



October 23, 2025

Vivasure Medical Limited
% Fernando Aguel
Vice President, Heart Failure & Circulatory Support Regulatory Affairs
MCRA LLC
803 7th Street, NW
3rd Floor
Washington, District of Columbia 20001

Re: K252309

Trade/Device Name: PerQseal Introducers
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: July 24, 2025
Received: July 24, 2025

Dear Fernando Aguel:

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/pmnmn.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 Malone, PhD

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)
K252309

Device Name
PerQseal Introducers

Indications for Use (Describe)

PerQseal Introducer: The PerQseal Introducers are intended to provide access and facilitate the insertion of diagnostic or endovascular devices into femoral vasculature.

PerQseal Elite Introducer: The PerQseal Elite Introducers are intended to provide access and facilitate the insertion of diagnostic or endovascular devices into femoral vasculature.

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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510(k) Summary

Device Trade Name: PerQseal Introducers

Manufacturer: Vivasure Medical Limited
Parkmore Business Park West
West Galway, Co. Galway, Ireland
H91 V3KP

Prepared by: MCRA, an IQVIA Business
803 7th Street, NW, 3rd Floor
Washington, DC 20001
Office: 202.552.5800

Date Prepared: July 24, 2025

Classifications: 21 CFR 870.1340

Class: II

Product Codes: DYB

Primary Predicate: Sentrant Introducer Sheath with Hydrophilic Coating
(Medtronic, K171866)

Indications For Use:

PerQseal Introducer: The PerQseal Introducers are intended to provide access and facilitate the insertion of diagnostic or endovascular devices into femoral vasculature.

PerQseal Elite Introducer: The PerQseal Elite Introducers are intended to provide access and facilitate the insertion of diagnostic or endovascular devices into femoral vasculature.

Device Description

Each PerQseal Introducer (‘S’, ‘L’, Elite 14F, and Elite 18F) includes an Introducer Sheath with a Dilator positioned within the lumen. The Introducer Sheath comprises a simple sheath that provides access to the site, while the Dilator is a component which guides the Introducer Sheath to the access site and provides a blood signal that is used to ensure proper positioning of the Introducer Sheath.

Predicate Device:

The purpose of this Traditional 510(k) is to demonstrate that the PerQseal Introducers are substantially equivalent to predicate device for the purpose of introducing the system to interstate commerce. It has been determined that the PerQseal Introducers are substantially equivalent to the following predicate:

- **Primary Predicate:** Sentrant Introducer Sheath with Hydrophilic Coating (Medtronic, K171866)

	Subject Device	Primary Predicate
Device Name	PerQseal Introducers	Sentrant Introducer Sheath with Hydrophilic Coating
K Number	N/A	K171866
Manufacturer	Vivasure Medical Limited	Medtronic Vascular, Inc.
Product Code	DYB	DYB
Indications	<p>PerQseal Introducer: The PerQseal Introducers are intended to provide access and facilitate the insertion of diagnostic or endovascular devices into femoral vasculature.</p> <p>PerQseal Elite Introducer: The PerQseal Elite Introducers are intended to provide access and facilitate the insertion of diagnostic or endovascular devices into femoral vasculature.</p>	<p>The Sentrant Introducer Sheath with Hydrophilic Coating is intended to provide a conduit for the insertion of diagnostic or endovascular devices into the vasculature and minimize blood loss associated with such insertions.</p>
Intended Use	Introduction of endovascular devices into patient vasculature	Introduction of endovascular devices into patient vasculature

	Subject Device	Primary Predicate
Device Name	PerQseal Introducers	Sentrant Introducer Sheath with Hydrophilic Coating
Image		
Condition of Use	Single Use	Singe Use
Sheath Diameters	14 Fr 18 Fr	12 Fr to 26 Fr (2 Fr Increments)
Sheath Working Length	Effective Length 15 cm	28cm – 64cm
Guidewire Compatibility	0.035"	0.035"
Hydrophilic Coating	Yes	Yes
Radiopacity	The dilator is radiopaque and has a flexible tapered tip that facilitates atraumatic tracking through the vasculature. Sheath - Radiopaque Tip	Dilator – Fully Radiopaque Sheath – Marker Band at Tip
Hemostasis Technology	Silicone Seal (Hemostatic Valve)	Silicone Seals
Device Materials	Dilator: LDPE, BaSO ₄ Sheath: HDPE, Orevac and Pebax, encapsulated stainless steel coil	Dilator: HDPE or HDPE/LDPE Blend, BaSO ₄ Sheath: Composite structure composed of HDPE, Orevac and Pebax with an encapsulated stainless steel coil
Sterility	Sterile to the SAL of 10 ⁻⁶	Sterile to the SAL of 10 ⁻⁶

	Subject Device	Primary Predicate
Device Name	PerQseal Introducers	Sentrant Introducer Sheath with Hydrophilic Coating
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Shelf Life	12 months	24 months

Performance Testing Summary:

The following bench testing has been conducted on the PerQseal Introducers:

- Cannula Insertion
- Coating Presence
- Compatibility with Accessories
- Device Blood Signal
- Device Surface
- Device Visualization
- Dilator Distal Inner Diameter
- Dilator Effective Length
- Dilator Guidewire Compatibility
- Dilator Hub Inner Diameter
- Dilator Hub Tensile
- Dilator Shaft Outer Diameter
- Dilator Taper Length
- Dilator Visual
- Introducer - Slip
- Lubricity
- Sheath Effective Length
- Sheath Hub Tensile
- Sheath Leak – No Valve
- Sheath Shaft Inner Diameter
- Sheath Shaft Outer Diameter
- Sheath Shaft to Tip Tensile
- Sheath Sidearm to Hub Tensile
- Sheath Sidearm to Stopcock Tensile
- Sheath Tip Inner Diameter
- Sheath Valve Leak
- Sheath Visual
- Biocompatibility, including:
 - Cytotoxicity
 - Sensitization

- Irritation
- Hemocompatibility
- Material Mediated Pyrogenicity
- Acute Systemic Toxicity
- Sterility, including
 - EO/ECH Residuals
 - Bioburden
 - Bacterial Endotoxins
 - Bacteriostasis and Fungistasis (B&F)
 - Product Sterility
- Shelf-Life to 12 months (per ASTM F1980)
- Animal Studies, to assess:
 - Device Usability
 - Device Compatibility
 - Performance (Bleeding control)
 - Site Re-access

Substantial Equivalence:

The subject device was demonstrated to be substantially equivalent to the predicate cited above with respect to indications, design materials, function, manufacturing, and performance. The non-clinical tests performed by the company demonstrated that the PerQseal Introducers are able to withstand physiological loading and is substantially equivalent to the predicate device.

Conclusion:

The subject device and the predicate device have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate device listed above. The PerQseal Introducers are as safe, as effective, and performs as well as, or better, than the predicate devices.