



November 25, 2024

Liquet Medical Inc.
Carrie Kuehn
Regulatory Affairs Consultant
Evergreen Strategic Consulting
108 N Rolling RD
Catonsville, Maryland 21228

Re: K241851
Trade/Device Name: Versus™ Catheter (VS110-8B)
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEY, KRA, DQO, DYG
Dated: June 20, 2024
Received: June 27, 2024

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 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,

Ariel G. Ash-
shakoor -S

Digitally signed by
Ariel G. Ash-shakoor -S
Date: 2024.11.25
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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

Indications for Use

510(k) Number (if known)
K241851

Device Name
Versus™ Catheter (VS110-8B)

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.

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510(K) SUMMARY - K241581
VERSUS™ CATHETER (VS110-8B)

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: November 21, 2024

II. Device Information

Proprietary Name: Versus™ Catheter (VS110-8B)
Common Name: Embolectomy Catheter
Classification Name: Mechanical Thrombolysis Catheter
Regulation Number: 870.5150
Classification Codes: QEY
Associated Product Codes: KRA, DQO, DYG

III. Predicate Devices

Primary Predicate Device: Bashir N-X Endovascular Catheter (K183290)
Secondary Predicate Device: Swan Ganz Catheters (K160084)

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. The device may include an additional lumen that is in communication with a distal flow-directed balloon.

V. Indications for Use

The Versus™ Catheter is indicated for:

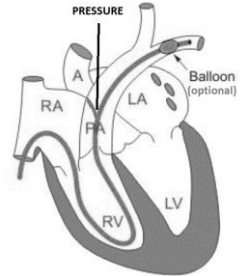
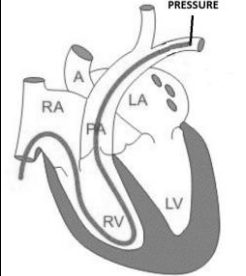
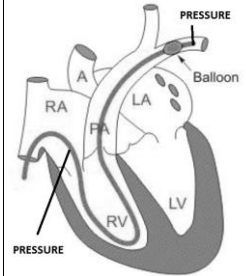
The controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary artery vasculature in adult patients.

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 Devices

Category	Subject Device – Versus™ Catheter (VS110-8B) K241851	Predicate Device – Bashir Endovascular Catheter Model 7201, Bashir N-X Endovascular Catheter, Mode 7200 K183290	Predicate Device – Swan-Ganz Catheters K160084	Comparison
Class	II	II	II	Same
Product Code	QEY – Mechanical Thrombolysis Catheter KRA – Catheter, Continuous Flush DQO – Catheter, Intravascular Diagnostic DYG – Catheter, Flow Directed	QEY – Mechanical Thrombolysis Catheter KRA – Catheter, Continuous Flush	DYG – Catheter, Flow Directed DQE – Catheter, Oximeter, Fiberoptic DQO – Catheter, Intravascular, Diagnostic KRA – Catheter, Continuous Flush	Similar A combination of the predicates’ product codes
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. The device may include an additional lumen that is in communication with a distal flow-directed balloon.	The Bashir N-X Endovascular Catheter (Ref. No. 7200) is a device intended for the localized infusion of physician-specified fluids, into the peripheral vasculature, including the pulmonary arteries. The distal infusion segment of the device is 12.50 cm (4.94 in) long and consists of a segment with mini-infusion catheters, each 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 handle. The catheter is advanced over a guidewire using standard endovascular interventional techniques and is compatible with standard infusion connectors, accessories and equipment.	The Swan-Ganz thermodilution catheters provide diagnostic information to rapidly determine hemodynamic pressures and cardiac output when used with a compatible cardiac output computer. In addition to the standard distal (pulmonary artery) and injectate lumens, the Swan-Ganz VIP thermodilution catheter (Models 831F75, 831F75P and 831VF75P) has an additional lumen that provides direct access to the right atrium. The Swan-Ganz VIP+ tri-lumen infusion thermodilution catheter (Model 834F75) is equipped with a right atrium lumen and an additional lumen. The catheter’s right ventricular (RV) lumen terminates 19 cm from the catheter tip and the right atrial (RA) lumen terminates at 31 cm. The VIP lumen allows for continuous infusion, even during cardiac output determinations.	Similar
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 Bashir N-X Endovascular Catheter is intended for the controlled and selective infusion of physician-specified fluids into the peripheral and pulmonary artery vasculature.	Swan-Ganz thermodilution catheters are indicated for the assessment of a patient’s hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination, and for infusing solutions. The distal (pulmonary artery) port also allows sampling of mixed venous blood for the assessment of oxygen transport balance and the calculation of derived parameters such as oxygen consumption, oxygen utilization coefficient, and intrapulmonary shunt fraction.	Same The subject device includes one intended use from the Primary Predicate and one intended use from the Secondary Predicate.
Indications for Use	The Versus™ Catheter is indicated for:	The Bashir N-X Endovascular Catheter is intended for the controlled and	Swan-Ganz thermodilution catheters are indicated for the assessment of a	Similar

