subject Device are the same outer dimensions, design, and indicated for use in the peripheral vasculature.

Trade Names:	Pronto XL 8 – 14F Thrombectomy System K112571 September 27, 2011
Common Name:	Thrombectomy catheter and/or embolectomy catheter
Classification Name:	Embolectomy catheter
Product Code:	DXE
Regulation:	Class II, 21 CFR 870.5150

Trade Names:	Heraeus DuraSheath K181463 December 13, 2018
Common Name:	Catheter or Sheath
Classification Name:	Introducer, Catheter
Product Code:	DYB and DRE
Regulation:	Class II, 21 CFR 870.1340

Device Description

The Subject Device includes (1) Aspire Aspirator and (1) MAX 7F – 11F Catheter. Subject Device and the Predicate are single-use, sterile, and short-term use medical devices designed to remove fresh soft emboli, debris, and thrombi from the peripheral vasculature.

PREDICATE DEVICE

Aspire Aspirator
K072299, K113757 and K131998

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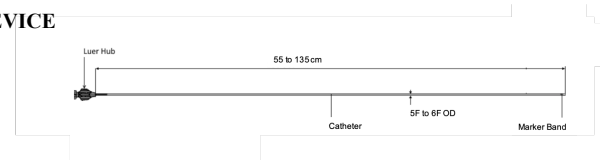

MAX 5 – 6F Catheter Component

The Subject Device's Intended Use and Fundamental Scientific Principle are the same as the Predicate. The Predicate and Subject Device are the same in the way they are inserted into the body over a guidewire and advanced to the target arterial or venous peripheral vascular anatomy. The Subject Device and Predicate share the same core Aspire Aspirator to create thrombectomy force. MAX 7 - 11F Catheters may be connected to basic syringes and other aspiration pumps. Aspire Mechanical Aspirators may be connected to other catheters. The Subject Device does not add any new materials or manufacturing processes to the manufacturing process.

SUBJECT DEVICE

Aspire Aspirator
K072299, K113757 and K131998

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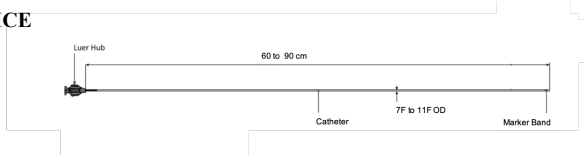

MAX 7 – 11F Catheter Component

Indication for Use

Indication: The Aspire MAX 7 - 11F Mechanical Thrombectomy System and Aspire Mechanical Aspirator are indicated for the removal of fresh soft emboli and thrombi from vessels in the peripheral vasculature. The indication and intended use are same as and substantially equivalent to the Predicate and same as other thrombectomy systems legally marketed under the DXE and QEZ product codes.

Predicate Comparison

	Predicate Device K113757	Subject Device K200871	Comments
Device Name	Embolectomy Catheter	Embolectomy Catheter	Same as Predicate.
Committee	Cardiovascular	Cardiovascular	Same as Predicate.
FDA Product Code	DXE	QEZ	Subject Device product code updated per new FDA thrombectomy device product codes.
Catheter Component Materials	Multi-layer nylon Pebax shaft, stainless steel wire braid, and PTFE liner.	Multi-layer nylon Pebax shaft, stainless steel wire coil, and PTFE liner with thermoplastic elastomers TPE dilator.	Subject Device and Predicate materials are common multi-layer catheter, metal, and liner designs.
Catheter Component Outer Diameters	5F and 6F	7F, 8F, 9F, 10F, 11F	Subject Device outer diameters are larger than the Predicate K113757, same as Reference K181463, and smaller in outer diameter than the largest Reference K112571. Catheters with outer diameters up to 14F like Reference K112571 are used for thrombectomy in peripheral vasculature.
Catheter Component Lengths	55 – 135cm	60 – 90cm	Subject Device is catheter component lengths are in between Predicate K113757 shortest and longest catheter component lengths.
Indication for Use	The Aspire MAX 5 – 6F Mechanical Thrombectomy System and Aspire Mechanical Aspirator are indicated for the removal of fresh soft emboli and thrombi from vessels in the peripheral vasculature.	The Aspire MAX 7 – 11F Mechanical Thrombectomy System and Aspire Mechanical Aspirator are indicated for the removal of fresh soft emboli and thrombi from vessels in the peripheral vasculature.	Subject Device is the same indication of use as the Predicate K113757.
Packaging Materials	Tray, Tyvek Lid, and Box commonly used with interventional devices.	Tray, Tyvek Lid, and Box commonly used with interventional devices.	Same as Predicate.
Sterilization	Ethylene Oxide Validated in accordance with ANSI/AAMI/ISO 11135-1 to achieve SAL 10^{-6}	Ethylene Oxide Validated in accordance with ANSI/AAMI/ISO 11135-1 to achieve SAL 10^{-6}	Same as Predicate.
Use	Single-use, disposable	Single-use, disposable	Same as Predicate.

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The Subject Device is substantially equivalent to Predicate device used to remove fresh, soft thrombi/emboli from the peripheral vasculature. Substantial equivalence is based on equivalence in:

Science
Fundamental Scientific Principle

Device Construction

Design	Mechanism of Action
Function	Manufacturing

Device Performance

Aspiration	Single-use, disposable

Labeling

Indication for Use	Instructions for Use
Warnings	Box labels

Manufacturing

Biocompatibility	Sterilization

Non-Clinical Testing
Non-clinical testing in this Submission confirms the Subject Device passes simulated use tracking, simulated aspiration, and simulated thrombectomy in the peripheral vasculature with test units accelerated aged up to 3-years. Accordingly, non-clinical testing confirms the Subject Device meets specifications, intended use, demonstration of claims, and equivalence to Predicate.

Clinical testing
Clinical testing is not required for the determination of substantial equivalence.

Statement of Substantial Equivalence
The Subject Device is substantially equivalent to the legally marketed Predicate based on comparison of the device classification, fundamental scientific technology, basic operating principle, indication for use, technical characteristics, packaging, and sterilization methods.

Conclusion
The Subject Device is substantially equivalent to the currently marketed Predicate based on comparison of the device classification, fundamental scientific technology, basic operating principle, indication for use, technical characteristics, packaging, and sterilization methods. Testing confirms the suitability of Subject Device for its intended use.