September 12, 2025

Jupiter Endovascular
Nicole Barber
Senior Director, Regulatory Affairs
155 Jefferson Dr.
Menlo Park, California 94025

Re: K252027
Trade/Device Name: Vertex™ Catheter
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: June 27, 2025
Received: June 30, 2025

Dear Nicole Barber:

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,

Misti L. Malone -S

Misti L. Malone, Ph.D.
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)*
K252027

Device Name
Vertex Catheter

Indications for Use *(Describe)*
The Vertex Catheter is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.

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.

Vertex™ Catheter
510(k) Summary

510(k) #: K252027 Prepared on: 2025-6-21

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92

1 Contact Details: 21 CFR 807.92(a)(1)

Applicant Name	Jupiter Endovascular
Applicant Address	155 Jefferson Dr., Menlo Park, CA 94025
Applicant Contact Telephone	(888) 271-9499
Applicant Contact	Nicole Barber, Senior Director Regulatory Affairs
Applicant Contact Email	nicole@jupiterendo.com

2 Device Name: 21 CFR 807.92(a)(2)

Trade Name	Vertex™ Catheter
Common Name	Catheter
Classification Name	Catheter Introducer
Regulation Number	870.1340
Product Code(s)	DYB

3 Legally Marketed Predicate Devices: 21 CFR 807.92(a)(3)

K160254, GORE® DrySeal Flex Introducer

4 Device Description Summary: 21 CFR 807.92(a)(4)

Jupiter Endovascular's Vertex™ Catheter is a single-use catheter consisting of a multilayer shaft, a hemostatic valve, and an included locking obturator ("dilator"). The effective length of the catheter is coated to improve lubricity. The handle of the catheter includes a flush line, a fixation line for fixation control, and a hemostatic valve. The catheter shaft and obturator bodies are radiopaque. The distal tip of the catheter has a non-radiopaque region that is no more than 5 mm in length. The device is packaged as sterile and is for single use only.

5 Intended Use/Indications for Use: 21 CFR 807.92(a)(5)

The Vertex™ Catheter is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.

6 Indications for Use Comparison: 21 CFR 807.92(a)(5)

The indications for use are the same for the proposed device and the predicate device.

Both devices are prescription, single-use devices intended for use in adults undergoing diagnostic or therapeutic procedures in a health care facility.

7 Technological Comparison: 21 CFR 807.92(a)(6)

Attribute	**Subject Device**	**GORE® DrySeal Flex Introducer Sheath K160254**
Main Components	The Vertex™ Catheter consists of a catheter (catheter introducer) with a hemostasis valve attached and an included locking obturator. The catheter is a composite tube including flat stainless steel wire, hydrophilic coating on the inner surface, hydrophobic coating on the outer surface, and a leading tip. The catheter body can be identified under fluoroscopy. The catheter is attached to a hemostasis valve. The valve is comprised of a silicone seal; its position is controlled using compression. The obturator has a tapered leading end and provides a smooth transition from the guidewire to the catheter leading tip. The obturator is 0.035” guidewire compatible and has a locking mechanism which mates with, and secures to, the hemostasis valve. The catheter hub is marked with its French size.	The GORE® DrySeal Flex Introducer Sheath consists of an introducer sheath (catheter introducer) with the GORE® DrySeal Valve attached, a twist style locking dilator, and a syringe. The introducer sheath is a composite tube which consists of a flat stainless steel wire reinforced hydrophilic coated Pebax® outer tube and PTFE liner with a tapered leading tip and marker band incorporated within the sheath material to allow identification under fluoroscopy. The sheath is attached to the GORE® DrySeal Valve. The GORE® DrySeal Valve is comprised of an outer silicone tube and an inner film tube. The region between the silicone tube and film tube is pressurized by injecting 2.5 mL of saline into the space, using the provided syringe, during procedural preparation of the device. The dilator has a tapered leading end and provides dilatation of the access vessel while providing a smooth transition from the guidewire to the introducer sheath leading tip. The dilator is 0.035" guidewire compatible and has a locking mechanism which

Attribute	**Subject Device**	**GORE® DrySeal Flex Introducer Sheath K160254**
		mates with, and secures to, the DrySeal Valve. The sheath hub is embossed with its French size and a visual marker on the trailing end of the dilator shaft that ensures correct combination of the dilator within the sheath.
Principles of Operation	The Vertex Catheter is operated manually by the practitioner. It is designed for use with accessory devices and can be fixed or relaxed on demand by applying pressure via the fixation line. When the device is in place in the fixed state, it allows accessory devices to advance or withdraw relative to the Vertex Catheter with minimal disturbance to surrounding anatomy. When the device is in the relaxed state, it is able to move relative to the patient anatomy.	The GORE® DrySeal Flex Introducer Sheath is operated manually by the practitioner. It is designed for use with accessory devices. When the device is in place, it allows accessory devices to advance or withdraw relative to the GORE® DrySeal Flex Introducer Sheath with minimal disturbance to surrounding anatomy. The device is also able to move relative to the patient anatomy.
Dimensions	OD = 6.0-8.7 mm (two sizes) ID = 4.1-6.7 mm (two sizes) Effective Length = 77-107 cm (three lengths)	OD = 4.0-9.5 mm (17 sizes) ID = 3.3-8.7 mm (17 sizes) Effective Length = 33-65 cm (three lengths)
Sterilization Method	Ethylene Oxide (EO) Sterilization	Ethylene Oxide (EO) Sterilization
Single-Use Disposition	Single-use device	Single-use device
Non-Clinical Testing	• Critical Dimensions – IDs and Lengths • Compatibility with Devices – Sheath (Catheter) and Obturator Dimensions	• Critical Dimensions – IDs and Lengths • Compatibility with Devices – Sheath Dimensions • Guidewire Compatibility • Sheath Tip to Dilator Transition

Attribute	**Subject Device**	**GORE® DrySeal Flex Introducer Sheath K160254**
	• Sheath (Catheter) Tip to Obturator Transition • Radiodetectability • Tortuosity • Kink Resistance • Peak Tensile Force - Critical Junctions • Obturator to Valve Locking Tensile Strength • Obturator Removal Force • System Freedom from Leakage • Lubricity • Particulation • Usability • Air Leak • Sheath (Catheter) Stiffness • Burst Pressure	• Radiodetectability • Tortuosity • Kink Resistance • Peak Tensile Force - Critical Junctions • Dilator to Valve Locking Tensile Strength • Dilator Removal Force • System Freedom from Leakage • Lubricity • Particulation • Usability • Shelf life
Biocompatibility	• Comply with ISO 10993-5, no cytotoxicity effect • Comply with ISO 10993-10, not an irritant • Comply with ISO 10993-10, not a sensitizer • Comply with ISO 10993-11, no acute systemic toxicity Comply with ISO 10993-11, non-pyrogenic • Comply with ISO 10993-4, non-hemolytic • Comply with ISO 10993-4, partial thromboplastin time • Comply with ISO 10993-4, complement activation • Comply with ISO 10993-4, *in vitro* hemocompatibility (heparinized blood platelet and leukocyte count)	• Comply with ISO 10993-5, no cytotoxicity effect • Comply with ISO 10993-10, not an irritant • Comply with ISO 10993-10, not a sensitizer

8 Non-clinical and/or Clinical Tests Summary & Conclusions: 21 CFR 807.92(b)

The Vertex Catheter has the same intended use and technological characteristics as the predicate device. After analyzing technology, materials, bench tests and safety testing data, it can be concluded that the Vertex Catheter is substantially equivalent to the predicate device for the proposed indications for use.