



February 28, 2025

Basis Medical  
Grace Powers  
Founder/ Principal Consultant  
Powers Regulatory Consulting  
2451 Cumberland Blvd SE  
Suite 3740  
Atlanta, Georgia 30339

Re: K243436  
Trade/Device Name: Seclusion Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous catheter  
Regulatory Class: Class II  
Product Code: DQY  
Dated: November 4, 2024  
Received: November 5, 2024

Dear Grace Powers:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**LYDIA S.**  
**GLAW -S**

Digitally signed by  
LYDIA S. GLAW -S  
Date: 2025.02.28  
14:55:23 -05'00'

Lydia Glaw  
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)  
K243436

Device Name  
Seclusion Catheter

### Indications for Use (Describe)

The Seclusion Catheter is indicated for localized infusion and aspiration of various therapeutic and diagnostic agents in isolated segments of the peripheral venous vasculature. The Seclusion Catheter may be repositioned for multiple treatments with the same patient. The Seclusion Catheter is not indicated for use in the neurovasculature.

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

**510(k) Summary**

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Seclusion Catheter Traditional 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

**Sponsor:** Basis Medical  
4080 McGinnis Ferry Road  
Building 300, Suite 304  
Alpharetta, GA 30005  
Tel: 404-308-0071

**Submission Contact:** Grace Powers, FRAPS, MS, MBA, RAC  
Founder/Principal Consultant  
Powers Regulatory Consulting  
Tel: 404-931-8730

**Submission Date:** November 4, 2024

**Subject Device:**

Trade Name:	Seclusion Catheter
Classification Regulation:	21 CFR § 870.1250
Class:	2
Common Name:	Percutaneous Catheter
Panel:	Cardiovascular
Product Code:	DQY

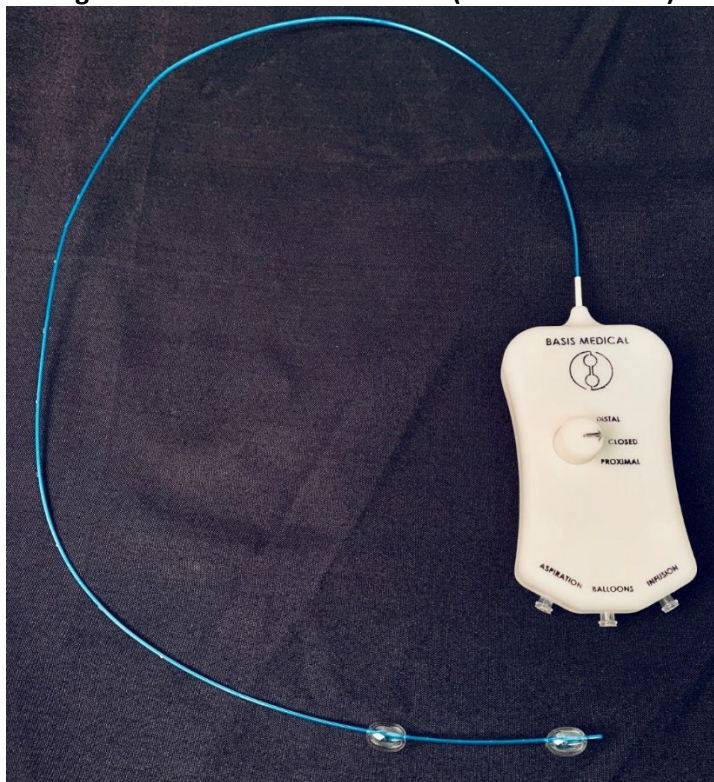
**Predicate Device:** Legally marketed device to which substantial equivalence is claimed:  
Occlusion Perfusion Catheter (K153488)

**Device Description**

The Seclusion Catheter is indicated for localized infusion and aspiration of various therapeutic and diagnostic agents in isolated segments of the peripheral venous vasculature. The Seclusion Catheter may be repositioned for multiple treatments with the same patient. A photograph of the Seclusion Catheter is shown in the figures below.

510(k) Summary

**Figure 1: The Seclusion Catheter (Balloons inflated)**



The device is EtO sterilized and is a single-use device.

There is a device-specific guidance that is applicable to the subject device: Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions.

**Indications for Use**

The Seclusion Catheter is indicated for localized infusion and aspiration of various therapeutic and diagnostic agents in isolated segments of the peripheral venous vasculature. The Seclusion Catheter may be repositioned for multiple treatments with the same patient. The Seclusion™ Catheter is not indicated for use in the neurovasculature.

