September 21, 2023

Poly Medicure Limited
% Sunita Teekasingh
Regulatory Consultant
GSA 2 Group LLC
8049 Hayes Street North East
Spring Lake Park, Minnesota 55432

Re: K231401
Trade/Device Name: Polysafety BC, Polysafety BC Adva, Polywin Safety, Polywin Safety Adva
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: August 18, 2023
Received: August 22, 2023

Dear Sunita Teekasingh:

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.
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)*
K231401

Device Name
Polysafety BC, Polysafety BC Adva, Polywin Safety, Polywin Safety Adva

Indications for Use *(Describe)*

The Polysafety BC IV Catheter are indicated for short-term use (less than 30 days) for insertion into a patient's vascular system to sample blood or administer fluids such as solutions, parenteral nutrition, and administration of other drugs. 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 18G-24G catheters may be used intravascularly with power injectors at a maximum pressure of 300psi.

The Polysafety BC Adva IV Catheter are indicated for short-term use (less than 30 days) for insertion into a patient's vascular system to sample blood or administer fluids such as solutions, parenteral nutrition, and administration of other drugs. 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 l 8G-24G catheters may be used intravascularly with power injectors at a maximum pressure of 300psi.

The Polywin Safety IV Catheter are indicated for short term use (less than 30 days) for insertion into a patient's vascular system to sample blood or administer fluids such as solutions, parenteral nutrition and administration of other drugs. 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 14G-24G catheters may be used intravascularly with power injectors at a maximum pressure of 300psi.

The Polywin Safety Adva IV Catheter are indicated for short term use (less than 30 days) for insertion into a patient's vascular system to sample blood or administer fluids such as solutions, parenteral nutrition and administration of other drugs. 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 14G-24G catheters may be used intravascularly with power injectors at a maximum pressure of 300psi.

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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K 231401 - 510(K) SUMMARY

1 SUBMISSION ADMINISTRATIVE INFORMATION

Device Name:	Polysafety BC, Polysafety BC Adva, Polywin Safety, Polywin Safety Adva IV Catheters
Type of 510(k) submission:	Traditional Bundled 510(k)
Manufacturer:	Poly Medicure Ltd Plot No. 115-117, Sector- 59 HSIIDC Industrial Area, Ballabgarh Faridabad-121004, Haryana INDIA
Phone:	+91-129-3355070
FDA Establishment Reg. Number:	9616991
Subject Device	
FDA Product Code:	FOZ
FDA Regulation Number:	21 CFR 880.5200
FDA Classification Name:	Intravascular catheter
Classification Panel:	General Hospital
Common Name:	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days
FDA Classification:	Class II
Submission Type:	510(k)
Date	September 19, 2023
Official Primary Correspondent	Sunita Teekasingh RN, BSN, CCRN, MSc Regulatory Consultant GSA2 Group LLC 8049 Hayes St NE Minneapolis, MN 55432
Email	GSA2Groupllc@gmail.com
Phone:	612-814-7999
Polysafety Blood Control (BC) Predicate	
Predicate Manufacturer:	B. Braun Medical Inc.
Predicate Trade Name:	Introcan Safety® 2 IV Catheter
Predicate 510(k) Number:	K192676
Class	II
Predicate Product Code	FOZ
FDA Classification Name:	21 CFR 880.5200
Classification Panel:	General Hospital
Common Name:	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days
Polywin Safety IV Catheter Predicate	
Predicate Manufacturer:	B. Braun Medical Inc
Predicate Trade Name:	Introcan Safety® IV Catheter
Predicate 510(k) Number:	K020785
Class	II
Predicate Product Code	FOZ
FDA Classification Name:	21 CFR 880.5200

Classification Panel:	General Hospital
Common Name:	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days

2 POLYSAFETY BLOOD CONTROL SUBSTANTIAL EQUIVALANCE

The Polysafety BC predicate is B. Braun Medical Inc, Introcan Safety® 2 IV Catheter (K192676). Both devices are under the same product code FOZ and classification (880.5200) and intended for short term use less than 30 days.

