October 24, 2025

Unity Medical, Inc.
Kim E. Aves
Vice President of Quality and Regulatory
6987 Washington Avenue South
Edina, Minnesota 55439

Re: K251372
Trade/Device Name: VersaD Delivery Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: September 26, 2025
Received: September 26, 2025

Dear Kim E. Aves:

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,

NAIRA MURADYAN -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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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.

510(k) Number *(if known)*
K251372

Device Name
VersaD Delivery Catheter

Indications for Use *(Describe)*
The VersaD Delivery Catheter is intended for use with compatible guide catheters in facilitating the insertion and guidance of catheters into selected blood vessels in the neuro and peripheral vascular systems.

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.

510(k) Summary

510(k) Number: K251372
Date Prepared: October 22, 2025

Submitter/Manufacturer	Unity Medical, Inc. 6987 Washington Ave South Edina, MN 55439
Contact	Kim E. Aves Phone: 763-205-1357
Trade Name	VersaD™ Delivery Catheter
Common/Usual Name	Percutaneous Catheter
Regulation Description	Percutaneous Catheter
Regulation Number	21 CFR 870.1250
Product Code	QJP, DQY
Device Class	Class II
Classification Panel	Neurology, Cardiovascular
Predicate Device	VersaD™ Delivery Catheter (K242051)

Device Description

The VersaD™ Delivery Catheter is a single-lumen, variable stiffness catheter with a long, tapered tip delineated by radiopaque markers. The catheter has a polytetrafluoroethylene (PTFE etched liner), the proximal end has a luer hub, and the distal portion has a hydrophilic coating to reduce friction. The delivery catheter is designed specifically for use with compatible catheters.

Indications for Use

The VersaD Delivery Catheter is intended for use with compatible guide catheters in facilitating the insertion and guidance of catheters into selected blood vessels in the neuro and peripheral vascular systems.

Comparison of Technological Characteristics with the Predicate Device

The device enhancements include transitioning the hub from Pebax 7233 to Pebax 7433 to improve durability and adding a PTFE liner to provide a smooth internal lumen with a low-friction surface.

Feature	**Predicate Device** **VersaD™ Delivery Catheter (K242051)**	**Subject Device** **VersaD™ Delivery Catheter (K251372)**
Regulation Name	Percutaneous Catheter	Percutaneous Catheter
Regulation	21 CFR 870.1250	21 CFR 870.1250
Product Code	QJP - Catheter, Percutaneous, Neurovasculature DQY - Catheter, Percutaneous	Same as predicate
Indications for Use	The VersaD Delivery Catheter is intended for use with compatible guide catheters in facilitating the insertion and guidance of catheters into selected blood vessels in the neuro and peripheral vascular systems.	Same as predicate

Feature	Predicate Device VersaD Delivery Catheter (K242051)	Subject Device VersaD Delivery Catheter (K251372)
Coating	Hydrophilic Coating	Same as predicate
Outer Diameter	Proximal: 0.062” Distal: 0.082”	Model 50347-001 (purple): Proximal: 0.062” Distal: 0.082” Model 50347-002 (teal): Proximal: 0.062” Distal: 0.062” Model 50347-003 (white): Proximal: 0.082” Distal: 0.062”
Inner Diameter	0.019”	0.022”
Liner	None	PTFE
Working Length	140 cm	Model 50347-001 (purple): 140 cm Model 50347-002 (teal): 160 cm Model 50347-003 (white): 140 cm
Hydrophilic Coating Length	90 cm	Same as predicate
Sterilization	Ethylene Oxide (EO)	Same as predicate
Packaging	The shelf carton contains one sterile pouch containing a Delivery Catheter, three wire insertion tools, and Instructions for Use.	Same as predicate
Accessory Device	Wire insertion tool - same material as catheter to introduce guidewires up to 0.018” (0.46mm) diameter.	Same as predicate

Performance Testing

To demonstrate substantial equivalence of the subject modified VersaD™ Delivery Catheter to the predicate VersaD Delivery Catheter, the following bench performance tests were conducted:

