May 5, 2023

Poly Medicure Limited
℅ Roger Gray
VP Quality and Regulatory
Donawa Lifescience Consulting Srl
Piazza Albania 10
Rome, 00153
Italy

Re: K230616
Trade/Device Name: Polyguard and Polyshield Safety IV Catheters
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: March 1, 2023
Received: March 7, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

David Wolloscheck, Ph.D.
Acting 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230616

Device Name

Polyguard and Polyshield Safety IV Catheters

Indications for Use *(Describe)*

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.

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.

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K230616 - 510(k) Summary

Type of 510(k) submission:	Traditional
Date of Preparation:	3 May 2023
Manufacturer:	Poly Medicure Ltd Plot No. 115-117, Sector- 59 HSIIDC Industrial Area, Ballabgarh Faridabad-121004, Haryana, INDIA
Phone:	+91-129-3355070
510(k) Owner and Submitter:	Poly Medicure Ltd Plot No. 115-117, Sector- 59 HSIIDC Industrial Area, Ballabgarh Faridabad-121004, Haryana, INDIA
510(k) Contact:	Mr. Roger Gray VP Quality and Regulatory Donawa Lifescience Consulting Piazza Albania 10 00153 Rome, ITALY
Phone: **Email:**	+39 06 578 2665 rgray@donawa.com
Subject Device Trade Name:	Polyguard and Polyshield Safety IV Catheters
Common Name:	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days
Regulation Number:	21 CFR 880.5200
Regulation Name:	Intravascular catheter
Product Code:	FOZ
Classification Panel:	General Hospital

Predicate Device:	BD Insyte Autoguard BC
Sponsor	Becton Dickinson Infusion Therapy Systems Inc
510(k) Number	K110443
Clearance Date:	19 July 2011
FDA Product Code	FOZ
Regulation No:	21 CFR 880.5200
Regulation Name	Intravascular catheter
Class:	II

A reference device has been identified as being relevant to this submission, this being:

Reference Device:	ViaValve Safety IV Catheter
Sponsor	Smiths Medical ASD, Inc.
510(k) Number	K160235
Clearance Date:	30 June 2016
FDA Product Code	FOZ
Regulation No:	21 CFR 880.5200
Regulation Name:	Intravascular catheter
Class:	II

Indications for Use:
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.

Device Description:
The Polyshield and Polyguard 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 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.

Polyguard+: An over-the-needle, peripheral active safety IV catheter that incorporates a push-back needle shield to help prevent needle-stick injuries.

Polyguard+ Adva: An over-the-needle, peripheral active safety IV catheter that incorporates a push-back 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.

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

Polyguard BC Adva: An over-the-needle, peripheral active safety IV catheter with wings that incorporates a push-back 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) technology. 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.

Table 1: Polyshield and Polyguard major design features								
Feature	**Polyshield**	**Polyshield Adva**	**Polyshield BC**	**Polyshield BC Adva**	**Polyguard+**	**Polyguard+ Adva**	**Polyguard BC**	**Polyguard BC Adva**
Safety mechanism type	Active	Active	Active	Active	Active	Active	Active	Active
Spring activated by button	Yes	Yes	Yes	Yes	No	No	No	No
Push-back mechanism	No	No	No	No	Yes	Yes	Yes	Yes
Blood control mechanism	No	No	Yes	Yes	No	No	Yes	Yes
Quick flash back	No	Yes	No	Yes	No	Yes	No	Yes
Hub wings	Optional	Optional	Optional	Optional	Optional	Optional	Optional	Optional
Shelf life of device	3 yrs	3 yrs	3 yrs	3 yrs	5 yrs	5 yrs	3 yrs	3 yrs

Polyshield and Polyguard 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^{-6}. Sterilization is achieved by ethylene oxide gas exposure.