Table 2-1 Polysafety BC Predicate Comparison

Feature	**Subject device** Polysafety BC Polysafety BC Adva	**Predicate device** Introcan Safety® 2 IV Catheter	**Comparison**
Device Manufacturer	Poly Medicure, India	B. Braun Medical Inc, Pennsylvania	N/A
510(k) Reference	This submission	K192676	N/A
Device Description:	The Polysafety-BC safety IV Catheter is an over-the-needle blood control. Peripheral passive Safety IV Catheter incorporates a safety clip to help prevent needle-stick injuries & blood control valve to reduce blood exposure during initial catheter placement, blood sampling, withdrawal of the needle, and connection of the luer. The Polysafety BC Safety IV Catheter is provided with a detachable or integrated, flexible perforated soft wing for providing ventilation & skin maceration. The device also incorporates a 'quick flash back'.	The Introcan Safety® 2 IV Catheter consists of an over-the-needle, peripheral catheter made of radiopaque polyurethane, an integrated one directional septum that controls the flow of blood during and after cannulation, and a passive safety needle-shielding mechanism. Introcan Safety® 2 is designed to reduce blood exposure at insertion until first connection of an infusion line or luer device to protect clinicians and patients from blood exposure. During needle withdrawal, the needle is withdrawn through a septum that seals after the needle has been removed, blood is thus contained within the Introcan Safety® 2 device. The pressure exerted on the needle as it passes through the septum wipes blood from the needle further reducing potential blood exposure. The passive safety needle shielding mechanism of the Introcan Safety® 2 is located inside the catheter hub. Upon withdrawal of the needle, the safety shield engages as the needle passes through the catheter hub and deploys automatically to shield the needle tip. The safety shield protects during disposal, aiding in the prevention of needlestick injuries. Once the safety shield engages and shields the needle tip, the user is unable to re-insert the needle which aids in the prevention of catheter shearing. This device may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy. The catheters may be used intravascularly with power injectors for which the maximum pressure setting is 300 psi with a luer lock connection only. The devices will be available in 18, 20, 22, and 24-	Different see **2.1.1 (Substantial equivalent)**

Feature	Subject device Polysafety BC Polysafety BC Adva	Predicate device Introcan Safety® 2 IV Catheter	Comparison
		gauge versions with and without a stabilization platform.	
Indications for use	The Polysafety BC IV Catheter are indicated for short-term use (less than 30 days) for insertion into a patient's vascular system to sample blood or administer fluids such as solutions, parenteral nutrition, and administration of other drugs. 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 18G-24G catheters may be used intravascularly with power injectors at a maximum pressure of 300psi. The Polysafety BC Adva IV Catheter are indicated for short-term use (less than 30 days) for insertion into a patient's vascular system to sample blood or administer fluids such as solutions, parenteral nutrition, and administration of other drugs. 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 l8G-24G catheters may be used intravascularly with power injectors at a maximum pressure of 300psi.	The Introcan Safety® 2 IV Catheter is inserted into a patient's vascular system for short term use to sample blood, monitor blood pressure, or administer fluids and blood intravascularly. The catheters may be used intravascularly with power injectors at a maximum pressure of 300 psi with a luer lock connection only.	Different see 2.1.2 **(Substantial equivalent)**
Sharps injury protection feature?	Yes – passive, tested in accordance with ISO 23908 and FDA 'Guidance for Industry and FDA Staff Medical Devices with Sharps Injury Prevention Features', August 2005.	Yes - passive	Same
Wings	With, without and Detachable wings with	Yes- and without wings	Same
Catheter tube material	Polyurethane + Barium Sulfate	Polyurethane + Barium Sulfate	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	Yes	Yes	Same
Blood control	Yes	Yes	Same
Gauge sizes	18 - 24G	18- 24G	Same
Needle lengths	19-45 mm	19-45 mm	Same
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 years	1 years	Different Testing on subject device supports 3 years shelf life, **see 2.1.6.3**

Feature	**Subject device** Polysafety BC Polysafety BC Adva	**Predicate device** Introcan Safety® 2 IV Catheter	**Comparison**
Physical properties	According to ISO 10555-1, ISO 10555-5	According to ISO 10555-1, ISO 10555-5	Same
Power injection usage?	Yes, 18-24G catheters up to 300 psi.	The 18-24 G devices are suitable for use with power injectors up to 300 psi	Same
Biocompatibility	Biocompatible in accordance with ISO 10993 series and FDA guidance	Biocompatible in accordance with ISO 10993 series.	Same
Environment of use	Rx only	Rx only	Same
MR Safety	MR Conditional	MR Conditional	Same

