February 1, 2024

Berpu Medical Technology Co., Ltd.
% Diana Hong, General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, Shanghai 200120, China

Re: K232165
Trade/Device Name: Sterile Safety Hypodermic Needles for Single Use; Sterile Hypodermic Needles for Single Use- Disposable Needles; Sterile Hypodermic Needles for Single Use- Self-sealing Hypodermic Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: January 2, 2024
Received: January 2, 2024

Dear Diana Hong:

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.

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,

Shruti N. Mistry -S

Shruti Mistry, MS
Assistant Director
DHT3C: Division of Drug Delivery and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232165

Device Name
Sterile Safety Hypodermic Needles for Single Use
Sterile Hypodermic Needles for Single Use- Disposable Needles
Sterile Hypodermic Needles for Single Use- Self-sealing Hypodermic Needles

Indications for Use *(Describe)*

The Sterile Safety Hypodermic Needles for Single Use are intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

The Sterile Hypodermic Needles for Single Use- Disposable Needles are intended to be used with a luer slip or luer lock syringes and injection devices for general purpose fluid injection/aspiration.

The Sterile Hypodermic Needles for Single Use- Self-sealing Hypodermic Needles are intended to be used with a luer slip or luer lock syringes and injection devices for general purpose fluid injection/aspiration.

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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K232165 510(k) Summary

1. Date of Preparation: 2/1/2024

2. Sponsor Identification

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Tingting Su (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Sterile Safety Hypodermic Needles for Single Use
Sterile Hypodermic Needles for Single Use- Disposable Needles
Sterile Hypodermic Needles for Single Use- Self-sealing Hypodermic Needles

Regulation Name: Hypodermic, Single Lumen Needle
Classification: II

Regulation Number: 21 CFR 880.5570
Product Code: FMI

Predicate Device:
510(k) Number: K180417
Product Name: Sterile Hypodermic Needles for Single Use
Sterile Safety Hypodermic Needles for Single Use

Indications for use:
The Sterile Safety Hypodermic Needles for Single Use are intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

The Sterile Hypodermic Needles for Single Use- Disposable Needles are intended to be used with a luer slip or luer lock syringes and injection devices for general purpose fluid injection/aspiration.

The Sterile Hypodermic Needles for Single Use- Self-sealing Hypodermic Needles are intended to be used with a luer slip or luer lock syringes and injection devices for general purpose fluid injection/aspiration.

Device Description
The proposed devices are provided in two types of configurations; one type is a Sterile Safety Hypodermic Needles for Single Use, the other is Sterile Hypodermic Needles for Single Use. The Sterile Hypodermic Needles also divided into two types, one type is an ordinary disposable needle contained in a sterility maintenance package, the other is self-sealing hypodermic needle with an end cap, the protective cap and end cap form a sterility maintenance package.

The Sterile Safety Hypodermic Needles for Single Use are intended for single use only, which consists of a hypodermic needle with a safety sheath attached to the needle hub. The proposed device is available in 28-34 gauge and 4-32 mm lengths. The safety sheath will be manually activated to cover the needle immediately after use to minimize risk of accidental needle sticks.

The Sterile Hypodermic Needles for Single Use are intended for single use only. The proposed device is

available in 18-34 gauge and 2-40 mm lengths.

The proposed devices are sterilized by Ethylene Oxide Gas to achieve a SAL of 10^{-6} and are supplied in a sterility maintenance package which could maintain the sterility of the device during the shelf life of five years.

Table 1 Specifications for Proposed Devices

Needle Type	Needle gauge	Needle Length
Sterile Safety Hypodermic Needles for Single Use	28G, 29G, 30G, 31G, 32G, 33G, 34G	4mm, 5mm, 6mm, 8mm, 9mm, 10mm, 12mm, 13mm, 16mm, 20mm, 22mm, 25mm, 30mm, 32mm
Sterile Hypodermic Needles for Single Use- Disposable Needle	27G, 30G, 31G, 32G, 33G, 34G	2mm, 2.5mm, 4mm, 5mm, 6mm, 8mm, 9mm, 10mm, 12mm, 13mm, 16mm, 20mm, 22mm, 25mm, 30mm, 32mm
Sterile Hypodermic Needles for Single Use- Self-sealing Hypodermic Needle	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G, 32G, 33G, 34G	2mm, 2.5mm, 4mm, 5mm, 6mm, 8mm, 9mm, 10mm, 12mm, 13mm, 16mm, 20mm, 22mm, 25mm, 30mm, 32mm, 35mm, 38mm, 40mm

