December 19, 2023

Abbott Medical
Namratha Manthani
Associate Director, Regulatory Affairs
3200 Lakeside Drive
Santa Clara, California 95054

Re: K232458
Trade/Device Name: JETi™ Hydrodynamic Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEZ, KDQ, FOX
Dated: August 11, 2023
Received: August 15, 2023

Dear Namratha Manthani:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2023.12.19 11:40:15 -05'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232458

Device Name
JETi™ Hydrodynamic Thrombectomy System

Indications for Use *(Describe)*
The JETi Hydrodynamic Thrombectomy System is intended to remove/aspirate fluid and break-up soft emboli and thrombus from the peripheral vasculature and to sub-selectively infuse/deliver diagnostics or therapeutics with or without vessel occlusion.

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

510(k) Summary Per 21 CFR §807.92	
510(k) Number	K232458
Date Prepared	December 18, 2023
Submitter Name & Address	Abbott Medical 3200 Lakeside Drive Santa Clara, CA 95054
Contact Person	Maidy Cordova Audon 408-219-8350
Alternative Contact Person	Namratha Manthani 408-220-5786
Proprietary/Trade Name	JETi ™ Hydrodynamic Thrombectomy System
Common/Usual Name	Embolectomy/Thrombectomy Catheter
Classification Name	Embolectomy Catheter (21 CFR 870.5150)
Primary Procode	QEZ
Secondary Procodes	KDQ, FOX
Predicate Device	Predicate Device: JETi All In One (AIO) Peripheral Thrombectomy System, K213565, Reference Device: JETi All In One (AIO) Peripheral Thrombectomy System, K201988
Device Description	The JETi™ Hydrodynamic Thrombectomy System is a hydro-mechanical aspiration system intended for the removal of intravascular thrombus. The system is comprised of the JETi™ Catheter, JETi™ Pump Set, JETi™ Saline Drive Unit (SDU), JETi™ Accessory Cart, JETi™ Suction Tubing, and JETi™ Non-sterile Canister Set. The JETi Hydrodynamic Thrombectomy System is designed to continuously aspirate thrombotic material into the JETi Catheter, where a high-pressure stream of saline within the catheter tip macerates the thrombus as it is

	aspirated. The JETi Catheter has two (2) lumens. The primary lumen (largest) is a conduit for thrombus aspiration. A secondary lumen, placed within the primary lumen, delivers saline through an orifice to break up and dilute the aspirated thrombus and facilitates rapid movement of the aspirate towards the vacuum. One (1) radiopaque (RO) marker band is located stiff proximal section which transitions to a more flexible distal section with a round, soft tip. A filter is incorporated into the catheter connector to ensure that no debris or foreign material is injected into the patient vasculature. The JETi Catheter is available in two sizes: 6 French size (6F) and 8 French size (8F). The JETi Pump Set is intended to deliver a high pressure sterile saline stream to the JETi Catheter. The pressure for the saline stream is created through the cassette's piston assembly, which snaps into the SDU. The JETi Saline Drive Unit (SDU) is a non-sterile reusable, (multiple patient, multiple use) device that incorporates the saline pumping components and the vacuum pump within a single enclosure. The fork drive of the SDU is designed to run the JETi Pump Set piston assembly to deliver a stream of saline to the JETi Catheter when activated by the handheld switch if the vacuum is present. In conjunction with the JETi Pump Set, the SDU can sub selectively infuse / deliver diagnostics or therapeutic fluids when utilizing the optional HYPER PULSE™ Fluid Delivery feature. The JETi Suction Tubing is a sterile single use device that incorporates the pressure monitoring sensor and valve into a single enclosure, that is in-line with the aspiration lumen, for the handheld switch. When the handheld switch is activated, within the aspiration lumen, the diluted thrombus and saline is then drawn back through the primary lumen of the JETi Catheter and deposited into the vacuum source (JETi Non-sterile Canister Set) via the JETi Suction Tubing. When the handheld switch is de-activated, a valve closes, stopping the flow of thrombus, and a relief valve inside the SDU briefly opens and closes to reduce foaming at the vacuum source (JETi Non-sterile Canister Set). The SDU contains a microprocessor-controller circuit board and firmware that monitors various functions of the motor and vacuum to ensure that the device is functioning as expected. A Liquid Crystal Display (LCD) screen on the front panel of the SDU indicates to the user the status of the system. Several safety features are incorporated into the firmware to ensure proper functionality. The SDU is supported by a mobile, height adjustable cart with an integrated IV pole. Energy is provided by a 24-volt external power supply, which is connected to the main supply. The external power supply is provided with the SDU and is part of the system.