2.1 POLYSAFETY SUBSTANTIAL EQUIVALENCE DISCUSSION

2.1.1 DEVICE Description

The subject device shares the same technological characteristics, principles of operation and the same fundamental scientific technology as the predicate device. The predicate device description wording is more extensive than the subject device, the devices have the same features. The predicate device uses the Introcan Safety 2 system, the Polymed system uses the same concepts for a safety clip system. Both the devices can be used with power injectors. The differences are minor and stylistic in nature and do not raise new questions about safety and effectiveness.

2.1.2 INDICATIONS FOR USE

The predicates are intended for the same patient population and are available in the same gauge sizes and needle lengths. The subject intended use is more descriptive than the intended use of the predicate, this difference is minor and stylistic in nature and does not raise new questions about safety and effectiveness.

The are no differences between the proposed Polysafety BC IV Catheter variants and predicate Introcan Safety® 3 Closed IV Catheter devices are listed below. These differences do not raise new issues of safety and effectiveness.

2.1.3 DEVICE FEATURES

2.1.3.1 Blood Control Feature

The subject and predicate devices both have a one directional septum used for “blood control’ feature in all models in all gauge sizes. The septum maintains a closed catheter system, before and after use.

2.1.3.2 Safety Mechanism

The subject and predicate both devices are provided with a safety mechanism i.e., passive safety tip clip to help prevent needle stick injuries.

2.1.3.3 Power Injection Usage

The subject and predicate device catheters in the range 18 - 24G have been verified for use with power injectors up to 300 psi.

2.1.3.4 Hub Wings

The predicate device offers the user the choice of having or not having hub wings on all models within the device family. Polysafety BC also offers integrated or detachable wings or without wings depending on customer requirement. The detachable wings do not introduce any new concerns about safety and effectiveness.

2.1.4 NON-CLINICAL TESTING

Bench testing has been carried out to ensure the safety and effectiveness of the Polysafety BC to verify conformity to specification and demonstrate substantial equivalence to the predicate cited in this submission. testing has included a demonstration of compliance testing with the standards and FDA guidance's.

Table 2-2 Standards

Tests	Standard
Intravascular Catheters- General Requirements- single sterile	ISO 10555-1:2013/AMD 1:2017
	ISO 10555-5:2013
Small -bore connectors for liquids and gases	ISO 80369-7:2016
Particulate matter Analysis	USP <788> Method 1
Sharps injury protection	ISO 23908:2011
Cytotoxicity	ISO 10993-5:2009
Skin Sensitization	ISO 10993-10:2010
Irritation or intracutaneous reactivity	ISO 10993-10:2010
Packaging Validation	ISO 11607-2:2019
Ethylene Oxide Sterilization Validation	ISO 11135:2014/Amd 1:2018
EO sterilization residuals	10993-7:2008/Amd 1:2019
Bacterial Endotoxins tests	USP<85>
Vibration Packaging Testing	ISTA 3A:2018
Packaging Leak test	ASTM F-1929
Packaging Leak Test	ASTM F-2096
Packaging Seal Test	ASTM F-88 / F-88M
Sterility Testing	USP <71>

To establish substantial equivalence and the safety and effectiveness of the Polysafety BC Safety IV catheter variants to bench testing was successfully conducted to verify conformity to specification to the predicate device.

The Polysafety BC and Polysafety BC Adva IV Catheters have been subjected to simulated clinical use testing in accordance with FDA 'Guide for Industry and staff – Medical Devices with Sharp Injury Prevention Features' and ISO 23908:2011 'Sharps injury protection. Requirements and Test method. Sharp protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling'.

2.1.5 BIOCOMPATIBILITY

Biocompatibility of finished device 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's and including the following test to support the contact category.

