November 1, 2022

Jiangsu Kangbao Medical Equipment Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K221247
Trade/Device Name: Sterile Disposable Syringe with Safety Needle, Sterile Disposable Syringe with Needle, Sterile Disposable Safety Needle, Sterile Disposable Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG, FMF, FMI
Dated: September 30, 2022
Received: September 30, 2022

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 (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,

CAPT Alan M. Stevens
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)*

K221247

Device Name
Sterile Disposable Syringe with Safety Needle; Sterile Disposable Syringe with Needle;
Sterile Disposable Safety Needle; Sterile Disposable Needle

Indications for Use *(Describe)*

The Sterile Disposable Syringe with Safety Needle is intended for use in the 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 needle sticks.

The Sterile Disposable Syringe with Needle is intended for use in the aspiration and injection of fluids for medical purpose.

The Sterile Disposable Safety Needle is 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 needle sticks.

The Sterile Disposable Needle is intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose.

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.

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92. The assigned 510(k) Number: K221247

1. Date of Preparation: November 1, 2022

2. Sponsor Identification

Jiangsu Kangbao Medical Equipment Co., Ltd.

78#, North Suzhong Road Baoying 225800 Yangzhou PEOPLE'S REPUBLIC OF CHINA

Establishment Registration Number: 3009742443

Contact Person: Rujun Tang

Position: Management Representative

Tel: +86-514-88223540

Fax: +86-514-88232089

Email: 76823131@qq.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)

Ms. Tingting Su (Alternative Contact Person)

Mid-Link Consulting Co., Ltd

P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,

Fax: 360-925-3199

Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Sterile Disposable Syringe with Safety Needle
Sterile Disposable Syringe with Needle
Sterile Disposable Safety Needle
Sterile Disposable Needle

Common Name: Syringes with Needle

Regulatory Information
Classification Name: Syringe, Piston
Classification: II;
Product Code: FMF;
Regulation Number: 21CFR 880.5860;
Review Panel: General Hospital;

Classification Name: Needle, Hypodermic, Single Lumen
Classification: II
Product Code: FMI;
Regulation Number: 21 CFR 880.5570
Review Panel: General Hospital;

Classification Name: Piston Syringe
Classification: II;
Product Code: MEG;
Regulation Number: 21 CFR 880. 5860;
Review Panel: General Hospital

Indications for use:
The Sterile Disposable Syringe with Safety Needle is intended for use in the 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 needle sticks.

The Sterile Disposable Syringe with Needle is intended for use in the aspiration and injection of fluids for medical purpose.

The Sterile Disposable Safety Needle is 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 needle sticks.

The Sterile Disposable Needle is intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose.

Device Description

The Sterile Disposable Safety Needle is intended for manual and single use only to aspirate and inject of fluids for medical purpose, which consists of needle cap, needle tube, needle hub and safety mechanism. The proposed device is available in variety of needle gauges and lengths. The safety needle is compatible for use with a luer slip and luer lock syringe. After withdrawal of the needle from the body, the attached needle safety mechanism can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks. Needle specification is same as the needle size of Sterile Disposable Syringe with Safety Needle.

Needle specification:

Needle Gauge	Needle length
18G	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"
20G	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"
21G	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"
22G	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"
25G	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"
27G	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"

Compared with Sterile Disposable Safety Needle, Sterile Disposable Needle has the same components and specifications except without safety mechanism.

The Sterile Disposable Syringe with Safety Needle is intended for manual and single use only to aspirate and inject of fluids for medical purpose. There are two kinds of sterile disposable syringe with safety needle: syringe with fixed needles and syringe without fixed needles. Sterile disposable syringe with safety needle of 0.5ml and 1ml are available syringe with fixed needles. Syringe without fixing needle are consists of syringe (piston, barrel, plunger) and hypodermic needle with a safety mechanism. The proposed device is available in a variety combination of syringe volume and needle size.

Syringe volume: 0.5ml,1ml,2ml,3ml,5ml,10ml,20ml,30ml,50ml and 60ml

Needle specification:

Needle Gauge	Needle length
18G	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"
20G	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"
21G	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"
22G	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"
25G	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"
27G	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"

Compared with Sterile Disposable Syringe with Safety Needle, Sterile Disposable Syringe with Needle has the same components and specifications except without safety mechanism. The Sterile Disposable Syringe with Needle do not have a type of the syringe with fixed needle.