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<table>
<tr><td>Indications for Use/Intended Use</td><td>The JETi™ Hydrodynamic Thrombectomy System is intended to remove / aspirate fluid and break-up soft emboli and thrombus from the peripheral vasculature and to sub-selectively infuse / deliver diagnostics or therapeutics with or without vessel occlusion.</td></tr>
<tr><td>Comparison to Predicate Device</td><td>The JETi ™ Hydrodynamic Thrombectomy System is substantially equivalent to the predicate JETi AIO Peripheral Thrombectomy System (K213565) in terms of indications for use, operational characteristics, fundamental design and technological characteristics.
<table>
<tr><th>Characteristic</th><th>Predicate Device
JETi AIO Peripheral Thrombectomy System (K213565)</th><th>Reference Device
JETi AIO Peripheral Thrombectomy System (K201988)</th><th>Subject Device
JETi Hydrodynamic Thrombectomy System</th></tr>
<tr><td>Indications for Use Statement</td><td>The JETi AIO Peripheral Thrombectomy System is intended to:
remove/aspirate fluid and break-up soft emboli and thrombus from the peripheral vasculature, and
subselectively infuse/deliver diagnostics or therapeutics with or without vessel occlusion.</td><td>Same as Predicate Device (K213565)</td><td>The JETi Hydrodynamic Thrombectomy System is intended to:
remove/aspirate fluid and break-up soft emboli and thrombus from the peripheral vasculature, and
subselectively infuse/deliver diagnostics or therapeutics with or without vessel occlusion.
Minor change to the product name, otherwise same as indications as the Predicate Device (K213565).</td></tr>
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	Contraindications	Contraindicated for use in vessels smaller than 4 mm (0.16”) and Coronary, pulmonary, and neurovasculature.	Same as Predicate Device (K213565)	Same as Predicate Device (K213565)
	Mode of Operation	Simultaneous saline delivery with aspiration Infuse/deliver diagnostics or therapeutics	Same as Predicate Device (K213565)	Same as Predicate Device (K213565)
	Catheter			
	Catheter Working Length (cm)	100 cm (8 Fr) 120 cm (6 Fr)	100 cm (8 Fr)	Same as Predicate Device (K213565)
	Catheter Connections (saline and aspiration) and location	Multi-port Luer adapter	Same as Predicate Device (K213565)	Same as Predicate Device (K213565)
	Pump Set			
	Saline Input Tube Length (feet)	6	Same as Predicate Device (K213565)	Same as Predicate Device (K213565)
	Saline Drive Unit (SDU)			

		On/Off Control	Hand-held controller	Same as Predicate Device (K213565)	Same as Predicate Device (K213565)
		Method to Stop Flow	Hand-held controller	Same as Predicate Device (K213565)	Same as Predicate Device (K213565)
		Aspiration Method	Vacuum pump	Same as Predicate Device (K213565)	Same as Predicate Device (K213565)
		Location	Mounted on cart outside sterile field	Same as Predicate Device (K213565)	Same as Predicate Device (K213565)
		Vacuum Sensor Connector	Standard RJ45	Same as Predicate Device (K213565)	Same as Predicate Device (K213565)
		Hyper Pulse Mode	Rocker switch on SDU to shut off the vacuum pump and enter Hyper Pulse mode	No rocker switch for Hyper Pulse mode. Hyper Pulse mode achieved by manual method	Same as Reference Device cleared under K201988. Minor modification.
		Accessory Cart			
		Saline Bag Mounting	Integrated IV pole	Same as Predicate Device (K213565)	Same as Predicate Device (K213565)
		Product code/ Classification Regulation	QEZ/ 21 CFR 870.5150	Same as Predicate Device (K213565)	FOX/ 21 CFR 880.6990

				Update to the product code and classification to align with the intended use/function.
	Suction Tubing			
	Accessory device required for procedure	• 3D-printed parts • Injection-molded Polypropylene Syringe • 3D-printed Acrylonitrile (ABS) Handle • Polyvinyl Chloride (PVC) Tubing containing DEHP	Same as Predicate Device (K213565)	• Molded parts • Injection-molded Polycarbonate Syringe • Injection-molded Polycarbonate Handle • DEHP-free Polyvinyl Chloride (PVC) Tubing
	Non-sterile Canister Set			
	Accessory devices	Canister with built-in filter and suction tubing	Canister, inline filter and suction tubing	Same as Predicate Device (K213565)
	Product code/ Classification Regulation	QEZ/ 21 CFR 870.5150	Same as Predicate Device (K213565)	KDQ/ 21 CFR 880.6740 Update to the product code and classification to align with the intended use/function.
	Sterile Kit			

	Sterile Kit	Present Contains: - Catheter - Pump set - Sterile suction tubing - Valve bypass tool	Same as Predicate Device (K213565)	Same as Predicate Device except optional accessory, Valve Bypass tool, is not included.
Summary on Non-Clinical Testing	Packaging validation including functional testing was performed on the JETi Hydrodynamic Thrombectomy System per ASTM D4332, ASTM 4169 and per Abbott's internal procedures. All the data met the acceptance criteria and fell within pre-determined product specifications. Human factors evaluation was performed for IFU changes and the evaluation demonstrated that the IFU conveys the appropriate information in a clear and concise manner, i.e., facilitates understanding of the device usage to support safe and effective use of the device. The following EMC testing per IEC 60601-1-2 was performed and the device met the acceptance criteria: • Evidence of conformance with the emission limits (both radiated and conducted) of CISPR 11 Class A • Air Electrostatic Discharge (ESD) tested at ±2, ±4, ±8, and ±15 kV and Contact Electrostatic Discharge (ESD) tested at ±8 kV • Radiated RF immunity testing data at 3 V/m • Proximity field immunity testing data (Table 9) of 60601-1-2 • Power frequency magnetic fields testing data at 30 A/m • Conducted disturbances induced by RF fields testing data for 3 Vrms outside industrial, scientific, and medical (ISM) and 6 Vrms in ISM bands • Electrical fast transient/burst immunity testing data • Surge immunity testing data in mains mode • Voltage dips, short interruptions and voltage variations testing data in mains mode			

	• Current Harmonics test • Voltage Fluctuation and Flicker test
Summary on Clinical Testing	No clinical testing is provided in this pre-market notification.
Statement of Equivalence	The JETi ™ Hydrodynamic Thrombectomy System is substantially equivalent to the predicate device, JETi AIO Peripheral Thrombectomy System (K213565) and reference device, JETi AIO Peripheral Thrombectomy System (K201988) in terms of indications for use, operational characteristics, fundamental design, and technological characteristics.