The contact category of the device is:

- External Communicating Device. Contact duration – B-
- Prolonged Exposure
- Area of Contact - Circulating Blood

Table 2-3 Biocompatibility Standards

Test	FDA Recognition number

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 # 2-24
Genotoxicity	ISO 10993-3:2014, FDA recognition # 2-228
USP <788> Method 1	Not FDA recognized

2.1.6 STERILIZATION, PACKAGING AND SHELF-LIFE

Sterilization was conducted as per standards ISO 11135:2014/Amd 1:2018 (FDA recognition # 14- 529)**:**

2.1.6.1 Sterile packaging

Sterile packaging is performed at Polymed in accordance with internal documentation (drawings and work instructions)

The sterile packaging materials used are: -

- Medical grade paper (80+10 GSM) supplied by Qingdao Medlight Trade Co Ltd or Anhui Harmony Medical
- Thermoforming PP+PE film (120 µm) supplied by Anhui Harmony Medical, Reliant Packaging Films, or Qingdao Medlight Trade Co

2.1.6.2 Sterilization

Sterilization is carried out on-site by Polymed by means of ethylene oxide (ETO) gas, resulting in a sterility assurance level (SAL) of 10-6. The ETO cycle parameters are provided in Section 14 of this submission. The cycle has been validated in accordance with ISO 11135:2014/Amd 1:2018 (FDA recognition # 14- 529).

ETO residuals have been assessed in accordance with ISO 10993-7:2008/Amd 1:2019 and found to be within acceptable limits.

Bacterial endotoxin levels of 'ready for release' devices have been assessed by means of a Limulus amebocyte lysate (LAL) test in accordance with USP <85> (FDA recognition # 14-570) and found to be less than the allowable limit of 20 EU/device. Further details regarding the sterilization of the subject devices are provided in Section 14 of this submission.

2.1.6.3 Shelf Life

Testing on subject device supports 3 years' shelf life. The subject device has a longer shelf life than the predicate, materials and sterilization methods have the same standards and performance specifications. The difference does not impact the safety and effectiveness of the device.

The shelf life for the subject devices has been assessed by subjecting them to accelerated aging per ASTM F1980-16 (FDA recognition # 14-497) and then by testing them to confirm compliance with specifications at the end of their designated shelf lives. These tests have resulted in the establishment of a shelf life of 3 years.

The subject devices are packed for transport in 5 ply corrugated boxes. A transit test has been successfully carried out in accordance with ISTA 3A:2018 (FDA recognition # 5-126).

Final testing is performed on each batch before release, testing samples for compliance with:

Table 2-4 Batch testing FDA Recognized Standards

Standard	FDA Recognition number
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

2.1.7 CLINICAL TESTING

Not applicable

2.1.8 CONCLUSION

The differences between the predicate device and the subject device do not raise any new or different questions of safety or effectiveness. The Polysafety BC and Polysafety BC Adva IV Catheter is substantially equivalent to the Introcan® Safety 2 IV Catheter with respect to the indications for use and the fundamental technological characteristics.

3 POLYWIN SAFETY SUBSTANTIAL EQUIVALANCE

The Polywin Safety predicted to the B. Braun Introcan Safety® IV Catheter (K020785). Both devices are under the same product code (FOZ) and regulation number (880.5200) classification and intended for short term use less than 30 days.

Table 3-1 Polywin Safety Predicate Comparison

Feature	**Subject device** Polywin Safety Polywin Safety Adva	**Predicate device** Introcan Safety® IV Catheter	**Comparison**
Device Manufacturer	Poly Medicure, India	B. Braun Medical Inc, Pennsylvania	N/A
510(k) Reference	This submission	K020785	N/A
Device Description:	The Polywin safety IV Catheter is an over the needle, Peripheral passive Safety IV Catheter that incorporates a safety clip to help prevent needle- stick injuries. The Polywin Safety Adva IV Catheter provided with quick flash back features.	B. Braun Medical's Introcan Safety IV Catheter is a passive needle stick prevention device used for arterial and venous access for the infusion of fluids, drugs and/or blood components. 14 - 22-gauge catheters may be used with power injectors for which the maximum pressure setting is 300 psi. The Introcan Safety IV Catheter is available in 14 - 24-components. 14 - 22-gauge catheters may be used with power injectors for which the maximum pressure setting is 300 psi. The Introcan Safety IV gauge sizes, and both winged and non-winged versions.	Different see **3.1.1 (Substantial equivalent)**
Indications for use	The Polywin Safety IV Catheter are indicated for short term use (less than 30 days) for insertion into a patient's vascular system to sample blood or administer fluids such as solutions, parenteral nutrition and administration of other drugs. 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 14G-	Passive anti-needle stick device for venous or arterial access for the infusion of fluids, drugs, and/or blood components. 14 - 22-gauge catheters may be used with power injectors for which the maximum pressure setting is 300 psi	Different see **3.1.2 (Substantial equivalent)**