5. Technological Characteristic Table

Table 2 Comparison of Sterile Safety Hypodermic Needles

ITEM	Proposed Device K232165		Predicate Device K180417		Remark
Product	Sterile Safety Hypodermic Needles for Single Use		Sterile Safety Hypodermic Needles for Single Use		/
Product Code	FMI		FMI		Same
Regulation No.	21 CFR 880.5570		21 CFR 880.5570		Same
Class	Class II		Class II		Same
Indication for Use	The Sterile Safety Hypodermic Needles for Single Use are intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.		The Sterile Safety Hypodermic Needles for Single Use are intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.		Same
Configuration and material	Needle hub	Polypropylene (PP)	Needle hub	Polypropylene (PP)	Same
	Protective cap	Polypropylene (PP)	Protective cap	Polypropylene (PP)	
	Needle	Stainless Steel	Needle	Stainless Steel	
	Safety sheath	Polypropylene (PP)	Safety sheath	Polypropylene (PP)	
Safety sheath					Same
Operation Mode	For manual use only		For manual use only		Same
Single Use	Single Use		Single Use		Same
Label/Labeling	Complied with 21 CFR part 801		Complied with 21 CFR part 801		Same
Needle Gauge	Available in 28G, 29G, 30G, 31G, 32G, 33G, 34G		Available in 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G		Different
Needle Length	Available in 4mm, 5mm, 6mm, 8mm, 9mm, 10mm, 12mm, 13mm, 16mm, 20mm, 22mm, 25mm, 30mm, 32mm		Available in 6-50mm		

Needle tube colors	Comply with ISO 6009 34G: Orange 33G: Black 32G: Deep green 31G: White 30G: Yellow 29G: Red 28G: Blue-green	Comply with ISO 6009 27G: Medium Grey 26G: Brown 25G: Orange 24G: Medium Purple 23G: Dark Blue 22G: Black 21G: Dark Green 20G: Yellow 19G: Cream 18G: Pink	Similar
Needle Performance	Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	Same
Luer Connector Performance	Complied with ISO 80369-7	Complied with ISO 594-2	Different
Biocompatibility			
Cytotoxicity	No cytotoxicity	No cytotoxicity	Same
Irritation	No intracutaneous reactivity	No intracutaneous reactivity	
Sensitization	No sensitization	No sensitization	
Systemic Toxicity	No systemic toxicity	No systemic toxicity	
Hemolysis	No Hemolysis	No Hemolysis	
Pyrogen	No Pyrogen	No Pyrogen	
Particulate	Comply with USP<788> no more than 6000 /device≥10μm, and no more than 600 /device≥25μm.	Comply with USP<788>	
Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same
Shelf life	5 years	5 years	Same

Different Analysis 1-Needle Size and Length

The needle size and length for the proposed device is different from the predicate devices. This difference is just in dimension. Different size and length devices will be selected by the physician per the patient's condition. Moreover, the needle length of the proposed device with safety needle is included in the range of the needle length of the predicate device. The performance of the needle was tested, and the test results showed that it was in accordance with ISO 7864 and ISO 9626 standards. Therefore, this difference does not raise new questions of safety and effectiveness.

Similar Analysis 2-Needle hub color

The color of needle hub for proposed devices is different from the predicate devices. The color is indicating the nominal outer diameter of the tube of the needle. The proposed device and the predicate device have different needle gauges, so the color of the needle hub is different, but the color of the needle hub complies with the ISO 6009 standard. Therefore, this difference does not raise new questions of safety and effectiveness.

Different Analysis 3-Luer Connector Performance

Although the proposed device and the predicate device follow different luer connector standards, this is because ISO 594-2 is replaced by ISO 80369-7 according to current recognitions. The test results of the proposed device show that the connector performance meets the requirements of ISO 80369-7. Therefore, this difference does not raise new questions of safety and effectiveness.

