March 24, 2025

Control Medical Technology, Inc. / dba VentiV Scientific
% Spencer Walker
CEO/ Founder
Peak Regulatory Consulting
370 South 300 East
Salt Lake City, Utah 84111

Re: K250013
Trade/Device Name: VentiV 7Fr -12Fr MP Mechanical Thrombectomy System (VS7-MP60S, VS7-MP90S, VS8-MP60S, VS8-MP90S, VS8-MP100B, VS10-MP100B, VS11-MP60S, VS11-MP90S, VS12-MP100B, 7F-MP60S, 7F-MP90S, 8F-MP60S, 8F-MP100B, 10F-MP100B, 11F-MP60S, 11F-MP90S, 11P-MP60S, 11P-MP90S, 12F-MP100B, V30-ASP)
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEZ
Dated: December 31, 2024
Received: January 2, 2025

Dear Spencer Walker:

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: 2025.03.24 09:57:51 -04'00'

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)*
K250013

Device Name
VentiV 7Fr -12Fr MP Mechanical Thrombectomy System (VS7-MP60S, VS7-MP90S, VS8-MP60S, VS8-MP90S, VS8-MP100B, VS10-MP100B, VS11-MP60S, VS11-MP90S, VS12-MP100B, 7F-MP60S, 7F-MP90S, 8F-MP60S, 8F-MP100B, 10F-MP100B, 11F-MP60S, 11F-MP90S, 11P-MP60S, 11P-MP90S, 12F-MP100B, V30-ASP)

Indications for Use *(Describe)*
The VentiV 7Fr – 12Fr MP Mechanical Thrombectomy System and VentiV Mechanical Aspirator are 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

(21 CFR 807.92)

GENERAL INFORMATION

Submitter:	Control Medical Technology, Inc. dba VentiV Scientific
Contact Person*:*	Spencer Walker, MSc. – Regulatory Affairs Peak Regulatory Consulting 370 South 300 East Salt Lake City, UT 84111 (801) 708-2238 Spencer@peakregulatory.com
Trade Names:	VentiV 7Fr – 12Fr MP Mechanical Thrombectomy System (VS7-MP60S, VS7-MP90S, VS8-MP60S, VS8-MP90S, VS8-MP100B, VS10-MP100B, VS11-MP60S, VS11-MP90S, VS12-MP100B, 7F-MP60S, 7F-MP90S, 8F-MP60S, 8F-MP100B, 10F-MP100B, 11F-MP60S, 11F-MP90S, 11P-MP60S, 11P-MP90S, 12F-MP100B, V30-ASP)
Common Name of Device	Thrombectomy Catheter and/or Embolectomy Catheter
Classification Name*:*	Embolectomy Catheter 21 CFR §870.5150, Product Code QEZ
Device Class:	Class II
Primary Predicate Device:	510(k) No.: K200871 Model: Aspire MAX 7 - 11F Mechanical Thrombectomy System and Aspire Mechanical Aspirator Manufacture: Control Medical Technology, Inc. Classification: QEZ
Reference Devices:	510(k) No.: K101497 Model: Delivery Sheath, Model Adelante Breezeway Manufacturer: Integer / Oscor Inc. Classification: DYB 510(k) No.: K122958 Model: Delivery Sheath, Model Adelante Breezeway Manufacturer: Integer / Oscor Inc. Classification: DYB

510(k) No.: K181463
Model: DuraSheath Introducer Sheath System
Manufacturer: Heraeus / Contract Medical International GmbH
Classification: DYB

510(k) No.: K210627
Model: Breezeway II
Manufacturer: Integer / Oscor Inc.
Classification: DYB

510(k) No.: K221914
Model: Catapult Guide Sheath
Manufacturer: Heraeus /Contract Medical International GmbH
Classification: DYB

510(k) No.: K240957
Model: Catapult Guide Sheath
Manufacturer: Heraeus /Contract Medical International GmbH
Classification: DYB

Device Description:
The VentiV Mechanical Thrombectomy System devices are single-use, sterile, short-term use medical devices designed to remove fresh soft emboli, debris, and thrombi from the peripheral vasculature. The System includes (1) VentiV Mechanical Aspirator and (1) VentiV 7Fr – 12Fr catheters and dilators.

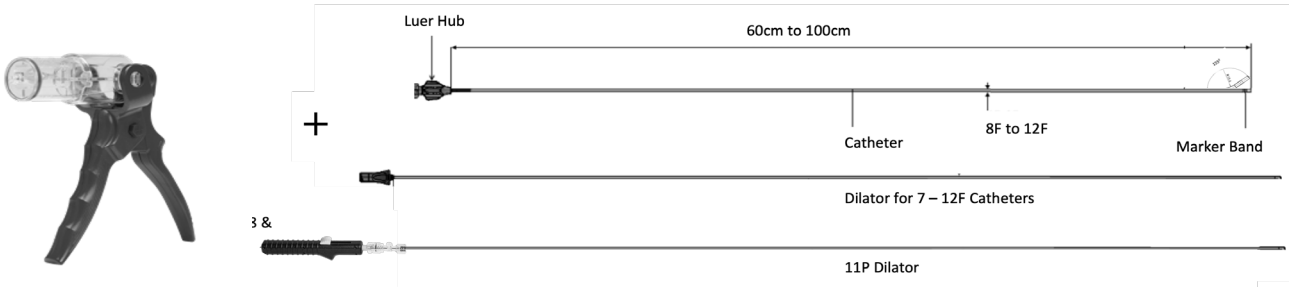

Figure 1: Representative image of the VentiV Mechanical Thrombectomy System and compatible devices.

