April 1, 2026

Poly Medicure Limited
% Sunita Teekasingh
Regulatory Consultant
GSA2 Group LLC
8049 Hayes Street North East
Spring Lake Park, Minnesota 55432

Re: K252513
Trade/Device Name: Polywin Safety (14G x 51mm; 16G x 51mm; 18G x 64mm; 20G x 64mm; 20G x 45mm; 22G x 64mm; 22G x 45mm; 24G x 32mm; 24G x 14mm, 26G x 14mm); Polywin Safety Adva (20G x 45mm; 22G x 64mm; 22G x 45mm ; 24G x 32 mm; 24G x 14mm; 14G x 51mm; 16G x 51mm; 18G x 64mm; 20G x 64mm, 26G x 14mm)
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: March 1, 2026
Received: March 2, 2026

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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

DAVID WOLLOSCHECK -S

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)*
K252513

Device Name
Polywin Safety (14G x 51mm; 16G x 51mm; 18G x 64mm; 20G x 64mm; 20G x 45mm; 22G x 64mm; 22G x 45mm; 24G x 32mm; 24G x 14mm, 26G x 14mm); Polywin Safety Adva (20G x 45mm; 22G x 64mm; 22G x 45mm ; 24G x 32 mm; 24G x 14mm; 14G x 51mm; 16G x 51mm; 18G x 64mm; 20G x 64mm, 26G x 14mm)

Indications for Use *(Describe)*
The Polywin Safety and Polywin Safety Adva IV Catheters 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K252513 - 510(K) SUMMARY PER 807.92(C)

1 ADMINISTRATIVE INFORMATION

Device Name	Polywin Safety (14G x 51mm; 16G x 51mm; 18G x 64mm; 20G x 64mm; 20G x 45mm; 22G x 64mm; 22G x 45mm; 24G x 32mm; 24G x 14mm, 26G x 14mm); Polywin Safety Adva (20G x 45mm; 22G x 64mm; 22G x 45mm ; 24G x 32 mm; 24G x 14mm; 14G x 51mm; 16G x 51mm; 18G x 64mm; 20G x 64mm, 26G x 14mm).
Type of 510(k) submission	Special 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
Date	April 1, 2026
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
Predicate	
Predicate Manufacturer:	Poly Medicure Ltd
Predicate Trade Name:	Polywin Safety and Polywin Safety Adva IV Catheter
Predicate 510(k) Number:	K231401
Class	II
Predicate Product Code	FOZ
FDA Classification Name:	21 CFR 880.5200

2 DEVICE DESCRIPTION

The Polywin Safety (thereafter, called Polywin Safety) is an over-the-needle, peripheral passive safety IV catheter that incorporates a safety clip to help prevent needle-stick injuries. There are two models of the device, one with quick flashback technology (Polywin Safety Adva) and one without quick flashback (Polywin Safety). The quick flash back provides instant confirmation of blood flow along catheter body increases clinician's ability to successfully access the vein. All models of the Polywin Safety IV Catheter have a passive safety clip to help prevent needle-stick injuries. This is a passive safety mechanism that does not require the user to operate safety feature. The indwelling catheter is composed of medical-grade polyurethane (PUR) with Barium Sulfate ($BaSO_4$) for radiopacity. All indwelling components, including the catheter hub and slip ring, are composed of non-conductive, non-metallic, and non-magnetic polymers.

3 SUBMISSION SCOPE

Poly Medicure Ltd. (PolyMed) is submitting this Special 510(k) to obtain market clearance for the Polywin Safety and Polywin Safety Adva IV catheters. The predicate devices were previously cleared under K231401 on September 21, 2023. The only modification in this submission is the addition of new length options for the existing gauge sizes, expanding the original length range of 19mm-45mm to 14mm-64mm.
This modification is being made in response to customer feedback and clinical needs, providing healthcare professionals with expanded options for catheter selection based on specific patient and procedural requirements. The new lengths complement the existing product portfolio while maintaining the same safety features, quality standards, and performance characteristics as the predicate devices.

Like the predicate device, the 26G catheter cannot be used with power injectors. Design control activities were conducted in accordance with 21CFR820.30 to ensure that the new lengths meet all performance requirements and maintain the safety and effectiveness of the devices.

4 INDICATIONS FOR USE

The Polywin Safety and Polywin Safety Adva IV Catheters 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.