Technological Characteristics: comparison with Predicate Device:
The following Table 2 provides evidence of substantial equivalence of the subject device with the selected predicate device, while taking into account certain specific features of the reference devices:

Table 2: Predicate device comparison table			
Feature	**Subject device K230616**	**Predicate device K110443**	**Similarity**
Device name	Polyguard and Polyshield Safety IV Catheters	BD Insyte Autoguard BC IV Catheter	N/A
Device Manufacturer	Poly Medicure, India	Becton Dickinson Infusion Therapy Systems Inc, USA	N/A
FDA Product Code	FOZ	FOZ	Same
FDA Classification Name	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days	Same
FDA Regulation Number	880.5200	880.5200	Same
Device description:	Polyshield: Over-the-needle, peripheral safety IV catheter that incorporates a spring-activated needle shield	Over-the-needle, peripheral safety IV catheter that incorporates a spring-activated needle shield and blood control feature	Substantially equivalent but without the blood control feature Note 1
	Polyguard: Over-the-needle, peripheral safety IV catheter that incorporates a push-back needle shield		Substantially equivalent to predicate, but without the blood control feature and with a push back safety mechanism instead of spring-activated safety mechanism
	'BC' models: Incorporate a blood control feature		Polyshield BC identical to predicate; Polyguard model substantially equivalent to predicate but with push back safety mechanism

Table 2: Predicate device comparison table			
Feature	**Subject device K230616**	**Predicate device K110443**	**Similarity**
	'Adva' models: Incorporate a 'quick flash back' feature		'Adva' models identical to predicate which includes a 'quick flash back' feature (BD Instaflash™ needle technology) on 20, 22 and 24G needles
Indications for use	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.	The BD Insyte Autoguard BC catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids.	Substantially equivalent, but with the addition of patient population details and power injector use for the subject device Note 5
Sharps injury protection feature?	Yes – active, tested in accordance with ISO 23908 and FDA 'Guidance for Industry and FDA Staff Medical Devices with Sharps Injury Prevention Features', August 2005.	Yes - active	Same
Sharps injury prevention mechanism	Polyshield and Polyshield BC: 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.	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.	Same
	Polyguard and Polyguard BC: 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.		Different. Push-back mechanism on subject device instead of push button-activated spring mechanism on predicate Note 2
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	Yes	Same for Adva models
Blood control	Yes, in BC models	Yes	Same

Table 2: Predicate device comparison table			
Feature	**Subject device K230616**	**Predicate device K110443**	**Similarity**
Gauge sizes	14 - 26G	16 - 24G	Similar Note 3
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^{-6}	Yes, SAL 10^{-6}	Same
Sterilization method	Ethylene oxide	Ethylene oxide	Same
Shelf life	3 or 5 years, depending on model	3 years	Similar Note 4
Physical properties	According to ISO 10555-1, ISO 10555-5	Unknown	N/A
Power injection usage?	Yes, 14 - 24G catheters up to 300 psi.	No	Different Note 5
Biocompatibility	Biocompatible in accordance with ISO 10993 series and FDA guidance	Biocompatible in accordance with ISO 10993 series	Same
Particulates	Complies with USP <788>	Not indicated	Different Note 6
Environment of use	Rx only	Rx only	Same
Hub wings?	Yes, as an option	Yes, as an option	Same
MR compatibility	MR Conditional	Not indicated	Different Note 7

The subject device and the predicate device have many identical, similar or substantially equivalent properties or features. The differences that exist and are identified in the above table are explained in further detail in the following paragraphs.

Note 1: Blood control feature: The subject device does not include a 'blood control' feature in all models in the range, whereas the predicate device does offer this in all models in the range. The non-availability of a blood control feature on some models in the subject device range does not raise new questions of safety or efficacy.

Note 2: Safety mechanism: The subject device range offers both a 'click to close' and a 'push back to close' option, depending on the model type, whereas the predicate device offers only a 'click to close' option. The reference device, however, offers the 'push back to close' option, and the subject device has been subjected to the same simulated clinical use test regime, in accordance with FDA *'Guide for Industry and staff – Medical Devices with Sharp injury Prevention Features'* and ISO 23908:2011. Use of the 'push back to close' mechanism on certain models of the subject device range does not raise new questions of safety or efficacy.

Note 3: Gauge sizes in range: The subject device includes a wider range of gauge sizes than the predicate device. 'Worst case' samples from the subject device range have been tested and found to be in compliance with ISO 80369-7, ISO 10555-1 and ISO 10555-5. On the basis of these tests, no new questions of safety or efficacy are raised by the inclusion of additional gauge sizes in the subject device range.