Table 3 Comparison of Sterile Hypodermic Needles for Single Use- Disposable Needles

ITEM	Proposed Device K232165		Predicate Device K180417		Remark
Product	Sterile Hypodermic Needles for Single Use- Disposable Needles		Sterile Hypodermic Needles for Single Use		/
Product Code	FMI		FMI		Same
Regulation No.	21 CFR 880.5570		21 CFR 880.5570		Same
Class	Class II		Class II		Same
Indication for Use	The Sterile Hypodermic Needles for Single Use-Disposable Needles are intended to be used with a luer slip or luer lock syringes and injection devices for general purpose fluid injection/aspiration.		The Sterile Hypodermic Needles for single Use are intended to be used with a luer slip or luer lock syringe and injection devices for general purpose fluid injection/aspiration.		Same
Configuration and material	Needle Hub	Polypropylene (PP)	Needle hub	Polypropylene (PP)	Same
	Protective cap	Polypropylene (PP)	Protective cap	Polypropylene (PP)	
	Needle	Stainless Steel	Needle	Stainless Steel	
Operation Mode	For manual use only		For manual use only		Same
Single Use	Single Use		Single Use		Same
Label/Labeling	Complied with 21 CFR part 801		Complied with 21 CFR part 801		Same
Needle Gauge	Available in 27G, 30G, 31G, 32G, 33G, 34G		Available in 14G, 15G, 16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 29G, 30G		Different
Needle Length	Available in 2mm, 2.5mm, 4mm, 5mm, 6mm, 8mm, 9mm, 10mm, 12mm, 13mm, 16mm, 20mm, 22mm, 25mm, 30mm, 32mm		Available in 6-60mm		
Needle hub color	Complied with ISO 6009 34G: Orange 33G: Black 32G: Deep green 31G: White 30G: Yellow 27G: Medium Grey		Complied with ISO 6009 30G: Yellow 29G: Red 27G: Medium Grey 26G: Brown 25G: Orange 24G: Medium Purple 23G: Dark Blue 22G: Black 21G: Dark Green 20G: Yellow 19G: Cream 18G: Pink		Similar

		17G: Red Purple 16G: White 15G: Blue Grey 14G: Light Green	
Needle Performance	Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	Same
Luer Connector Performance	Complied with ISO 80369-7	Complied with ISO 594-2	Different
Biocompatibility			
Cytotoxicity	No cytotoxicity	No cytotoxicity	Same
Irritation	No intracutaneous reactivity	No intracutaneous reactivity	
Sensitization	No sensitization	No sensitization	
Systemic Toxicity	No systemic toxicity	No systemic toxicity	
Hemolysis	No Hemolysis	No Hemolysis	
Pyrogen	No Pyrogen	No Pyrogen	
Particulate	Comply with USP<788> no more than 6000 /device≥10μm, and no more than 600 /device≥25μm.	Comply with USP<788>	
Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same
Shelf life	5 years	5 years	Same

Different Analysis 4-Needle Size and Length

The needle size and length for the proposed device is different from the predicate devices. This difference is just in dimension. Different size and length devices will be selected by the physician per the patient's condition. Moreover, the needle length of the proposed device with disposable needle is similar to the needle length of the predicate device. The performance of the needle was tested, and the test results showed that it was in accordance with the ISO 7864 and ISO 9626 standards. Therefore, this difference does not raise new questions of safety and effectiveness.

Similar Analysis 5-Needle hub color

The color of needle hub for the proposed devices is different from the predicate devices. The color is indicating the nominal outer diameter of the tube of the needle. The proposed device and the predicate device have different needle gauges, so the color of the needle hub is different, but the color of the needle hub complies with the ISO6009 standard. Therefore, this difference does not raise new questions of safety and effectiveness.

Different-Analysis 6-Luer Connector Performance

Although the proposed device and the predicate device follow different luer connector standards, this is because ISO 594-2 is replaced by ISO 80369-7 according to current recognitions. The test results of the proposed device show that the connector performance meets the requirements of ISO 80369-7. Therefore, this difference does not raise new questions of safety and effectiveness.

Table 4 Comparison of Sterile Hypodermic Needles for Single Use- Self-sealing Hypodermic Needles