Table 1: Predicate Comparison

Feature	Predicate Device Polywin Safety and Polywin Safety Adva	Subject Device Polywin Safety and Polywin Safety Adva	Comparison
Device Manufacturer	**Poly Medicure, India**	**Poly Medicure, India**	Same
510(k) Reference	K231401	K252513	N/A
FDA Product Code	FOZ	FOZ	Same
Trade Name	Polywin Safety and Polywin Safety Adva	Polywin Safety and Polywin Safety Adva	Same
Common Name	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days	Same
FDA Classification Name	Intravascular catheter	Intravascular catheter	Same
FDA Regulation Number	880.5200	880.5200	Same
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 provides quick flashback features.	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 provides quick flashback features.	Same
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-24G catheters may be used intravascularly with power injectors at a maximum pressure of 300psi.	The Polywin Safety and Polywin Safety Adva IV Catheters 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.	Same
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',	Yes – passive, tested in accordance with ISO 23908 and FDA 'Guidance for Industry and FDA Staff Medical Devices with Sharps Injury Prevention Features',	Same
Catheter tube material	Polyurethane + Barium Sulfate	Polyurethane + Barium Sulfate	Same
X-ray visible	Yes	Yes	Same
Needle material	Stainless steel-304	Stainless steel-304	Same
Needle distal end configuration	Back cut ground beveled needle	Back cut ground beveled needle	Same
Flashback visualization Adva feature	Yes	Yes	Same
Gauge sizes and Lengths	Polywin Safety and Polywin Safety Adva:	Additional Polywin Safety and Polywin Safety Adva gauge lengths	Similar

<table>
<tr><th>Feature</th><th>Predicate Device
Polywin Safety and Polywin Safety Adva</th><th>Subject Device
Polywin Safety and Polywin Safety Adva</th><th>Comparison</th></tr>
<tr><td></td><td>
Cleared Models
<table>
<tr><th colspan="2">Polywin Safety Gauges and Lengths</th><th>Flashback Chamber</th></tr>
<tr><td>26G</td><td>0.6mm x19mm</td><td>Square</td></tr>
<tr><td>24G</td><td>0.7mm x 19mm</td><td>Square /Standard</td></tr>
<tr><td>22G</td><td>0.9 mm x 25mm</td><td>Square/Standard</td></tr>
<tr><td rowspan="2">20G</td><td>1.1mm x 32mm</td><td>Square/Standard</td></tr>
<tr><td>1.1mm x 25mm</td><td>Square/Standard</td></tr>
<tr><td rowspan="2">18G</td><td>1.3mm x 45mm</td><td>Square/Standard</td></tr>
<tr><td>1.3mm x 32 mm</td><td>Square/Standard</td></tr>
<tr><td>16G</td><td>1.7mm x 45mm</td><td>Square/Standard</td></tr>
<tr><td>14G</td><td>2.1mm x 45mm</td><td>Square/Standard</td></tr>
</table>
<table>
<tr><th colspan="2">Polywin Safety Adva</th><th>Flashback Chamber</th></tr>
<tr><td>26G</td><td>0.6mm x19mm</td><td>Square/Standard</td></tr>
<tr><td>24G</td><td>0.7mm x 19mm</td><td>Square/Standard</td></tr>
<tr><td>22G</td><td>0.9mm x 25mm</td><td>Square/Standard</td></tr>
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</table>
</td><td>
<table>
<tr><th colspan="2">Polywin Safety Gauges and Lengths</th><th>Flashback Chamber</th></tr>
<tr><td>26G</td><td>0.6mm x 14mm</td><td>Square</td></tr>
<tr><td rowspan="2">24G</td><td>0.7mm x 32mm</td><td>Square</td></tr>
<tr><td>0.7mm x 14mm</td><td>Square</td></tr>
<tr><td rowspan="2">22G</td><td>0.9mm x 64mm</td><td>Square</td></tr>
<tr><td>0.9mm x 45mm</td><td>Square</td></tr>
<tr><td rowspan="2">20G</td><td>1.1mm x 64mm</td><td>Square</td></tr>
<tr><td>1.1mm x 45mm</td><td>Square</td></tr>
<tr><td>18G</td><td>1.3mm x 64mm</td><td>Square</td></tr>
<tr><td>16G</td><td>1.7mm x 51 mm</td><td>Square</td></tr>
<tr><td>14G</td><td>2.1mm x 51 mm</td><td>Square</td></tr>
</table>
<table>
<tr><th colspan="2">Polywin Safety Adva</th><th>Flashback Chamber</th></tr>
<tr><td>26G</td><td>0.6mm x 14mm</td><td>Square</td></tr>
<tr><td>24G</td><td>0.7mm x 32 mm</td><td>Square</td></tr>
<tr><td>24G</td><td>0.7mm x 14mm</td><td>Square</td></tr>
<tr><td rowspan="2">22G</td><td>0.9mm x 64mm</td><td>Square</td></tr>
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<tr><td>18G</td><td>1.3mm x 64mm</td><td>Square</td></tr>
<tr><td>16 G</td><td>1.7mm x 51 mm</td><td>Square</td></tr>
<tr><td>14 G</td><td>2.1mm x 51mm</td><td>Square</td></tr>
</table>
</td><td>Additional lengths to existing gauges.</td></tr>
<tr><td>Flow Rate</td><td>
<table>
<tr><th colspan="3">Polywin Safety and Polywin Safety Adva</th></tr>
<tr><th>Gauge</th><th>Length</th><th>Flow Rate</th></tr>
<tr><td>26G</td><td>19 ± 1</td><td>17 ml/min</td></tr>
<tr><td>24G</td><td>19 ± 1</td><td>23 ml/min</td></tr>
<tr><td>22G</td><td>25 ± 1</td><td>36 ml/min</td></tr>
<tr><td>20G</td><td>32± 1</td><td>61 ml/min</td></tr>
<tr><td>20G</td><td>25 ± 1</td><td>65 ml/min</td></tr>
<tr><td>18G</td><td>45 ± 1</td><td>100 ml/min</td></tr>
<tr><td>18G</td><td>32± 1</td><td>105 ml/min</td></tr>
</table>
</td><td>
<table>
<tr><th colspan="3">Polywin Safety and Polywin Safety Adva</th></tr>
<tr><th>Gauge</th><th>Length</th><th>Flow Rate</th></tr>
<tr><td>26G</td><td>14 ± 1</td><td>20 ml/min</td></tr>
<tr><td>24G</td><td>32± 1</td><td>17 ml/min</td></tr>
<tr><td>24G</td><td>14± 1</td><td>24 ml/min</td></tr>
<tr><td>22G</td><td>64± 1</td><td>25 ml/min</td></tr>
<tr><td>22G</td><td>45± 1</td><td>28 ml/min</td></tr>
<tr><td>20G</td><td>64± 1</td><td>52 ml/min</td></tr>
<tr><td>20G</td><td>45± 1</td><td>55 ml/min</td></tr>
</table>
</td><td>Meets specification</td></tr>
</table>