	<ul style="list-style-type: none"> 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. 	selective infusion of physician-specified fluids into the peripheral and pulmonary artery vasculature.	patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination, and for infusing solutions. The distal (pulmonary artery) port also allows sampling of mixed venous blood for the assessment of oxygen transport balance and the calculation of derived parameters such as oxygen consumption, oxygen utilization coefficient, and intrapulmonary shunt fraction.	The indications for use contains an indication from each predicate device.
Anatomical site(s)	Insertion through venous access to pulmonary arteries	Insertion through venous access to pulmonary arteries or peripheral vasculature	Insertion through venous access to pulmonary arteries	Same
Principles of Operation	<p>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.</p> <p>The catheter is advanced over a guidewire using standard endovascular interventional techniques and is compatible with standard infusion connectors, accessories and equipment.</p> <p>Alternatively, the device may include an inflatable balloon at the tip, which facilitates its placement into the pulmonary artery through the flow of blood.</p> <p>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.</p>	<p>Localized infusion of physician-specified fluids, into the peripheral vasculature, including the pulmonary arteries. The distal infusion segment consists 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 handle.</p> <p>The catheter is advanced over a guidewire using standard endovascular interventional techniques and is compatible with standard infusion connectors, accessories and equipment.</p>	<p>The Swan-Ganz catheters are well known pulmonary artery catheters intended for use on critical care patients. A Swan-Ganz Catheter includes an inflatable balloon at the tip, which facilitates its placement into the pulmonary artery through the flow of blood.</p> <p>The Swan-Ganz catheters can be used with compatible cardiac output patient monitors and/or with oximetry modules (depending on the model number) to transmit signals for hemodynamic pressure monitoring, cardiac output measurements, and/or oximetry measurements. The Swan-Ganz catheters are to be used with the Edwards and/or Edwards' compatible patient monitors, such as the Vigilance II.</p>	<p>Same</p> <p>Guidewire placement is the same as Primary Predicate.</p> <p>Balloon placement and pressure monitoring is the same as Secondary Predicate.</p>
Pressure measurement location(s)	 <p>Proximal lumen port has the capability for direct blood pressure measurement at ~20cm from distal tip</p>	 <p>Distal lumen port has the capability for direct blood pressure measurement at the distal tip</p>	 <p>Proximal lumen port has the capability for direct blood pressure measurement at ~30cm from the catheter tip, and also at the distal tip</p>	Similar

Pressure measurement outputs	mmHg intracardiac or pulmonary artery pressure when connected to an in-line pressure transducer external to the patient	mmHg distal pulmonary artery pressure when connected to an in-line pressure transducer external to the patient	mmHg intracardiac proximal lumen port, distal pulmonary artery pressure, Cardiac Output (CO), Stroke Volume (SV)	Same as Primary Predicate. Similar to Secondary Predicate (Subject device does not include a thermistor to output CO, SV parameters)
Energy Used and/or Delivered	The subject device does not use or deliver any energy.	This predicate does not use or deliver any energy.	Thermal energy emitted by the thermal filament located on the catheter.	Same as Primary 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”	Not reported.	Same as Primary Predicate.
Working Length	100 – 107 cm	92.50 cm	75 – 110 cm	Similar
Outer Diameter	8 French	7 French	7 – 7.5 French	Similar
Radiopaque Marker	Radiopaque marker bands at distal and proximal ends of infusion segments, and at bifurcation.	The distal 12.50 cm (4.94 in) infusion segment is radiopaque and visible under fluoroscopy along its full length.	Not reported.	Similar
Guidewire Compatibility	A 0.035” guidewire for placement of the Primary Catheter. Guidewire of 0.014” for placement of the Secondary Catheter.	A 0.035” guidewire, of the required length to fit the sheath. Guidewire of 0.018” for placement.	A 0.025” guidewire for placement	Same as Primary Predicate
Treatment zone/infusion port	Infusion segment length of 12cm for both Primary and Secondary Catheters.	Infusion segment length of 12.50 cm.	Distal tip infusion, some catalog numbers include 3 or 4 infusion lumens.	Similar to Primary 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.	Not relevant	Same as Primary Predicate.
Diameter of inflated balloon	13 mm ±2 mm	Not applicable. Device does not have a balloon.	13 mm.	Same as Secondary Predicate.
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 .	Sterile (EtO)	Same as Primary and Secondary Predicates.
Single Use	Yes	Yes	Yes	Same
Environment for use	Healthcare facility/hospital	Healthcare facility/hospital	Healthcare facility/hospital	Same as Primary and Secondary Predicates.
Electrical Safety	Contains no electrical components	Contains no electrical components	Warning: Compliance to IEC 60601-1 is only maintained when the catheter or probe (CF applied part, defibrillation proof) is connected to a patient monitor or equipment that has a Type CF defibrillation proof rated input connector. If attempting to use a third party monitor or equipment, check with the monitor or equipment manufacturer to ensure IEC 60601-1 compliance and compatibility with the catheter or probe. Failure to ensure monitor or equipment compliance to IEC 60601-1 and	Same as Primary Predicate.

			catheter or probe compatibility may increase the risk of electrical shock to the patient/operator.	
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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 Primary and Secondary Predicate devices. 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 was established through accelerated aging studies and support a shelf life of 3 months.

Biocompatibility: Biocompatibility evaluation has been performed 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 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
- Luer hub compatibility
- Balloon inflation and integrity
- Corrosion resistance
- Radiopacity
- Joint tensile strengths

The performance data demonstrate that the new devices are substantially equivalent to the Primary and Secondary Predicate devices.

Performance Testing – Animal: The Versus™ Catheter was evaluated in a GLP porcine study with comparison to the primary predicate device. All success criteria established for the study were met. Use of the catheter had no adverse effects systemically or pathologically supporting substantially equivalent safety and performance outcomes of the Versus™ Catheter when used in the target vasculature.

VIII. Determination of Substantial Equivalence to Predicate Devices

The information presented in the 510(k) Submission demonstrates that the Lique Medical Versus™ Catheter (VS110-8B) is substantially equivalent to the Primary and Secondary Predicate devices.