Feature	**Subject device** Polywin Safety Polywin Safety Adva	**Predicate device** Introcan Safety® IV Catheter	**Comparison**
	24G catheters may be used intravascularly with power injectors at a maximum pressure of 300psi. The Polywin Safety Adva IV Catheter are indicated for short term use (less than 30 days) for insertion into a patient's vascular system to sample blood or administer fluids such as solutions, parenteral nutrition and administration of other drugs. 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 14G-24G catheters may be used intravascularly with power injectors at a maximum pressure of 300psi.		
Sharps injury protection feature?	Yes – passive, tested in accordance with ISO 23908 and FDA 'Guidance for Industry and FDA Staff Medical Devices with Sharps Injury Prevention Features', August 2005.	Yes - passive	Same
Wings	Does not have wings	Available with/without wings	Different see 3.1.1.2 **(Substantial equivalent)**
Catheter tube material	Polyurethane + Barium Sulfate	Polyurethane + Barium Sulfate	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	Yes	Yes	Same
Blood control	Yes	Yes	Same
Gauge sizes	14 - 26G	14- 24G	Different see 3.1.1 **(Substantial Equivalent)**
Needle lengths	19-45 mm	19-45 mm	Same
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	5 years	5 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, 18-24G catheters up to 300 psi.	The 18-24 G devices are suitable for use with power injectors up to 300 psi	Same
Biocompatibility	Biocompatible in accordance with ISO 10993 series and FDA guidance	Biocompatible in accordance with ISO 10993 series.	Same
Environment of use	Rx only	Rx only	Same

3.1 POLYWIN SAFETY SUBSTANTIAL EQUIVALENCE DISCUSSION

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.

3.1.1 DEVICE DESCRIPTION

The subject device shares the same technological characteristics, principles of operation and the same fundamental scientific technology as the predicate device. The predicate wording for predicate device description is more expansive than the subject device. The systems are similar. Both the devices can be used with power injectors, the predicate has a range 14-22G and the subject has the range of 14-24 G. Performance testing was conducted to establish the safety profile of the 24 G no new concerns for safety and effectiveness were found.

3.1.1.2 HUB WINGS

The subject device does not contain wings, the predicate device is available with or without wings.

3.1.2 INDICATIONS FOR USE

The predicates are intended for the same patient population and are available in the same gauge sizes and needle lengths for the same intended purpose. The subject intended use is more descriptive than the intended use of the predicate, this difference is minor and stylistic in nature and does not raise new questions about safety and effectiveness.

3.1.3 DEVICE FEATURES:

The subject and predicate both devices are provided with the same safety mechanism i.e., passive safety tip clip to help prevent needle stick injuries.

The subject device catheters are available in gauge sizes 14 to 26 however the14 – 24G have been verified for use with power injectors up to 300 PSI. Both the predicate and subject devices are compatible for power injections.

3.1.4 NON-CLINICAL TESTING

Tests	Standard
Intravascular Catheters- General Requirements- single sterile	ISO 10555-1:2013/AMD 1:2017
	ISO 10555-5:2013
Small -bore connectors for liquids and gases	ISO 80369-7:2016
Particulate matter Analysis	USP <788> Method 1
Sharps injury protection	ISO 23908:2011
Cytotoxicity	ISO 10993-5:2009
Skin Sensitization	ISO 10993-10:2010
Irritation or intracutaneous reactivity	ISO 10993-10:2010
Acute systemic toxicity	ISO 10993-11:2017
Subacute/subchronic toxicity	ISO 10993-11:2017
Material-mediated pyrogenicity	ISO 10993-11:2017
Hemocompatibility	ISO 10993-4:2017
Implantation	ISO 10993-6:2016