Feature	Predicate Device Polywin Safety and Polywin Safety Adva	Subject Device Polywin Safety and Polywin Safety Adva	Comparison
	16G 45 ± 1 200 ml/min 16G 32± 1 210 ml/min 14G 32 ± 1 305 ml/min 14G 45 ± 1 305 ml/min	18G 64 ± 1 90 ml/min 16G 51 ± 1 190 ml/min 14G 51 ± 1 305 ml/min	
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, 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
Environment of use	Rx only	Rx only	Same
MRI Safety	MR Safe	MR Safe without needle	Same

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5 SUBSTANTIAL EQUIVALENCE DISCUSSION

This section provides a comprehensive analysis of substantial equivalence between the proposed device modifications and the predicate device (Polywin Safety and Polywin Safety Adva, K231401). The Polywin Safety and Polywin Safety Adva IV catheters with expanded length ranges (14mm-64mm) maintain identical intended use and technological characteristics as the predicate devices.

The only modification is the addition of new length options to the previously cleared gauge sizes. The original length range of 19mm-45mm is being expanded to 14mm-64mm, while maintaining all other device characteristics including design, materials, chemical composition, manufacturing processes, sterilization methods, packaging configuration and fundamental technology. This modification responds directly to clinical needs while preserving the established safety and effectiveness profile of predicate devices.

The new models meet all specifications for gauge dimensions and have been thoroughly validated to ensure safety and effectiveness of the new lengths. Product labeling has been updated accordingly to reflect the new models.

5.1 Design Control Activities

In accordance with 21CFR 820.30, Poly Medicure Ltd. has completed comprehensive design control activities for the new length configurations ensuring that the expanded catheter lengths maintain the same level of safety and effectiveness as the predicate devices.

