



November 5, 2025

Poly Medicure Limited  
% Roger Gray  
VP QA/RA  
Donawa Lifescience  
Piazza Albania 10  
Rome, 00153  
Italy

Re: K252677

Trade/Device Name: Polyshield Safety IV Catheters  
Regulation Number: 21 CFR 880.5200  
Regulation Name: Intravascular Catheter  
Regulatory Class: Class II  
Product Code: FOZ  
Dated: October 7, 2025  
Received: October 7, 2025

Dear Roger Gray:

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,

**Colleen J. Lawrimore -S**

Colleen Lawrimore, Ph.D.

*For* David Wolloscheck, Ph.D.

Assistant Director

DHT3C: Division of Drug Delivery and  
General Hospital Devices, and  
Human Factors

OHT3: Office of Gastrorenal, ObGyn,  
General Hospital, and Urology Devices

Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K252677

Device Name  
Polyshield Safety IV Catheters

### Indications for Use (Describe)

The Polyshield Safety IV Catheters are indicated for short term use (less than 30 days) for insertion into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids. The catheters may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. The 14 - 24G catheters may be used intravascularly with power injectors at a maximum pressure of 300 psi.

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: K252677**

**Trade Name:** Polyshield Safety IV Catheters  
**Type of 510(k) submission:** Special  
**Date of Preparation:** 5 November 2025  
**510(k) Owner and Submitter:** Poly Medicure Ltd  
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Faridabad-121004, Haryana  
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**Common Name:** Catheter, Intravascular, Therapeutic, Short-Term Less than 30 Days  
**Product Code:** FOZ  
**Regulation Number:** 21 CFR 880.5200  
**Regulation Name:** Intravascular catheter  
**Classification Panel:** General Hospital  
**Device Class:** Class II

**Indications for Use:**

The Polyshield Safety IV Catheters are indicated for short term use (less than 30 days) for insertion into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids. The catheters may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. The 14 - 24G catheters may be used intravascularly with power injectors at a maximum pressure of 300 psi.

**Device Description:**

The Polyshield Safety IV Catheters are over-the-needle, peripheral safety IV catheters that incorporate an active sharps prevention needle shield. The 'BC' versions also incorporate a blood control feature, and the 'Adva' versions include 'quick flash back' needle technology. The devices are available in multiple gauge sizes and lengths, in both with and without wings on the catheter hub. In more detail:

Polyshield: An over-the-needle, peripheral active safety IV catheter that incorporates a spring-activated needle shield to help prevent needle-stick injuries

Polyshield Adva: An over-the-needle, peripheral active safety IV catheter that incorporates a spring-activated needle shield to help prevent needle-stick injuries. The device is also provided with quick flash back (Adva needle) technology. Instant confirmation of blood flow along catheter body increases clinician's ability to successfully access the vein.



**Polyshield BC:** An over-the-needle, peripheral active safety IV catheter with wings that incorporates a spring-activated needle shield to help prevent needle-stick injuries, together with a blood control feature that prevents blood flow until a distal connection is made.

**Polyshield BC Adva:** An over-the-needle, peripheral active safety IV catheter with wings that incorporates a spring-activated needle shield to help prevent needle-stick injuries, together with a blood control feature that prevents blood flow until a distal connection is made. The device is also provided with quick flash back (Adva needle). Instant confirmation of blood flow along catheter body increases clinician’s ability to successfully access the vein.

Color-coding of the catheter hub (and wings, where fitted) is used to help identify the catheter gauge size, in accordance with ISO 10555-5.

The major features of the available models are indicated in Table 1.