ITEM	Proposed Device K232165		Predicate Device K180417		Remark
Product	Sterile Hypodermic Needles for Single Use- Self-sealing Hypodermic Needles		Sterile Hypodermic Needles for Single Use		/
Product Code	FMI		FMI		Same
Regulation No.	21 CFR 880.5570		21 CFR 880.5570		Same
Class	Class II		Class II		Same
Indication for Use	The Sterile Hypodermic Needles for Single Use- Self-sealing Hypodermic Needles are intended to be used with a luer slip or luer lock syringes and injection devices for general purpose fluid injection/aspiration.		The Sterile Hypodermic Needles for single Use are intended to be used with a luer slip or luer lock syringe and injection devices for general purpose fluid injection/aspiration.		Same
Configuration and material	Needle Hub	Polypropylene (PP)	Needle hub	Polypropylene (PP)	Different
	Protective cap	Polypropylene (PP)	Protective cap	Polypropylene (PP)	
	Needle	Stainless Steel	Needle	Stainless Steel	
	End cap	Polypropylene (PP)	/	/	
Operation Mode	For manual use only		For manual use only		Same
Single Use	Single Use		Single Use		Same
Label/Labeling	Complied with 21 CFR part 801		Complied with 21 CFR part 801		Same
Needle Gauge	Available in 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G, 32G, 33G, 34G		Available in 14G, 15G, 16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 29G, 30G		Different
Needle Length	Available in 2mm, 2.5mm, 4mm, 5mm, 6mm, 8mm, 9mm, 10mm, 12mm, 13mm, 16mm, 20mm, 22mm, 25mm, 30mm, 32mm, 35mm, 38mm, 40mm		Available in 6-60mm		
Needle hub color	Complied with ISO 6009 34G: Orange 33G: Black 32G: Deep green 31G: White 30G: Yellow 29G: Red 28G: Blue-green 27G: Medium Grey 26G: Brown 25G: Orange		Complied with ISO 6009 30G: Yellow 29G: Red 27G: Medium Grey 26G: Brown 25G: Orange 24G: Medium Purple 23G: Dark Blue 22G: Black 21G: Dark Green 20G: Yellow		Similar

	24G: Medium Purple 23G: Deep Blue 22G: Black 21G: Deep Green 20G: Yellow 19G: Cream 18G: Pink	19G: Cream 18G: Pink 17G: Red Purple 16G: White 15G: Blue Grey 14G: Light Green	
Needle Performance	Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	Same
Luer Connector Performance	Complied with ISO 80369-7	Complied with ISO 594-2	Different
Biocompatibility			
Cytotoxicity	No cytotoxicity	No cytotoxicity	Same
Irritation	No intracutaneous reactivity	No intracutaneous reactivity	
Sensitization	No sensitization	No sensitization	
Systemic Toxicity	No systemic toxicity	No systemic toxicity	
Hemolysis	No Hemolysis	No Hemolysis	
Pyrogen	No Pyrogen	No Pyrogen	
Particulate	Comply with USP<788> no more than 6000 /device≥10μm, and no more than 600 /device≥25μm.	Comply with USP<788>	
Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same
Shelf life	5 years	5 years	Same

Different Analysis 7- Configuration

The configuration of the proposed device is similar as the configurations of the predicate device. The proposed device has an end cap, and the predicate devices do not have an end cap. The end cap is the protection, and it's taken off when it's used. The presence or absence of an end cap does not affect the intended use of the product, nor does it affect its use. Therefore, the differences in configuration does not raise new questions of safety and effectiveness.

Different Analysis 8-Needle Size and Length

The needle size and length for the proposed device is different from the predicate devices. This difference is just in dimension. Different size and length devices will be selected by the physician per the patient's condition. Moreover, the needle length of the proposed device with self-sealing needle is similar to the needle length of the predicate device. The performance of the needle was tested, and the test results showed

that it was in accordance with the ISO 7864 and ISO 9626 standards. Therefore, this difference does not raise new questions of safety and effectiveness.

Similar Analysis 9-Needle hub color

The color of needle hub for the proposed devices is different from the predicate devices. The color is indicating the nominal outer diameter of the tube of the needle. The proposed device and the predicate device have different needle gauges, so the color of the needle hub is different, but the color of the needle hub complies with the ISO6009 standard. Therefore, this difference does not raise new questions of safety and effectiveness.

Different Analysis 10-Luer Connector Performance

Although the proposed device and the predicate device follow different luer connector standards, this is because ISO 594-2 is replaced by ISO 80369-7 according to current recognitions. The test results of the proposed device show that the connector performance meets the requirements of ISO 80369-7. Therefore, this difference does not raise new questions of safety and effectiveness.

6. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications and is Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5: 2009 Biological evaluation of medical Devices-Part 5: Tests for in Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological evaluation of medical devices- Part 10: Test for irritation and skin sensitization.
- ISO 10993-11: 2017 Biological evaluation of medical devices- Part 11: Tests for systemic toxicity
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials
- ASTM F1886 / F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials. (Sterility)
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- ISO 7864:2016 Sterile hypodermic needles for single use — Requirements and test methods
- ISO 9626:2016, Stainless Steel Needle Tubing For The Manufacture of Medical Devices
- ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
- ISO 23908:2011 Sharps injury protection - Requirements and test methods-Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

- ISO 10993-7:2008 Biological evaluation of medical devices-Part 7: Test of Ethylene Oxide Residues.
- USP<85> Bacterial Endotoxins Test
- USP<151> Pyrogen Test
- USP <788> Particulate Testing
- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and System

Physical, Mechanical, Chemical testing listed in below were performed on the proposed device. The test results show that the device conforms with the requirements of related standards.