The proposed devices are sterilized by Ethylene Oxide Gas to achieve a SAL of 10-6 and supplied sterility maintenance package which could maintain the sterility of the device during the shelf life of 5 years.

5. Identification of Predicate Device

Predicate Device
510(k) Number: K170651
Product Name: Sterile Disposable Syringe with Safety Needle
Sterile Disposable Syringe with Needle
Sterile Disposable Syringe
Sterile Disposable Safety Needle
Sterile Disposable Needle

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was 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
- ISO 10993-4:2017 Biological Evaluation of Medical Devices--Part 4: Selection of Tests for Interactions with Blood
- 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 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
- ISO 7886-1:2017 Sterile hypodermic syringes for single use- Part 1: Syringes for manual use.
- ISO 10993-7:2008 Biological Evaluation of Medical Device-Part 7: Ethylene Oxide Sterilization Residuals
- 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
- USP<85> Bacterial Endotoxins Test
- USP<151> Pyrogen Test
- USP<788> Particulate Matter in Injections
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems (DC-13, Level II)

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

General requirements	Clause 5 of ISO 7886-1:2017
Extraneous matter	Clause 6 of ISO 7886-1:2017
Lubricant	Clause 7 of ISO 7886-1;2017
Tolerance on graduated capacity	Clause 8 of ISO 7886-1:2017
Graduated scale	Clause 9 of ISO 7886-1:2017
Barrel	Clause 10 of ISO 7886-1:2017
Piston/ plunger assembly	Clause 11 of ISO 7886-1:2017
Nozzle	Clause 12 of ISO 7886-1:2017
Performance	Clause 13 of ISO 7886-1:2017
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
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 80369-7:2016
Sub-atmospheric pressure air leakage	Clause 6.2 of ISO 80369-7:2016
Stress cracking	Clause 6.3 of ISO 80369-7:2016
Resistance to separation form axial load	Clause 6.4 of ISO 80369-7:2016
Resistance to separation form unscrewing	Clause 6.5 of ISO 80369-7:2016
Resistance to overriding	Clause 6.6 of ISO 80369-7:2016
Particulate testing	USP <788>

Sterile barrier packaging testing were performed on the proposed device, which include 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 in following table were performed on the proposed device. EO ECH residue did not exceed the limit of ISO 10993-7. 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 contact level of the proposed device is blood path, indirect, and the contact duration is limited contact (<24 hours). The proposed device was evaluated for the following tests. The results for the

biocompatibility testing showed that there are no negative impacts from the materials that are used in the proposed device.

- Cytotoxicity,
- Sensitization,
- Irritation,
- Acute Systemic Toxicity,
- Hemolysis,
- Complement activation,
- Thromboresistance study
- Pyrogen

Simulated Clinical Study

A simulated clinical study was performed on 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 demonstrated that the proposed device met the pre-established criteria.

Safety Feature Test

The safety feature test was performed on both proposed device and predicate device to determine its safety feature. The results demonstrated 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. Summary of Technology Characteristics

Table 1. Comparison of Sterile Disposable Syringe with Safety Needle

ITEM	Proposed Device		Predicate Device K170651		Remark
Product	Sterile Disposable Syringe with Safety Needle		Sterile Disposable Syringe with Safety Needle		/
Product Code	FMF FMI MEG		FMF FMI MEG		Same
Regulation Number	21 CRF 880.5860 21 CRF 880.5570		21 CRF 880.5860 21 CRF 880.5570		Same
Class	Class II		Class II		Same
Indications for Use	The Sterile Disposable Syringe with Safety Needle is intended for use in the 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 needle sticks.		The Sterile Disposable Syringe with Safety Needle is intended for use in the 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 needle sticks.		Same
Configuration	Syringe	Barrel (luer lock/ luer slip/ fixed needle)	Syringe	Barrel (luer lock/luer slip)	Different
		Plunger		Plunger	
		Piston		Piston	
	Needle	Needle hub	Needle	Needle hub	
		Needle tube		Needle tube	
		Needle cap		Needle cap	
		Safety mechanism		Safety sheath	
Operation Mode	For manual use only		For manual use only		Same
Sterilized	Yes		Yes		Same

