February 17, 2026

Liquet Medical, Inc.
% Carrie Kuehn
Head of Regulatory
Evergreen Strategic Consulting
108 N Rolling Rd.
Catonsville, Maryland 21228

Re: K260149
Trade/Device Name: Versus™ Catheter (VS110-9NB)
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEY, KRA, DQO
Dated: January 16, 2026
Received: January 20, 2026

Dear Carrie Kuehn:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

KRINA M. PATEL -S

Digitally signed by KRINA M. PATEL -S
Date: 2026.02.17 12:37:14 -05'00'

For,

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)*
K260149

Device Name
Versus™ Catheter (VS110-9NB)

Indications for Use *(Describe)*
The Versus™ Catheter is indicated for:

The controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary artery vasculature in adult patients.

The assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring.

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 - K260149

VERSUS™ CATHETER (VS110-9NB)

I. SUBMITTER'S NAME

Liquet Medical Inc.
5619 Country Hills Ln
Glen Allen VA 23059,
United States

Contact Name: Carrie M. Kuehn, Head of Regulatory
Email: c.kuehn@liquetmedical.com
Phone: 301-337-8159
Date prepared: February 13, 2026

II. Device Information

Proprietary Name: Versus™ Catheter (VS110-9NB)
Common Name: Embolectomy Catheter
Classification Name: Mechanical Thrombolysis Catheter
Regulation Number: 870.5150
Classification Codes: QEY
Associated Product Codes: KRA, DQO

III. Predicate Devices

Versus™ Catheter VS110-8B (K241851)

IV. Device Description

The Versus™ Pulmonary Artery Catheter is a dual-tip, infusion catheter. Two lumens access and deliver physician-specified fluids, including thrombolytics, into the pulmonary arteries of each lung via a single access site. The Secondary Catheter tip telescopes independently to facilitate infusion into the contralateral lung. The device may allow for assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring. Pressure is measured through an interface between the catheter's fluid lumen and an externally located, FDA-cleared, pressure transducer.

V. Indications for Use

The Versus™ Catheter is indicated for:

The controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary artery vasculature in adult patients.

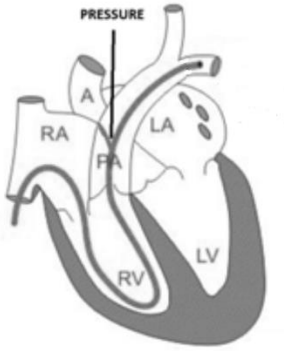
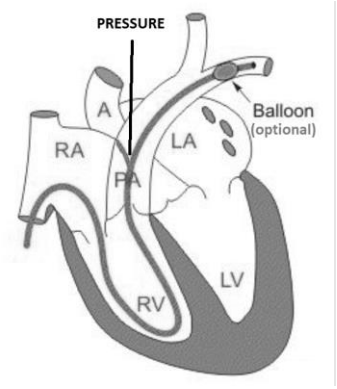
The assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring.

VI. Comparison of Technological Characteristics with the Predicate Devices

Table 1. Comparison of Subject Device to Predicate Device

Category	Subject Device: Versus™ Catheter VS110-9NB	Versus™ Catheter VS110-8B	Assessment
K-Number	K260149	K241851	N/A
Class	II	II	Same as predicate.
Ref. No.	VS110-9NB	VS110-8B	N/A
Product Code	QEY – Mechanical Thrombolysis Catheter KRA – Catheter, Continuous Flush DQO – Catheter, Intravascular Diagnostic	QEY – Mechanical Thrombolysis Catheter KRA – Catheter, Continuous Flush DQO – Catheter, Intravascular Diagnostic DYG – Catheter, Flow Directed	Same as predicate. Subject device does not have a flow-directed balloon. Therefore, code DYG does not apply.
Device Description	The Versus™ Pulmonary Artery Catheter is an intelligent, dual-tip, infusion catheter. Two lumens access and deliver physician-specified fluids, including thrombolytics, into the pulmonary arteries of each lung via a single access site. The Secondary Catheter tip telescopes independently to facilitate infusion into the contralateral lung. The device may allow for assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring. Pressure is measured through an interface between the catheter's fluid lumen and an externally located, FDA-cleared, pressure transducer.	The Versus™ Pulmonary Artery Catheter is an intelligent, dual-tip, infusion catheter. Two lumens access and deliver physician-specified fluids, including thrombolytics, into the pulmonary arteries of each lung via a single access site. The Secondary Catheter tip telescopes independently to facilitate infusion into the contralateral lung. The device may allow for assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring. Pressure is measured through an interface between the catheter's fluid lumen and an externally located, FDA-cleared, pressure transducer. The device may include an additional lumen that is in communication with a distal flow-directed balloon.	Same as predicate. Subject device does not have a flow-directed balloon.