Indications for Use:

The VentiV 7Fr – 12Fr MP Mechanical Thrombectomy System is indicated for the removal of fresh soft emboli and thrombi from vessels in the peripheral vasculature.

Comparative Analysis:
It has been demonstrated that the VentiV 7Fr – 12Fr MP Mechanical Thrombectomy System is comparable to the predicate device in intended use, fundamental scientific technology, design, principles of operation and functional performance evaluations. The VentiV 7Fr – 12Fr MP Mechanical Thrombectomy System has been fully assessed within the VentiV Scientific Risk

Management and Design Controls systems. All necessary verification steps met pre-determined acceptance criteria to demonstrate substantial equivalence to the predicate device.
It has been demonstrated that the VentiV 7Fr – 12Fr MP Mechanical Thrombectomy System is comparable to the predicate device in the following manner:

- Same intended use
- Same indications for use
- Same fundamental scientific technology
- Same material properties
- Same operating principle
- Same performance specifications
- Same patient-user interface

Table 1: Substantial Equivalence Comparison Chart – VentiV 7Fr – 12Fr MP Mechanical Thrombectomy System

	Predicate – K200871 (Control 7Fr – 11Fr Mechanical Thrombectomy System)	**Subject Device – (VentiV 7Fr – 12Fr MP Mechanical Thrombectomy System)**
Device Name	Control 7Fr – 11Fr Mechanical Thrombectomy System	VentiV 7Fr – 12Fr MP Mechanical Thrombectomy System
Classification Name	Aspiration Thrombectomy Catheter 21 CFR §870.5150 Product Code: QEZ Class II	Same – No Change
Ind. for Use	The Control 7Fr – 11Fr Mechanical Thrombectomy System and Control Mechanical Aspirator are indicated for the removal of fresh soft emboli and thrombi from vessels in the peripheral vasculature.	The VentiV 7Fr – 12Fr MP Mechanical Thrombectomy System and VentiV Mechanical Aspirator are indicated for the removal of fresh soft emboli and thrombi from vessels in the peripheral vasculature.
Single Use	Yes	Same – No Change
Prescription (Rx Only)	Yes	Same – No Change
Anatomical Access	Catheters are used in the peripheral vasculature via the patient's legs, arms, or chest	Same – No Change
Fundamental Scientific Technology	Over-the-wire intravascular catheters are introduced via percutaneous or open surgical technique, advanced to a target thrombus, then an aspirator, syringe, or pump is attached to the proximal end of the catheter, and the user creates thrombectomy force to remove the soft fresh thrombus or emboli from the vessel.	Same – No Change
Aspirator	30ml Control Aspirator FDA Cleared K072299, K113757, K131998, and K200871	30ml VentiV Aspirator FDA Cleared K072299, K113757, K131998, and K200871
Compatible Catheter Component	Over-the-Wire 7Fr – 11Fr Catheters	Over-the-Wire 7Fr – 12Fr Catheters
Tip Shape	Straight	Multipurpose

Table 1: Substantial Equivalence Comparison Chart – VentiV 7Fr – 12Fr MP Mechanical Thrombectomy System		
	Predicate – K200871 (Control 7Fr – 11Fr Mechanical Thrombectomy System)	**Subject Device – (VentiV 7Fr – 12Fr MP Mechanical Thrombectomy System)**
Aspiration Lumen Shape	Round	Same – No Change
Catheter Shaft OD	7Fr, 8Fr, 9Fr, 10Fr, 11Fr	7Fr, 8Fr, 9Fr, 10Fr, 11Fr, 12Fr
Usable lengths	60 – 90cm	60cm to 100cm
Aspiration Lumens	Single	Same – No Change
Guidewire	0.035”	Same – No Change
Integrated Radiopaque Marker	Yes	Same – No Change
Tip, Shaft & Dilator Body contact	Direct circulating blood <24h	Same – No Change
Hubs, liner, Aspirator valves and tubing	Indirect <24h	Same – No Change
Syringe Action	Manual	Same – No Change
Syringe maximum Vacuum Potential	-760mmHG -1ATM -14.69PSI	Same – No Change
Sterilization	ETO	Same – No Change
Packaging	Catheter in Hoop and Tyvek Tray	Same – No Change
Biocompatibility	ISO 10993 compliant	Same – No Change

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.

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.