Item	Standard
Cleanliness	Clause 4.3 of ISO 7864:2016
Limits for acidity or alkalinity	Clause 4.4 of ISO 7864:2016
Limits for extractable metals	Clause 4.5 of ISO 7864:2016
Size designation	Clause 4.6 of ISO 7864:2016
Colour coding	Clause 4.7 of ISO 7864:2016
Needle hub	Clause 4.8 of ISO 7864:2016
Needle Cap	Clause 4.9 of ISO 7864:2016
Needle tube	Clause 4.10 of ISO 7864:2016
Needle point	Clause 4.11 of ISO 7864:2016
Bond between hub and needle tube	Clause 4.12 of ISO 7864:2016
Patency of lumen	Clause 4.13 of ISO 7864:2016

Item	Standard
Surface finish and appearance	Clause 5.2 of ISO 9626:2016
Cleanliness	Clause 5.3 of ISO 9626:2016
Limits for acidity and alkalinity	Clause 5.4 of ISO 9626:2016
Size designation	Clause 5.5 of ISO 9626:2016
Dimensions	Clause 5.6 of ISO 9626:2016
Stiffness	Clause 5.8 of ISO 9626:2016
Resistance to breakage	Clause 5.9 of ISO 9626:2016
Resistance to corrosion	Clause 5.10 of ISO 9626:2016

Item	Standard
Fluid leakage	Clause 6.1 of ISO 80369-7:2021
Sub-atmospheric pressure air leakage	Clause 6.2 of ISO 80369-7:2021
Stress cracking	Clause 6.3 of ISO 80369-7:2021
Resistance to separation form axial load	Clause 6.4 of ISO 80369-7:2021
Resistance to separation form unscrewing	Clause 6.5 of ISO 80369-7:2021
Resistance to overriding	Clause 6.6 of ISO 80369-7:2021

Particulate testing	USP <788>

Sterile barrier packaging testing was performed on the proposed device, which included visual inspection

(ASTM F1886/F1886M-16), seal strength (ASTM F88/F88-15) and dye penetration test (ASTM F1929-15). The test result showed that the device package can maintain its integrity.

Sterilization and shelf-life testing listed below were performed on the proposed device. EO/ECH residuals did not exceed the limit of ISO 10993-7. The Endotoxin limit did not exceed 20EU/device. Shelf life test result showed that the device can maintain its performance during the claimed shelf life.

EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacteria Endotoxin Limit	USP <85>
Shelf-Life Evaluation	Physical, Mechanical, Chemical, Package Tests were performed on aging samples to verify the claimed shelf life of the device

Biocompatibility testing

The proposed device has an indirect contact with the blood path, and is a limited contact duration (<24 hours) device. The proposed device was evaluated for the following tests. The results for the biocompatibility testing show that there are no negative impacts from the materials that are used in the proposed device.

- Cytotoxicity,
- Sensitization,
- Irritation,
- Acute Systemic Toxicity,
- Hemolysis,
- Pyrogen

Simulated Clinical Study

A simulated clinical study was performed on the proposed device according to FDA Guidance, "Guidance for Industry and FDA Staff: Medical Device with Sharps Injury Prevention Feature", issued on August 9, 2005 and ISO 23908:2011 to evaluate the safety mechanism of the proposed device. The results demonstrate that the proposed device meets the pre-established criteria.

Safety Feature Test

The safety feature test was performed on both the proposed device and the predicate device to determine its safety feature. The results demonstrate that both the proposed device and predicate device meet the acceptance criteria.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Conclusions

The differences between the predicate device and the subject device do not raise new or different question

of safety or effectiveness. The Sterile Safe Safety Hypodermic Needles for Single Use, The Sterile Hypodermic Needles for Single Use-Disposable Needles and The Sterile Hypodermic Needles for Single Use-Self-sealing Hypodermic Needles are substantially equivalent to K180417 Sterile Hypodermic Needles for Single Use and Sterile Safety Hypodermic Needles for Single Use with respect to Indications for Use, target populations, treatment method, and technological characteristics.