5.2 Design Control Assessment

5.2.1 Verification and Validation Activities

- Comprehensive verification and validation activities have been completed for all new catheter lengths:
- **Dimensional Verification** conducted according to ISO 10555-1:2023, confirming precise adherence to specifications.
- **Biocompatibility & Sterilant Residuals:** Subject-specific residual testing per ISO 10993-7 was performed. Results demonstrated compliance with allowable limits for limited exposure devices. Biocompatibility device Categorization as per ISO 10993-1:2018 :
  - Contact Duration: B (Prolonged)
  - Nature of Body Contact: External communicating device
  - Area of contact: Circulating Blood
- **Performance Testing** executed using identical protocols and standards as the predicate device
- **Sterilization Validation** confirming achievement of SAL 10^{-6} for all new configurations using the same EtO sterilization process as the predicate.

5.3 Testing and Performance Data

Comprehensive bench testing was conducted on final, finished, sterile devices subjected to worst-case preconditioning, including 2x sterilization cycles, distribution simulation (ASTM D4169), and accelerated aging (ASTM F1980).

5.3.1 Standards Compliance

Testing protocols were identical to those used for the predicate devices, ensuring direct comparability. Verification confirmed compliance with the following FDA-recognized standards:

Table 2: FDA Recognized Standards

Standard	FDA Recognition Number
ISO 10555-1:2023 Intravascular catheters- Sterile and single use catheters – Part 1: General requirements	6-408
ISO 10555-5:2013 – Intravascular catheters – Sterile and single use catheters- Part 5: Over the needle peripheral catheters	6-303
ISO 80369-7:2021 Small bore connectors for liquids and gases in healthcare application – Part 7: Connectors for intravascular or hypodermic applications	5-115
ISO 9626:2016 Stainless steel needle tubing for medical devices- Requirements and test methods	6-455
ISO 11607-1:2019 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems	14-530
Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods.	14-531
ASTM F2503-23 Marking Medical Devices for Safety in the MR Environment	8-544

5.3.2 Performance Results Summary

Quantitative statistical analysis was performed for all mechanical tests. Testing was conducted on final, finished, sterile. The results demonstrate:

- **Fluid Path Integrity:** 100% pass rate for liquid and air leakage testing (ISO 80369-7 / ISO 10555-1), mitigating risks of infection and sepsis.
- **Mechanical Strength:** Tensile strength of the hub-to-tube bond and needle resistance to breakage (ISO 9626) met all requirements.
- **Flow Dynamics:** Flow rates and burst pressures meet specifications across all gauges and new lengths.
- **Sharps Protection:** Safety mechanism functionality is identical to the predicate, providing consistent sharps injury protection.
- **Power Injection:** Verification confirmed that 14G to 24G configurations safely withstand power injection at a maximum pressure of 300 psi. In accordance with the predicate device labeling, the 26G configuration is excluded from power injection use.

- **Equivalence:** All other performance characteristics remain equivalent to those documented in K231401.

5.4 Material and Manufacturing

The subject devices are composed of the same materials as the predicate; a biocompatibility assessment per ISO 10993-1 confirmed that the expanded surface area of the 64 mm configurations does not alter the biological safety profile of the device.

- **Material Identity:** No changes to the catheter material (Polyurethane + Barium Sulfate), needle material (Stainless Steel 304), or hub polymers. PolyMed confirms that **no metallic slip ring** is present in the subject or predicate configurations.
- **Manufacturing Consistency:** Devices are produced using the same validated processes, equipment, and facilities as the predicate.
- **Sterilization:** Achievement of SAL 10^{-6} is confirmed using the same validated Ethylene Oxide process.
- **Shelf Life:** Validated to maintain a 5-year shelf life post-aging.

5.5 MRI Safety Status

In accordance with ASTM F2503-23, the MRI safety status has been standardized based on the clinical configuration:

- **Complete Device Assembly:** MR Unsafe due to the transient metallic introducer needle.
- **In-Situ Device (Post-Needle Removal):** MR Safe. The indwelling catheter contains no metallic, magnetic, or conductive materials, posing no risk of RF-induced heating or significant image artifacts.

5.6 Conclusion

Based on the comprehensive design controls, performance testing, and Polywin Safety and Polywin Safety Adva IV catheters with expanded length range (14mm-64mm) are substantially equivalent to the predicate device (K231401). The subject devices raise no new questions of safety or effectiveness and perform as safely and effectively as the cleared predicate.