Note 4: Shelf life: Certain models of the subject device range have a different shelf life from the devices in the predicate device range. Packaging samples from the subject device range with a longer labeled shelf life (5 years) than the predicate device range (3 years) have been successfully subjected to testing in accordance with ASTM F-1929, ASTM F-2096, and ASTM F-88/F-88M, with no new questions of safety or efficacy being raised.

Note 5: Power injection usage: The subject device catheters in the range 14 - 24G have been verified for use with power injectors up to 300 psi, similar to the reference device, which has been verified for the same power injector pressure for catheters in the 18 - 24G range. Verification of subject device and reference device suitability for power injection was established by successful testing in accordance with ISO 10555-1, with no new questions of safety or efficacy being raised.

Note 6: Particulates: The predicate device was not tested for particulates in accordance with USP <788>, but the subject device has been tested and meets the requirements of this test protocol. The subject device therefore has a lower risk associated with particulate inclusion than the predicate device.

Note 7: Metal slip ring material / MR compatibility: The predicate device is not labelled with respect to its compatibility with magnetic resonance (MR) systems. The reference device includes a similarly sized stainless steel type 305 insert (identified as an 'eyelet actuator') as a slip ring in the subject device. The reference device is identified on www.mrisafety.com as being suitable for labeling as an 'MR Conditional' device, so the subject device has also been labeled 'MR Conditional' as a result of the similarity between the components of interest in each device, thus no new questions of safety or efficacy are raised.

Performance data:
Non-clinical testing of the Polyshield and Polyguard Safety IV Catheters has included successful compliance testing with the following standards, most of which are FDA-recognized:

- ISO 10555-1:2013/AMD 1:2017, FDA recognition # 6-408
- ISO 10555-5:2013, FDA recognition # 6-303
- ISO 80369-7:2021, FDA recognition # 5-115
- ISO 11135:2014/AMD 1:2019, FDA recognition #14-529
- ISO 11607-2:2019, FDA recognition # 14-531
- ISTA 3A transportation test
- ASTM 640-20, FDA recognition # 8-556
- USP <788> Method 1
- Blood sample collection times, for applicable devices

Biocompatibility of components in direct or indirect contact with the patient has been established by testing in accordance with the matrix included in Annex A of ISO 10993-1:2018, while taking into consideration relevant FDA guidance, according to which the subject device components are externally communicating items in either prolonged direct contact with circulating blood or indirect contact with the blood path. The tests undertaken were:

- Cytotoxicity (ISO 10993-5:2009, FDA recognition # 2-245)
- Sensitization (ISO 10993-10:2010, FDA recognition # 2-174)
- Irritation or intracutaneous reactivity (ISO 10993-10:2010, FDA recognition # 2-174)
- Acute systemic toxicity (ISO 10993-11:2017, FDA recognition # 2-255)
- Subacute/subchronic toxicity (ISO 10993-11:2017, FDA recognition # 2-255)
- Material mediated pyrogenicity (ISO 10993-11:2017, FDA recognition # 2-255)
- Hemocompatibility (ISO 10993-4:2017, FDA recognition # 2-248)
- Implantation (ISO 10993-6:2016, FDA recognition # 2-247)
- Genotoxicity (ISO 10993-3:2014, FDA recognition # 2-228)

A shelf life of 3 or 5 years, depending on the specific model, has been established by testing the integrity of the sterile packaging following accelerated aging (per ASTM F 1980-16) in accordance with the following standards:

- ISO 10555-1:2013/AMD 1:2017, FDA recognition # 6-408
- ISO 10555-5:2013, FDA recognition # 6-303
- ISO 80369-7:2016, FDA recognition # 5-115
- USP <788> Method 1
- USP <71>
- USP <85>
- ASTM F-1929, FDA recognition # 14-484

- ASTM F-2096, FDA recognition # 14-359
- ASTM F-88 / F-88M, FDA recognition # 14-573

A clinical simulation study has also been carried out in accordance with ISO 23908:2011, while taking into consideration relevant FDA guidance.

Clinical Data:
Not applicable.

Conclusion:
The subject and predicate devices have similar indications for use and fundamental technological characteristics. Any differences in technological characteristics between subject and predicate devices do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.