January 17, 2025

Unity Medical, Inc.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services
1000 Westgate Drive, Suite #510k
Saint Paul, Minnesota 55114

Re: K242051
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: December 2, 2024
Received: December 2, 2024

Dear Prithul Bom:

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,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
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Office of Product Evaluation and Quality
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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)*
K242051

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Unity Medical, Inc.
VersaD™ Delivery Catheter
Traditional 510(k) Premarket Submission

510(k) Summary

510(k) Number: K242051

Date Prepared: 17 January 2025

Submitter/Manufacturer	Unity Medical, Inc. 6087 Washington Ave South Edina, MN 55439
Contact	Matthew Ogle Phone: 612-381-7674
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	Route 92 Medical 088 Access System (K200121) - Delivery Catheter

Device Description

The VersaD™ Delivery Catheter is a single-lumen, variable stiffness catheter with a long, tapered tip delineated by radiopaque markers. 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

Feature	**Subject Device VersaD Delivery Catheter (K242051)**	**Predicate Device Delivery Catheter from Route 92 Medical 088 Access System (K200121)**
Regulation Name	Percutaneous Catheter	Percutaneous Catheter
Regulation	21 CFR 870.1250	21 CFR 870.1250
Product Code	QJP - Catheter, Percutaneous, Neurovasculature DQY - Catheter, Percutaneous	QJP
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.	The Route 92 Medical 088 Access System, 110 cm, is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system.
Coating	Hydrophilic Coating	Hydrophilic Coating

Feature	Subject Device VersaD Delivery Catheter (K242051)	Predicate Device Delivery Catheter from Route 92 Medical 088 Access System (K200121)
Materials	Polymers and metals commonly used in the manufacture of medical devices. Catheter Shaft: Stainless steel and varying durometers of Pebax. Luer: Pebax Markers: Pebax / 20% BaSO4	Polymers and metals commonly used in the manufacture of medical devices. Catheter Shaft: Stainless steel and varying durometers of Pebax. Luer: Polycarbonate Markers: Tungsten/Pebax
Inner Diameter	0.019”	0.019”
Outer Diameter	Proximal: 0.062” Distal: 0.082”	Proximal: 0.062” Distal: 0.080”
Working Length	140cm	151cm
Length of Polymer Section (non-hypotube section)	62cm	71cm
Hydrophilic Coating Length	90cm	90cm
Sterilization	Ethylene Oxide (EO)	EO
Packaging	The shelf carton contains one sterile pouch containing a Delivery Catheter, three wire insertion tools, and Instructions for Use.	The shelf carton contains one sterile pouch containing a Delivery Catheter and one Instructions for Use.

Performance Testing

To demonstrate substantial equivalence of the subject VersaD Delivery Catheter to the predicate Route 92 Medical 088 Access System Delivery Catheter, the bench performance, biocompatibility, and sterility of the VersaD Delivery Catheter were evaluated via the following test assessments:

- Design Verification Bench Testing
- Biocompatibility
- Shelf-Life
- Sterilization
- Packaging Validation

Performance Testing - Bench

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.
Tip Inspection	The distal tip of the catheter was evaluated.	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.
Corrosion	The catheter was evaluated for corrosion.	No corrosion was noted on the catheter.
Radiopacity	The catheter marker bands visibility were evaluated under fluoroscopy.	The device was visible under fluoroscopy.
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.

Test Category	Method	Result
Cytotoxicity	MEM Elution with L-929 Cells (ISO 10993-5)	Non-Cytotoxic
Irritation	Intracutaneous Reactivity Test (ISO 10993-23) – (saline and sesame oil extracts)	Non-Irritant
Sensitization	Guinea Pig Maximization Sensitization Test (ISO 10993-10) – (saline and sesame oil extracts)	Non-Sensitizing
Systemic Toxicity	Acute Systemic Injection Test (ISO 10993-11) – (saline and sesame oil extracts)	No evidence of Acute Systemic Toxicity
Material-Mediated Pyrogenicity	Rabbit Pyrogen test (USP <151>)	Non-Pyrogenic
Complement Activation	SC5b-9 Assay (with comparator control)	Non- Activator
Thrombogenicity - In Vitro Blood Flow Loop Assay	In vitro blood flow loop with comparator control (ISO 10993-4 and *In Vitro Blood Flow Loop System for Thrombogenicity Evaluation of Medical Devices and Biomaterial*[1])	Thromboresistant
Thrombogenicity - Coagulation	Partial Thromboplastin Time (PTT) Assay Human Blood (ISO 10993-4 and ASTM 2382)	No effect on the PTT
Thrombogenicity - Platelet Leukocyte	Direct contact Platelet Leukocyte Count Test (ISO 10993-4 and ASTM 2888)	No effect on the platelet and leukocyte count
Hemolysis	Hemolysis Test (ASTM F756) – Indirect (Extract) and Direct Contact Method	Non- Hemolytic

[1] FDA *Catalog of Regulatory Science Tools to Help Assess New Medical Devices*

Sterilization and Shelf Life

The VersaD™ Delivery Catheter is labeled as a single-use sterile device with a shelf life of 12 months. 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}. Shelf-life studies have demonstrated that the product and packaging remain functional and sterile for 12 months.

Conclusions

The VersaD™ Delivery Catheter has the same intended use and similar technological characteristics and principles of operation as the currently marketed predicate Delivery Catheter from the Route 92 Medical 088 Access System. Any 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, biocompatibility, and sterility testing. Based on the information submitted in this 510(k) submission, the VersaD™ Delivery Catheter is substantially equivalent to the currently marketed Delivery Catheter from the Route 92 Medical 088 Access System.