November 25, 2025

Akura Medical
Theresa Brandner
VP, Regulatory Affairs
170 Knowles Drive
Los Gatos, California 95032

Re: K251070
Trade/Device Name: Akura Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: October 30, 2025
Received: October 31, 2025

Dear Theresa Brandner:

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: 2025.11.25 16:16:03 -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)*
K251070

Device Name
Akura Thrombectomy System

Indications for Use *(Describe)*

The Akura Thrombectomy Catheter System
As part of the Akura Thrombectomy System, the Akura Thrombectomy Catheter System is indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.

The Akura Thrombectomy Accessory Kit
As part of the Akura Thrombectomy System, the Akura Accessory Kit is indicated to connect the Akura Thrombectomy Catheter to the Akura Thrombectomy Console.

The Akura Thrombectomy Console
The Akura Thrombectomy Console is indicated as a vacuum source for the Akura Thrombectomy System.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY FOR THE AKURA THROMBECTOMY SYSTEM

510(k) Number: K251070

A. SPONSOR

Akura Medical, Inc.
170 Knowles Drive
Los Gatos, CA 95032
USA

B. CONTACT

Theresa Brandner
VP, Regulatory Affairs
Tel: 650-868-7268
Email: theresa@akuramed.com

C. DEVICE NAME

Trade Name:	Akura Thrombectomy System
Common/Usual Name:	Embolectomy/Thrombectomy Catheter
Classification Name:	Embolectomy Catheter (21 CFR § 878.5150, Class II, Pro-Code QEW)
Classification Panel:	Cardiovascular

D. PREDICATE DEVICE

510(k):	K192981
Trade Name:	Indigo Aspiration System - Aspiration Catheter 12 and Separator 12
Common/Usual Name:	Embolectomy Catheter
Classification Name:	Embolectomy Catheter (21 CFR § 878.5150, Class II, Pro-Code QEW)
Classification Panel:	Cardiovascular

E. REFERENCE DEVICE

510(k):	K183403
Trade Name:	JETi 88 Peripheral Thrombectomy System
Common/Usual Name:	Embolectomy/Thrombectomy Catheter
Classification Name:	Embolectomy Catheter (21 CFR § 878.5150, Class II, Pro-Code QEZ)
Classification Panel:	Cardiovascular

F. DEVICE DESCRIPTION

The subject Akura Thrombectomy System is designed to remove thrombus from the vasculature. The System is used by interventionalists trained in percutaneous endovascular thrombectomy procedures. The subject Akura Thrombectomy System is comprised of several devices.

- Akura Thrombectomy Catheter System
  - Akura Thrombectomy Catheter
  - Akura Thrombectomy Sheath
  - Akura Thrombectomy Dilator
- Akura Thrombectomy Console
- Akura Accessory Kit
  - Saline Pump
  - Irrigation Tubing
  - Aspiration Canister Assembly

During use, the Akura Thrombectomy Catheter System and Akura Thrombectomy Accessory Kit are connected to the Akura Thrombectomy Console that is placed outside the sterile field. The Akura Thrombectomy System is introduced through percutaneous access using a commercially available 16F vascular introducer sheath and a 0.035 in exchange length guidewire. The Akura Thrombectomy Catheter System is delivered to the target treatment site under fluoroscopic guidance. The Akura Thrombectomy Dilator is removed from the Akura Thrombectomy Sheath. The Akura Thrombectomy Catheter is inserted through the Akura Thrombectomy Sheath, and the Akura Thrombectomy Catheter funnel is deployed. Thrombus is removed by fragmentation using internal saline jets and aspiration. After the procedure, the Akura Thrombectomy Catheter System is removed from the vasculature and disposed of using standard hospital practices. The Akura Thrombectomy Console is cleaned and stored in accordance with the Akura Thrombectomy System User Manual.

G. INDICATIONS FOR USE

The Akura Thrombectomy Catheter System

As part of the Akura Thrombectomy System, the Akura Thrombectomy Catheter System is indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.

The Akura Thrombectomy Accessory Kit

As part of the Akura Thrombectomy System, the Akura Accessory Kit is indicated to connect the Akura Thrombectomy Catheter to the Akura Thrombectomy Console.

The Akura Thrombectomy Console

The Akura Thrombectomy Console is indicated as a vacuum source for the Akura Thrombectomy System.

H. STERILIZATION AND SHELF LIFE

The Akura Thrombectomy System is sterilized using ethylene oxide. The suitability of the packaging to protect the subject Akura Thrombectomy System and to ensure sterility within the stated shelf life was verified through a series of tests performed by independent test laboratories. These tests confirm the packaging integrity, sterility, and distribution cycle. This testing demonstrated that the packaging is sufficiently robust to withstand extreme distribution and environmental conditions while maintaining packaging integrity and sterility.

I. BIOCOMPATIBILITY

The Akura Thrombectomy System includes components that are provided sterile for single use and disposal. The sterile components, the Akura Thrombectomy Catheter and Akura Thrombectomy Accessory Kit, have met the biocompatibility testing requirements identified in ISO 10993-1, including the tests for cytotoxicity, sensitization, irritation, systemic toxicity, pyrogenicity, and hemocompatibility.

J. TECHNOLOGY CHARACTERISTICS

The predicate device, the Indigo Aspiration System - Aspiration Catheter 12 and Separator 12 (K192981), and the reference device, the JETi 88 Peripheral Thrombectomy System (K183403), were used to support substantial equivalence of the subject Akura Thrombectomy System. The subject device, the predicate device, and the reference device include the following similar technical characteristics.

- Both the proposed device and predicate device are designed for the non-surgical removal of thrombi or emboli from vasculature.
- Both the subject device and predicate device are intended to be used with commonly available vascular access tools (e.g., guidewire, vascular introducer) to facilitate the removal of thrombus, embolus, and clot during minimally invasive percutaneous procedures.
- Both the subject device and predicate device are large bore catheters with a pump aspiration source.
- Both the subject device and predicate device have similar operating principles by being advanced through a sheath and over a guidewire to the target treatment location along with a mechanical aspiration source that is used to aspirate thrombus/emboli from vasculature.
- Both the subject device and the reference device use internal saline jetting for clot fragmentation during aspiration.

The technological characteristics of the proposed Akura Thrombectomy System are substantially equivalent with respect to the basic system design, function, materials, dimensions, and manufacturing to that of the predicate device.

K. PERFORMANCE DATA

Comprehensive bench testing (integrity and functional performance) was performed to support substantial equivalence to the predicate devices. The Akura Thrombectomy System met the specified design and performance requirements based on the following tests.

- Visual And Dimensional
- Funnel Integrity
- Funnel Radial Force
- Deployment Force
- Flexibility
- Torsion
- Fluidics
- Pressure Sensor
- Pressure/Leak
- Water Resilience
- Contrast Injection
- Tensile
- Simulated Use
- Particulate
- Corrosion Resistance
- Radiopacity
- Electromagnetic Compatibility
- Electrical Safety
- Electrical Emitter/Immunity
- Human Factors Evaluation/Usability Evaluation

L. CLINICAL TESTING

No clinical data were generated to establish substantial equivalence. Bench data are considered adequate to support a determination of substantial equivalence.

M. CONCLUSIONS

The results of the non-clinical testing and a comparison of similarities and differences demonstrate that the Akura Thrombectomy System and predicate device are substantially equivalent.