Category	Subject Device: Versus™ Catheter VS110-9NB	Versus™ Catheter VS110-8B	Assessment
Intended Use	The Versus™ Catheter is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary artery vasculature in adult patients. The Versus™ Catheter is also intended for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring.	The Versus™ Catheter is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary artery vasculature in adult patients. The Versus™ Catheter is also intended for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring.	Same as predicate.
Indications for Use	The Versus™ Catheter is indicated for: • The controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary artery vasculature in adult patients. • The assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring.	The Versus™ Catheter is indicated for: • The controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary artery vasculature in adult patients. • The assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring.	Same as predicate.
Anatomical site(s)	Insertion through venous access to pulmonary arteries	Insertion through venous access to pulmonary arteries	Same as predicate.
Principles of Operation	The Versus™ Catheter employs dual lumens to facilitate the delivery of localized infusion of physician-specified fluids into the pulmonary arteries. The distal infusion segment consists of a segment with multiple infusion holes. It is used for the delivery of the physician-specified fluids at multiple cross-sectional points of the target vessel location. The infusion line connector is located on the proximal hub. The catheter is advanced over a guidewire using standard endovascular interventional techniques and is compatible with standard infusion connectors, accessories and equipment.	The Versus™ Catheter employs dual lumens to facilitate the delivery of localized infusion of physician-specified fluids into the pulmonary arteries. The distal infusion segment consists of a segment with multiple infusion holes. It is used for the delivery of the physician-specified fluids at multiple cross-sectional points of the target vessel location. The infusion line connector is located on the proximal hub. The catheter is advanced over a guidewire using standard endovascular interventional techniques and is compatible with standard infusion connectors, accessories and equipment.	Same as predicate. Subject device does not have a flow-directed balloon.

Category	Subject Device: Versus™ Catheter VS110-9NB	Versus™ Catheter VS110-8B	Assessment
	The Versus™ Catheter has a proximal luer that can be connected to a standard pressure transducer in line with an IBP-compatible patient monitor for direct intracardiac and pulmonary artery pressure monitoring.	Alternatively, the device may include an inflatable balloon at the tip, which facilitates its placement into the pulmonary artery through the flow of blood. The Versus™ Catheter has a proximal luer that can be connected to a standard pressure transducer in line with an IBP-compatible patient monitor for direct intracardiac and pulmonary artery pressure monitoring.	
Pressure measurement location(s)	 Proximal lumen port has the capability for direct blood pressure measurement at ~20cm from distal tip	 Proximal lumen port has the capability for direct blood pressure measurement at ~20cm from distal tip	Same as predicate.
Pressure measurement outputs	mmHg intracardiac or pulmonary artery pressure when connected to an in-line pressure transducer external to the patient	mmHg intracardiac or pulmonary artery pressure when connected to an in-line pressure transducer external to the patient	Same as predicate.
Energy Used and/or Delivered	The subject device does not use or deliver any energy.	The subject device does not use or deliver any energy.	Same as predicate.
Biocompatibility	Both ISO 10993 and FDA Draft Guidance "Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process"	Both ISO 10993 and FDA Draft Guidance "Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process"	Same as predicate.
Working Length	100 – 107 cm	100 – 107 cm	Same as predicate.
Outer Diameter - Primary	9 French	8 French	Similar to predicate.