**Technological Characteristics**

The Seclusion Catheter has similar technological characteristics as the predicate device.

**Subject Device compared to the Predicate Device**

	<b>Subject Device: Seclusion Catheter</b>	<b>Predicate Device: Occlusion Perfusion Catheter (OPC)</b>
<b>Regulation Number</b>	21 CFR 870.1250	21 CFR 870.1250
<b>Device Classification Name</b>	Percutaneous Catheter	Percutaneous Catheter
<b>FDA Product Code</b>	DQY	DQY

## 510(k) Summary

-	<b>Subject Device: Seclusion Catheter</b>	<b>Predicate Device: Occlusion Perfusion Catheter (OPC)</b>
<b>Classification</b>	Class 2	Class 2
<b>Indications for Use</b>	<p>The Seclusion™ Catheter is a percutaneous catheter that is indicated for localized infusion and aspiration of various therapeutic and diagnostic agents in isolated segments of the peripheral venous vasculature.</p> <p>The Seclusion Catheter may be repositioned for multiple treatments with the same patient.</p>	<p>The Occlusion Perfusion Catheter™ is indicated for localized infusion or irrigation of various diagnostic and therapeutic agents into the peripheral vasculature. The Occlusion Perfusion Catheter™ may be repositioned for multiple treatments with the same patient. It is not indicated for use in neurovasculature.</p>
<b>Prescription or OTC?</b>	Prescription	Prescription
<b>Fluids Delivered</b>	Various therapeutic and diagnostic agents	Various diagnostic and therapeutic agents
<b>Vasculature</b>	Venous peripheral vasculature	Peripheral vasculature
<b>Lumen and Tip</b>	Four (4) lumen catheter with rounded tip.	Five (5) lumen catheters with rounded tip.
<b>Number of Balloons</b>	Two (2) balloons that can be independently inflated to create the treatment area.	Two (2) balloons that can be simultaneously inflated to create the treatment area and one (1) center balloon to occupy space in the treatment area.
<b>Balloon Diameter</b>	4 mm to 12 mm	3mm to 10mm
<b>Balloon inflation</b>	Air	Saline
<b>Treatment region length</b>	The treatment area between balloons is 7 cm.	The treatment chamber is between balloons. There are multiple sizes available from 3cm to 15cm.
<b>Maximum Pressure/ Rated Balloon Pressure</b>	Rated burst volume (RBV) no less than 1.5x the volume required to reach the maximum balloon diameter. Additionally, the minimum burst volume is no less than 6 mL ambient air when using a 3 mL syringe to inflate the balloons.	4 atm
<b>Coating</b>	No catheter coating.	No catheter coating.
<b>Guidewire compatibility</b>	0.014" and 0.018" guidewire compatibility (via the aspiration lumen for stiffness if needed). The guidewire does not pass through the tip.	0.014" guidewire compatibility. There is a lumen used solely for the guidewire. The guidewire does pass through the tip.
<b>Sheath Compatibility</b>	Compatible with a 7Fr sheath.	Unknown

510(k) Summary

-	<b>Subject Device: Seclusion Catheter</b>	<b>Predicate Device: Occlusion Perfusion Catheter (OPC)</b>
<b>Number and types of ports</b>	Three (3) ports: 1: Balloon inflation/deflation 2: Aspiration 3: Infusion	Five (5) ports: 1: Fluid Inflow (Infusion) 2: Fluid Outflow (Aspiration) 3: Occlusion Balloon inflation/ deflation 4: Center Balloon Inflation/deflation 5: Guidewire
<b>Sensor technology</b>	None	The OPC has pressure sensing technology.
<b>Sterilization</b>	Ethylene Oxide (EO)	Ethylene Oxide (EO)

**Performance Data**

The Seclusion Catheter was subjected to ship testing, packaging testing and functional testing. The testing was based off the FDA guidance document listed below that is applicable to the subject device.

- Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions: Guidance for Industry and Food and Drug Administration Staff issued on April 14, 2023.

The following testing was conducted:

- Visual and Dimensional Testing
- Cycle and Simulated Use Testing
- Physical Characteristics Testing
- Functional Testing
- Usability Testing
- Packaging Testing
- Biocompatibility testing per ISO 10993-1 for an external communicating device with circulating blood contact for a limited duration (less than 24 hours)

**Conclusion**

The Seclusion Catheter is substantially equivalent to the legally marketed predicate device as demonstrated by the same intended use, similar technologies and performance data, and does not raise different questions of safety and effectiveness.