



October 20, 2025

Vascular Flow Technologies Limited
Angela Paterson
Head of QA/RA
Prospect Business Centre
Gemini Crescent
Dundee, DD2 1TY
United Kingdom

Re: K252277

Trade/Device Name: Spiral Laminar Flow™ Vascular Arteriovenous Graft (AV0645)
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular graft prosthesis
Regulatory Class: Class II
Product Code: DSY
Dated: July 18, 2025
Received: July 22, 2025

Dear Angela Paterson:

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,

Rohini Retarekar -S

for Carmen Johnson, PhD
Assistant Director
DHT2B: Division of Circulatory Support,
Structural, and Vascular 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)
K252277

Device Name
Spiral Laminar Flow Vascular Arteriovenous Graft

Indications for Use (Describe)

The Spiral Laminar Flow Vascular Arteriovenous Graft is intended for use as a subcutaneous arteriovenous conduit for vascular access during hemodialysis.

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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Vascular Flow Technologies Ltd.
Traditional 510(k)
For Spiral Laminar Flow™ Vascular Arteriovenous Graft

510(k) Summary K252277

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Submitter's Name: Vascular Flow Technologies Limited.

Submitter's Address:

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Dundee
DD2 1TY,
United Kingdom

Contact Person: Angela Paterson

Telephone: +44 7884274220

Date Prepared: 23rd September 2025

Vascular Flow Technologies Ltd.
Traditional 510(k)
For Spiral Laminar Flow™ Vascular Arteriovenous Graft

Device Classification Information:

Regulation Number	Device	Device Class	Product Code	Classification Panel
870.3450	Prosthesis, Vascular Graft, of 6mm and greater Diameter	Class 2	DSY	Cardiovascular

Device Trade Name:

Spiral Laminar Flow™ Vascular Arteriovenous Graft

Device Common Name:

Spiral Laminar Flow™ Vascular Arteriovenous Graft

Predicate Device:

Spiral Flow Vascular Arteriovenous Grafts cleared under 510(k) number K141124 and K094044

Indications for Use:

The SLF™* Vascular Arteriovenous Graft is a vascular prosthesis, which is intended for use as a subcutaneous arteriovenous conduit for vascular access during hemodialysis.

ONLY trained and qualified physicians and/or surgeons, under the controlled conditions of a hospital operating theatre environment are indicated for use of this device for implantation.

Vascular Flow Technologies Ltd.
Traditional 510(k)
 For Spiral Laminar Flow™ Vascular Arteriovenous Graft

Device Description:

SLF™ Vascular Arteriovenous Grafts are straight tubes constructed of expanded polytetrafluoroethylene (ePTFE) with the unique spiral flow inducer and nonremovable external inducer indicator ring (palpable ring) formed from ChronoFlex™* AL-80A, a Biodurable Medical Grade polyurethane. The spiral flow inducer is a helical deformation in the wall of the graft. The inducer indicator ring is on the outer surface of the proximal end of the spiral flow inducer, indicating the beginning of the spiral inducer segment and the no cannulation area of the graft.

A Shaped Hood is provided to guide the surgeon when creating the distal anastomosis. Although not critical to the functioning of the device, the hood does provide for an effective attachment angle and alignment of the spiral flow inducer with the native vessel

All grafts are supplied sterile and will remain so for the stated shelf life unless the packaging is opened or damaged.

SLF™ Vascular Arteriovenous grafts are available in one size (Table 1).

Table 1: SLF Graft Dimensions

Device	Diameter	Length
SLF™ Vascular Arteriovenous Grafts	6 mm	450 mm

Comparison to Predicate Device

The modifications in comparison to the previously cleared devices are as follows

- Supplier of base ePTFE Graft Material
- Chemical structure of polyurethane overmould material

Non-Clinical Tests (Performance/Physical Data)

A summary of performance testing carried out on the subject device to confirm that it met its specifications and demonstrate substantial equivalence to the predicate device is provided in Table 3.

Table 3: Summary of Non-Clinical Performance- Bench Testing

Test Name	Test Description	Individual tests	Results
ISO 7198 Testing	Testing of the Spiral Laminar Flow Vascular Arteriovenous Graft demonstrated compliance to ISO 7198:2016 Cardiovascular implants and extracorporeal systems- Vascular prostheses- Tubular vascular grafts and vascular patches.	Useable Length Relaxed internal Diameter Suture Retention Strength Wall Thickness Water Entry Pressure Longitudinal Tensile Strength Strength after repeated puncture Kink Diameter Circumferential Tensile Strength	Passed

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Biocompatibility	Testing and analysis of the finished device demonstrated compliance to ISO 10993-1:2018- Biological evaluation of medical devices: Part 1: Evaluation and testing within a risk management process	Endpoints Evaluated Physical and chemical information Cytotoxicity Sensitization Irritation or intracutaneous reactivity Material mediated pyrogenicity Acute systemic toxicity Sub-acute toxicity Sub-chronic toxicity Chronic toxicity Implantation Hemocompatibility Genotoxicity Carcinogenicity	Passed
Ethylene Oxide Sterilization Validation	Validation in accordance with ISO 11135:2014 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	Overkill method Sterility assurance level 1 x 10 ⁻⁶ confirmed Half cycle Sub lethal cycle Sterility tests Bioburden Endotoxin Bacteriostasis & Fungistatic Inhibition and Enhancement	Passed
Transit Testing & Environmental Conditioning	Provides objective evidence that the packaging of the Spiral Laminar Flow Vascular Arteriovenous Graft	Transportation Testing Variable Conditioning Package dye penetration Package Bubble leak Aseptic presentation Visual inspection Package tensile testing Package seal width Product package interaction Useable Length Relaxed internal Diameter Suture Retention Water Entry Pressure Longitudinal Tensile Strength Strength after repeated puncture Kink Diameter Circumferential Tensile Strength	Passed

All testing was successfully completed, and the results show that Spiral Laminar Flow Vascular Arteriovenous Graft is safe and performs as expected when used as intended.

Spiral Laminar Flow Vascular Arteriovenous Graft is considered substantially equivalent to the predicate device.

Animal Studies

No animal studies were conducted as part of the submission to prove substantial equivalence.

Vascular Flow Technologies Ltd.
Traditional 510(k)
For Spiral Laminar Flow™ Vascular Arteriovenous Graft

Clinical Studies

No clinical studies were conducted as part of the submission to prove substantial equivalence.

Conclusion:

The available data supports that the SLF™ Vascular Arteriovenous Graft is substantially equivalent to the predicate device.