<b>Table 1: Polyshield major design features</b>				
<b>Feature</b>	<b>Polyshield</b>	<b>Polyshield Adva</b>	<b>Polyshield BC</b>	<b>Polyshield BC Adva</b>
Safety mechanism type	Active	Active	Active	Active
Spring activated by button	Yes	Yes	Yes	Yes
Push-back mechanism	No	No	No	No
Blood control mechanism	No	No	Yes	Yes
Quick flash back	No	Yes	No	Yes
Hub wings	Optional	Optional	Optional	Optional

Polyshield Safety IV Catheters are labeled for prescription use only (Rx only) and supplied sterile for single use with a sterility assurance level (SAL) of 10<sup>-6</sup>. Sterilization is achieved by ethylene oxide gas exposure.

The purpose of this submission is to introduce minor design changes to the Polyshield BC models and to add new catheter lengths to all four Polyshield models.

**Substantial equivalence**

The predicate device selected for comparison with the revised design of Polyshield Safety IV Catheters is the original design of the devices, viz:

- Predicate Device.....Polyshield and Polyguard Safety IV Catheters
- Sponsor.....Poly Medicure Ltd
- 510(k) Number .....K230616
- Clearance Date .....5 May 2023
- FDA Product Code .....FOZ
- Classification Name .....Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days
- Regulation No:.....21 CFR 880.5200
- Class..... II

**Predicate device comparison table:**

Table 2 provides evidence of substantial equivalence of the subject device with the selected predicate device:



Table 2: Predicate device comparison table			
Feature	Subject device (Polyshield Safety IV Catheters)	Predicate device (Polyshield and Polyguard Safety IV Catheters, K230616)	Similarity
Device description:	<p><u>Polyshield</u>: Over-the-needle, peripheral safety IV catheter that incorporates a spring-activated needle shield</p> <p><u>'BC' models</u>: Incorporate a blood control feature</p> <p><u>'Adva' models</u>: Incorporate a 'quick flash back' feature</p>	<p><u>Polyshield</u>: Over-the-needle, peripheral safety IV catheter that incorporates a spring-activated needle shield</p> <p><u>Polyguard</u>: Over-the-needle, peripheral safety IV catheter that incorporates a push-back needle shield</p> <p><u>'BC' models</u>: Incorporate a blood control feature</p> <p><u>'Adva' models</u>: Incorporate a 'quick flash back' feature</p>	Same as predicate, but without the Polyguard model
Indications for use	The Polyshield Safety IV Catheters are indicated for short term use (less than 30 days) for insertion into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids. The catheters may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. The 14 - 24G catheters may be used intravascularly with power injectors at a maximum pressure of 300 psi.	The Polyshield and Polyguard Safety IV Catheters are indicated for short term use (less than 30 days) for insertion into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids. The catheters may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. The 14 - 24G catheters may be used intravascularly with power injectors at a maximum pressure of 300 psi.	Same as predicate, but without the Polyguard model
Sharps injury protection feature?	Yes – active	Yes – active	Same
Sharps injury prevention mechanism	<u>Polyshield and Polyshield BC</u> : User-activated button initiates needle retraction into the needle-shielding barrel. Once the button has been pushed and the needle retracted, the user cannot override the shielding mechanism to re-expose the needle tip.	<p><u>Polyshield and Polyshield BC</u>: User-activated button initiates needle retraction into the needle-shielding barrel. Once the button has been pushed and the needle retracted, the user cannot override the shielding mechanism to re-expose the needle tip.</p> <p><u>Polyguard and Polyguard BC</u>: User-activated push-back mechanism retracts the needle into the needle-shielding barrel. Once activated, the user cannot override the shielding mechanism to re-expose the needle tip.</p>	Same as predicate, but without the Polyguard model
Catheter tube material	Polyurethane	Polyurethane	Same
X-ray visible	Yes	Yes	Same
Needle material	Stainless steel	Stainless steel	Same
Needle distal end configuration	Back cut ground beveled needle	Back cut ground beveled needle	Same
Flashback visualization	Adva models	Adva models	Same