Tests	Standard
Genotoxicity	ISO 10993-3:2014
Packaging Validation	ISO 11607-2:2019
Ethylene Oxide Sterilization Validation	ISO 11135:2014/Amd 1:2018
EO sterilization residuals	10993-7:2008/Amd 1:2019
Bacterial Endotoxins tests	USP<85>
Vibration Packaging Testing	ISTA 3A:2018
Packaging Leak test	ASTM F-1929
Packaging Leak Test	ASTM F-2096
Packaging Seal Test	ASTM F-88 / F-88M
Sterility Testing	USP <71>

Bench testing has been carried out to ensure the safety and effectiveness of the Polywin safety catheter variants, to verify conformity to specification, and demonstrate substantial equivalence to the predicate cited in this submission. testing has included a demonstration of compliance testing with the following standards:

To establish substantial equivalence and the safety and effectiveness of the Polywin Safety IV catheter variants to bench testing was successfully conducted to verify conformity to specification to the predicate device.

The Polywin Safety IV Catheter variants have been subjected to simulated clinical use testing in accordance with FDA 'Guide for Industry and staff – Medical Devices with Sharp Injury Prevention Features' and ISO 23908:2011 'Sharps injury protection. Requirements and Test method. Sharp protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling'.

3.1.5 BIOCOMPATIBILITY

Biocompatibility of finished device 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's and, including the following test: to support the contact duration.

The contact category of the device is:

- External Communicating Device. Contact duration – B-
- Prolonged Exposure
- Area of Contact - Circulating Blood

Biocompatibility Recognized Standards

Tests	FDA Recognition number
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
USP <788> Method 1	Not FDA recognized

3.1.6 STERILIZATION, PACKAGING AND SHELF-LIFE

Sterilization was conducted as per standards ISO 11135:2014/Amd 1:2018 (FDA recognition # 14- 529):

Sterile packaging is performed at Polymed in accordance with internal documentation (drawings and work instructions).

The sterile packaging materials used are:

- Medical grade paper (80+10 GSM) supplied by Qingdao Medlight Trade Co Ltd or Anhui Harmony Medical
- Thermoforming PP+PE film (120 µm) supplied by Anhui Harmony Medical, Reliant Packaging Films, or Qingdao Medlight Trade Co Ltd.

3.1.6.1 Sterilization

Sterilization is carried out on-site by Polymed by means of ethylene oxide (ETO) gas, resulting in a sterility assurance level (SAL) of 10-6. The ETO cycle parameters are provided in Section 14 of this submission. The cycle has been validated in accordance with ISO 11135:2014/Amd 1:2018 (FDA recognition # 14- 529).

ETO residuals have been assessed in accordance with ISO 10993-7:2008/Amd 1:2019 and found to be within acceptable limits.

Bacterial endotoxin levels of 'ready for release' devices have been assessed by means of a Limulus amebocyte lysate (LAL) test in accordance with USP <85> (FDA recognition # 14-570) and found to be less than the allowable limit of 20 EU/device.

Further details regarding the sterilization of the subject devices are provided in Section 14 of this submission.

3.1.6.2 Shelf Life

The shelf life for the subject devices has been assessed by subjecting them to accelerated aging per ASTM F1980-16 (FDA recognition # 14-497) and then by testing them to confirm compliance with specifications at the end of their designated shelf lives. These tests have resulted in the establishment of a shelf life of 5 years, depending on the specific catheter model.

The subject devices are packed for transport in 5 ply corrugated boxes. A transit test has been successfully carried out in accordance with ISTA 3A:2018 (FDA recognition # 5-126).

Final testing is performed on each batch before release, testing samples for compliance with:

Table **Batch testing FDA Recognized Standards**

Standard	**FDA Recognition number**
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	Not FDA recognized.

3.1.7 CLINICAL TESTING

Not applicable

3.1.8 Conclusion

The differences between the predicate device and the subject device do not raise any new or different questions of safety or effectiveness. The Polywin Safety and Polywin Safety Adva

IV Catheter is substantially equivalent to the Introcan® Safety IV Catheter with respect to indications for use and fundamental technological characteristics.