April 4, 2025

Abbott Medical
Fiona Pu
Manager, Regulatory Affairs
3200 Lakeside Drive
Santa Clara, California 95054

Re: K243549
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: March 4, 2025
Received: March 4, 2025

Dear Fiona Pu:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2025.04.04 14:49:22 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
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Office of Product Evaluation and Quality
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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.

Submission Number *(if known)*

K243549

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, including deep vein thrombosis (DVT), and to subselectively 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.

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

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ATTACHMENT 011-04

510(K) SUMMARY

510(k) Summary Per 21 CFR §807.92	
510(k) Number	K243549
Date Prepared	November 15, 2024
Submitter Name & Address	Abbott Medical 3200 Lakeside Drive Santa Clara, CA 95054
Contact Person	Fiona Pu 408-748-4990
Alternative Contact Person	Claire Elkins 408-845-0625
Proprietary/Trade Name	JETi ™ Hydrodynamic Thrombectomy System
Common/Usual Name	Embolectomy/Thrombectomy Catheter
Classification Name	Embolectomy Catheter (21 CFR 870.5150, Product Code QEZ) Infusion stand (21 CFR 880.6990, Product Code FOX) Vacuum-powered body fluid suction apparatus (21 CFR 880.6740, Product Code KDQ)
Predicate Device	Predicate device: ZelanteDVT Thrombectomy System, K202218 Reference device: JETi Hydrodynamic Thrombectomy System, K232458
Device Description	The JETi™ Hydrodynamic Thrombectomy System (JETi HTS) 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.
Indications for Use/Intended Use	The JETi™ Hydrodynamic Thrombectomy System is intended to remove/aspirate fluid and break-up soft emboli and thrombus from the peripheral vasculature, including deep vein thrombosis (DVT), and to sub-selectively infuse/deliver diagnostics or therapeutics with or without vessel occlusion.
Comparison to Predicate Device	The JETi Hydrodynamic Thrombectomy System (JETi HTS) is substantially equivalent to the predicate ZelanteDVT Thrombectomy

	System (K202218). Although the Indications for Use statement of the subject device is not identical to the predicate device, the differences do not alter the intended therapeutic use of the device and do not affect the safety and effectiveness of the device relative to the predicate. Both the JETi HTS and predicate device have the same intended use: removal of thrombi or emboli from and infusion of fluids into the peripheral vasculature including DVT. The technological principle for both the subject and predicate device is based on a clot fragmentation mechanism, which uses aspiration and a jet with fluid delivery features. Although JETi HTS and predicate device have different clot fragmentation mechanism and catheter size offering, the different technological characteristics between the subject device and predicate do not raise different questions of safety and effectiveness.
Summary on Non-Clinical Testing	Non-clinical testing was not required to support the update to the Indications for Use. The JETi HTS (K232458) is used as a reference device to account for differences in the technological features between the predicate ZelanteDVT Thrombectomy System and the JETi HTS. JETi HTS (K232458) is identical in design, technological, and performance characteristics to the subject device.
Summary on Clinical Testing	The JETi Registry collected real-world data on the safety, performance, and clinical benefits of the JETi HTS System for the treatment of thrombosis in the peripheral vasculature. It is a prospective, single-arm, multicenter study that registered 260 subjects treated for thrombosis in the peripheral vasculature from 27 sites in the United States (US) and Europe. Subjects were treated for arterial, venous, or arteriovenous thromboses and are followed for 12 months, with data collection at baseline, during the procedure, discharge, 30-day, and 12-month visits. This was a standard of care all-comers registry, and there were no restrictions on presenting thrombus location in the peripheral vasculature or onset of signs and symptoms. A total of 116 registered subjects were treated for lower extremity (LE) DVT. Subject mean age was 56.6 ± 18.5 years, with the youngest subject being 18 and oldest subject being 85 years old. The majority, 55.2% (64/116), were under 65 years old. The split between male 50.0% (58/116) and female 50.0% (58/116) subjects was even. Of the analysis population, 50.9% (59/116) identified as Caucasian, 6.9% (8/116) identified as Black; 1.7% (2/116) identified as American Indian or Alaskan Native; 31.9% (37/116) of subjects declined to disclose or did not disclose their race information due to Europe's

	local regulation. Self-identification of ethnicity of the subjects were 10.3% (12/116) as Hispanic or Latino, 59.5% (69/116) as non-Hispanic or Latino, 30.2% (35/116) as declined or non-disclosed due to Europe's local regulations. Treatment strategy, including the use of adjunctive therapy, was per investigator's discretion. The majority of patients in the registry (66.1% of limbs) were not treated with any adjunctive interventional device(s) (CDT or other thrombectomy device). The primary effectiveness endpoint, defined as at least 75% reduction in modified Marder Score from pre-JETi venogram to final venogram, per core laboratory assessment, was achieved in 84.5% (93/110) limbs, with a one-sided 97.5% lower confidence limit of 76.4% comparing to a performance goal of 64% with a p value of < 0.0001. The primary effectiveness endpoint of the JETi Registry was met. Primary effectiveness endpoint was comparable when the JETi system was used with or without adjunctive interventional device(s); with at least 75% thrombus reduction achieved in 86.8% and 83.3% of limbs, respectively. The primary safety endpoint, defined as the composite of JETi-related major adverse events up to 30 days post-JETi per CEC adjudication, was 1.7% (2/116) (95% CI, 0.21%, 6.09%). The rate of 1.7% (2/116) is less than the acceptance criterion of 10%. The primary safety endpoint of the JETi Registry was met. Treated vessel patency and compressibility, Villalta post-thrombotic syndrome score, leg pain, and quality of life were all improved at 30 days.
Statement of Equivalence	The proposed changes to the Indications for Use, namely adding the specific use for DVT, is supported by the clinical data presented and thus, has been shown to not raise new or different questions of safety and effectiveness relative to the predicate, therefore, it can be concluded that the JETi HTS is substantially equivalent to the predicate device.