Table 2: Predicate device comparison table			
Feature	Subject device (Polysield Safety IV Catheters)	Predicate device (Polysield and Polyguard Safety IV Catheters, K230616)	Similarity
Blood control	Yes, in BC models	Yes, in BC models	Same
Gauge sizes	14 - 26G	14 - 26G	Same
Catheter lengths	14 mm – 48 mm	19 mm – 45 mm	Different – see Discussion #1
Catheter hub design	Catheter with wings hub design simplified to integrate hub and wings and improve operation	Original design with separate catheter hub and wings	Different – see Discussion #2
Color-coding	Yes, according to ISO 10555-5	Yes, according to ISO 10555-5	Same
Proximal end configuration	Female 6 % Luer	Female 6 % Luer	Same
Single use	Yes	Yes	Same
Sterile	Yes, SAL 10 <sup>-6</sup>	Yes, SAL 10 <sup>-6</sup>	Same
Sterilization method	Ethylene oxide	Ethylene oxide	Same
Shelf life	3 years	3 years	Same
Physical properties	According to ISO 10555-1, ISO 10555-5	According to ISO 10555-1, ISO 10555-5	Same
Power injection usage?	Yes, 14 - 24G catheters up to 300 psi.	Yes, 14 - 24G catheters up to 300 psi.	Same
Biocompatibility	Biocompatible in accordance with ISO 10993 series and FDA guidance	Biocompatible in accordance with ISO 10993 series and FDA guidance	Same
Particulate contamination	Complies with USP <788>	Complies with USP <788>	Same
Environment of use	Rx only	Rx only	Same
Hub wings?	Yes, as an option	Yes, as an option	Same
Metal slip ring material	Polyacetal (PA)	Stainless steel 305	Different – See Discussion #3
MR compatibility	MR Conditional	MR Conditional	Same

**Substantial Equivalence Discussion:**

The subject device and the predicate device have many identical or similar properties or features, however none of the identified differences introduce new or different aspects of safety or effectiveness. The differences are discussed in the following paragraphs:

Discussion #1 Extended length range: The new lengths introduced with this range extension are 14 mm, 30 mm and 48 mm, depending on the gauge size. Device samples of each of the new length/gauge combinations were tested against the same standards as the original size combinations for both freshly manufactured devices and devices that has reached the end of their labeled shelf lives. All tests were successfully completed, therefore it is concluded that no new or different issues of safety or effectiveness have been introduced.

Discussion #2 Catheter Hub design: The design of the catheter hub component has been changed to allow the elimination of a previously separate component in the design of the catheter with wings and also to improve catheter operation. Device samples of each of the winged and non-winged designs were tested against the same standards as the original designs for both freshly manufactured devices and devices that has reached the end of their labeled shelf lives. All tests were successfully completed, therefore it is concluded that no new or different issues of safety or effectiveness have been introduced.



Discussion #3 Slip Ring material: The slip ring has changed from a metallic material to a polymeric material. While this component has indirect contact with the patient, the identical material has been used previously in FDA-cleared Poly Medicure IV catheter devices. It is therefore concluded that no new or different issues of safety or effectiveness have been introduced.

**Performance data:**

The impact of the design changes has been risk-assessed and certain bench tests have been carried out in response, in accordance with the same protocols as used for the original design, as verification of the acceptability of the design changes. Specifically, the following tests have been repeated on the new design on both freshly manufactured and end of shelf life samples:

- Back leakage of blood control feature
- Flow rate
- Aspiration
- Freedom from leakage during pressurization
- Power injection
- Peak tensile force for catheter
- New catheter lengths verification tests

This testing has been carried out in accordance with the following standard:

- ISO 10555-1:2023, FDA recognition # 6-499

The design changes have not impacted the results of performance testing of the original design for biocompatibility, sterilization, packaging validation or human factors.

**Conclusion**

The subject and predicate devices have the same indications for use and fundamental technological characteristics. The design changes planned for introduction of the subject device have been risk assessed and all risks resulting from the design changes have been mitigated and verified in accordance with the same test protocols used for the predicate device. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.