Test	Test Method Summary	Conclusion
Surface Integrity	The surface of the catheter was evaluated for surface defects.	The device met the established criteria.
Coating Uniformity	The surface of the catheter was evaluated for coating defects and voids.	The device met the established criteria.
Device Compatibility	A full-length silicone neurovascular model was used to simulate use. The procedure included using a test catheter with worst-case ancillary devices.	The device was found to be compatible with ancillary devices.
Push/Track	Simulated use was performed, and the catheter was tracked through a challenge neurovascular model to determine the deliverability of the subject catheter and compatibility with ancillary devices.	The device performed as intended under simulated use conditions.
Torque Response	The catheter was constrained, torqued, and evaluated.	The device met the established criteria.
Particulate	The catheter was tracked through the tortuous neurovascular model with ancillary devices, and particulate generation was measured.	Device particulate generation was similar to the predicate device.

Test	Test Method Summary	Conclusion
Coating Adhesion	The surface of the catheter was evaluated for coating voids after simulated use.	The device met the established criteria.
Dimensional Verification	The catheter dimensional attributes were evaluated and measured.	The device met the established criteria.
Kink Resistance	The proximal and distal sections of the catheter were evaluated using a radius apparatus.	The device met the established criteria.
Liquid Leak Under Pressure	The catheter was evaluated by holding hydrostatic pressure.	The device met the established criteria.
Air Leak Under Aspiration	The catheter was evaluated for air leakage into the hub assembly during aspiration.	The device met the established criteria.
Burst Strength	The catheter was pressurized to burst with fluid.	The device met the established criteria.
Tip Stiffness	The tip buckling force of the catheter was evaluated in comparison with the predicate.	The tip buckling force was similar to the predicate.
Tensile Strength (Tip, Mid Joints, and Hub)	The force required to separate the joints in the catheter was evaluated.	The device met the established criteria.
Delivery and Retrieval Force	The forces to deliver and retrieve the catheter within a neurovascular model were measured.	Delivery and retrieval forces were comparable to the predicate device.

Biocompatibility

Biocompatibility was assessed per ISO 10993-1 for an external communicating device directly contacting circulating blood for a limited (≤24 hours) duration. The table below summarizes the testing performed to evaluate changes to the VersaD Delivery Catheter subject to this submission.

Test Category	Method	Result
Cytotoxicity	MEM Elution with L-929 Cells (ISO 10993-5)	Non-Cytotoxic
Irritation	Intracutaneous Reactivity Test (ISO 10993- 23) – (saline, sesame oil extracts)	Non-Irritant

Sensitization	Guinea Pig Maximization Test (ISO 10993-10) – (saline, sesame oil extracts)	Non-Sensitizing
Acute Systemic Toxicity	Acute Systemic Injection Test (ISO 10993-11) – (saline, sesame oil extracts)	No evidence of Acute Systemic Toxicity
Material-Mediated Pyrogenicity	Rabbit Pyrogen test (USP <151>)	Non-Pyrogenic
Indirect Hemolysis	Hemolysis Test (ASTM F756) – Indirect (Extract) Contact Method	Non-Hemolytic

Sterilization and Shelf Life

The VersaD™ Delivery Catheters, both the subject device and predicate device, utilize the same packaging and sterilization cycle parameters. The sterilization process has been validated, and process monitoring controls are in place to ensure the device is EO sterilized to achieve a minimum sterility assurance level (SAL) of 10^{-6}. They are labeled as single-use sterile devices with a shelf life of 12 months.

Conclusions

The modified VersaD™ Delivery Catheter has the same intended use and principles of operation, and similar technological characteristics as the currently marketed predicate VersaD™ Delivery Catheter. The differences between the subject and predicate devices do not raise new questions of safety and effectiveness. The subject device was evaluated through design verification and validation, and biocompatibility testing. Based on the information submitted in this 510(k) submission, the subject VersaD™ Delivery Catheter is substantially equivalent to the currently marketed VersaD™ Delivery Catheter.