Category	Subject Device: Versus™ Catheter VS110-9NB	Versus™ Catheter VS110-8B	Assessment
Radiopaque Marker	Radiopaque marker bands at distal and proximal ends of infusion segments, and at bifurcation.	Radiopaque marker bands at distal and proximal ends of infusion segments, and at bifurcation.	Same as predicate.
Guidewire Compatibility	A 0.035" guidewire for placement of the Primary Catheter. Guidewire of 0.035" for placement of the Secondary Catheter.	A 0.035" guidewire for placement of the Primary Catheter. Guidewire of 0.014" for placement of the Secondary Catheter.	Similar as predicate.
Treatment zone/infusion port	Infusion segment length of 12cm for both Primary and Secondary Catheters.	Infusion segment length of 12cm for both Primary and Secondary Catheters.	Same as predicate.
Infusion flow rate	Set the infusion pump to the desired infusion rate and activate per standard practice.	Set the infusion pump to the desired infusion rate and activate per standard practice.	Same as predicate.
Diameter of inflated balloon	N/A	13 mm ±2 mm	Subject device does not have a flow-directed balloon
Sterility	The devices are sterilized using standard methods and the sterilization cycles have been validated following international standards. The sterilization validation complied with ISO 11135:2014. The sterilization cycle was validated to a sterility assurance level of 10^{-6}	The devices are sterilized using standard methods and the sterilization cycles have been validated following international standards. The sterilization validation complied with ISO 11135:2014. The sterilization cycle was validated to a sterility assurance level of 10^{-6}	Same as predicate.
Single Use	Yes	Yes	Same as predicate.
Environment for use	Healthcare facility/hospital	Healthcare facility/hospital	Same as predicate.
Electrical Safety	Contains no electrical components	Contains no electrical components	Same as predicate.
Materials	Platinum 90/Iridium 10, Pebax 5533 SA01 MED, Mobilize, Stabilized, Natural, Pebax 3533 SA01 MED, Stabilized – Clear, ABS, Pebax 7233 SA01 MED, Mobilize, Stabilized – Pantone 360C, Loctite 4307, Pellethane 65D, Stabilized – Pantone 107C, Pellethane 65D, Stabilized – Pantone 2935C, Pellethane 65D, Stabilized – Pantone Clear, Polycarbonate, Ink Type P RNT Black, Nylon, PVC, Silicone	Polyisoprene, Platinum 90/Iridium 10, Pebax 5533 SA01 MED, Mobilize, Stabilized, Natural, Pebax 3533 SA01 MED, Stabilized – Clear, ABS, Pebax 7233 SA01 MED, Mobilize, Stabilized – Pantone 360C, Loctite 4307, Pellethane 65D, Stabilized – Pantone 179C, Pellethane 65D, Stabilized – Pantone 107C, Pellethane 65D, Stabilized – Pantone 2935C, Pellethane 65D, Stabilized – Pantone Clear, Polycarbonate, Ink	Same as predicate. Subject device does not have a flow directed balloon, associated syringe and stopcock, and associated proximal tubing. .

Category	Subject Device: Versus™ Catheter VS110-9NB	Versus™ Catheter VS110-8B	Assessment
		Type P RNT Black, Nylon, PVC, Silicone, HDPE, Polypropylene.	

VII. Summary of Performance Testing (Non-Clinical Testing)

This 510(k) notification provides performance data to establish the substantial equivalence of the Liquet Medical Versus™ Catheter to the Predicate device. The following is a summary of the performance data.

Sterilization and Shelf Life: The device is sterilized using standard methods and the sterilization cycles have been validated following international standards. The shelf life of the devices has been established through stability studies. The sterilization validation complied with ISO 11135:2014. The sterilization cycle was validated to a sterility assurance level of 10^{-6}. The shelf life of the Versus™ Catheter is 6 months.

Biocompatibility: Biocompatibility evaluation was performed on the Predicate device (VS110-8B), and leveraged here for the VS110-9NB, to show the finished, sterilized device is biocompatible and suitable for its intended use. Both ISO 10993 and FDA Draft Guidance "Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process" were taken into account to evaluate the biocompatibility of the subject device. The testing included an evaluation of:

- Acute Systemic Toxicity
- Complement Activation Assay
- Cytotoxicity
- Hemolysis
- Heparinized Blood Platelet and Leukocyte Count Assay
- Intracutaneous Irritation
- Material Mediated Pyrogenicity
- Maximization Sensitization Test
- Partial Thromboplastin Time (PTT) Assay
- Particulate Infrared Spectroscopy

Human Factors Testing: Usability testing was conducted on the Predicate device (VS110-8B), and leveraged here for the VS110-9NB, per IEC 62366-1:2015 and FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices". The study performed, using the to-be marketed device with intended users, demonstrated that the users were able to perform novel critical tasks of the Versus™ Catheter in an anatomical model in a simulated environment. The results of this testing met the predefined acceptance criteria.

Performance Testing - Bench: Performance testing was performed to characterize the Versus™ Catheter. The testing included an evaluation of:

- Kink radius
- Trackability
- Advancement force
- Retraction force
- Infusion uniformity
- Pressure lumen measurement
- Dimensional and visual verification
- Corrosion resistance
- Radiopacity
- Joint tensile strengths

Performance Testing - Animal: The Versus™ Catheter was previously evaluated in a GLP porcine study under K241851 and that animal study is leveraged here for the Versus™ Catheter VS110-9NB. For the VS110-8B all success criteria established for the study were met. Use of the VS110-8B catheter had no adverse effects systemically or pathologically, supporting substantially equivalent safety and performance outcomes of the Versus™ Catheter to the primary predicate device (i.e., Bashir N-X Endovascular Catheter) when used in the target vasculature.

Package and Transit Testing: Packaging and transit testing were conducted in accordance with ASTM D4332-22 for conditioning and ASTM D4169 for simulated distribution testing. Results demonstrated that the packaging system maintained its integrity and provided adequate protection of the device under simulated distribution conditions.

The performance data demonstrate that the new device is substantially equivalent to the Predicate device.

VIII. Determination of Substantial Equivalence to Predicate Devices

The information presented in the 510(k) Submission demonstrates that the Liquet Medical Versus™ Catheter (VS110-9NB) is substantially equivalent to the Predicate device.