Single Use		Single Use	Single Use	Same
Label/Labeling		Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Syringe	Volume	0.5ml, 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml	1ml, 2ml 3ml, 5ml, 10ml, 20ml, 30ml, 50ml,60ml	Different
	Connector Type	0.5ml,1ml: Luer Lock, Luer Slip, Fixed needle; Others: Luer Lock and Luer Slip	Luer Lock/ Luer slip	Different
Needle	Size	18G, 20G, 21G, 22G, 25G, 27G	16G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	Different
	Length	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"	5/16", 1/2", 5/8", 1", 1-1/4", 1-1/2" 3/4",	
Syringe Performance		Complied with ISO 7886-1	Complied with ISO 7886-1	Same
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
Barrel		Polypropylene (PP)	Polypropylene (PP)	Same
Plunger		Polypropylene (PP)	Polypropylene (PP)	
Piston		Polyisoprene	Polyisoprene	
Needle hub		Polypropylene (PP)	Polypropylene (PP)	
Needle tube		Stainless Steel SUS 304	Stainless Steel SUS 304	
Lubricants		Silicone oil	Silicone Oil	
Adhesive		UV adhesive	UV glue	
Cytotoxicity		No cytotoxicity	No cytotoxicity	Same
Irritation		No intracutaneous reactivity	No intracutaneous reactivity	
Sensitization		No sensitization	No skin sensitization	
Systemic Toxicity		No systemic toxicity	No systemic toxicity	

Hemolysis	No Hemolysis	No Hemolysis	No Hemolysis	
Pyrogen	No Pyrogen	No Pyrogen	No Pyrogen	
Complement Activation	Not show potentials to activate complete system	Not show potentials to activate complete system	Not show potentials to activate complete system	
In-vivo Thrombogenicity	No thrombogenicity	No thrombogenicity	No thrombogenicity	
Sterilization				
Method	EO Sterilized	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	20 EU per device	Same

Different - Configuration

The configuration of proposed device is similar to the configurations of predicate device. For 0.5ml and 1ml syringe, the proposed device has luer lock connector, luer slip connector and fixed needle, the other volumes have luer lock and luer slip connector. The predicate device only has luer lock or luer slip connector. The proposed device has luer lock connector, luer slip connector and fixed needle have been tested and meet the requirements of relevant standards. Based on above analysis, the difference on configuration will not raise new questions on safety and effectiveness of the proposed device.

Different -Syringe Volume

The syringe volume for proposed device is similar to the predicate devices. The predicate device does not have a 0.5ml syringe. This difference will not raise new questions on safety and effectiveness of the proposed device.

Different - Syringe Connector Type

The syringe connector type of proposed device is similar as the predicate device. For 0.5ml and 1ml syringe, the proposed device has luer lock connector, luer slip connector and fixed needle, the other volumes have luer lock connector and luer slip. The predicate device has luer lock or luer slip connector.

In addition, the proposed device has luer lock connector, luer slip connector and fixed needle have been tested and meet the requirements of relevant standards. Based on above analysis, the difference on connector type will not raise new questions on safety and effectiveness of the proposed device.

Different -Needle Size and Length

The needle size and length for proposed device is different from the predicate device. The needle length is very close to that of the predicate device. This difference will not raise new questions on safety and effectiveness of the proposed device.

Different -Luer Connector Performance

Although the proposed device and the predicate device follow different luer connector standards - this is because ISO 594-1,594-2 is replaced by ISO 80369-7. The test results of the proposed device show that the connector performance meet the requirements of ISO 80369-7. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

Table 2. Comparison of Sterile Disposable Syringe with Needle

ITEM		Proposed Device		Predicate Device K170651		Remark
Product		Sterile Disposable Syringe with Safety Needle		Sterile Disposable Syringe with Safety Needle		/
Product Code		FMF FMI		FMF FMI		Same
Regulation Number		21 CRF 880.5860 21 CRF 880.5570		21 CRF 880.5860 21 CRF 880.5570		Same
Class		Class II		Class II		Same
Indication for Use		The Sterile Disposable Syringe with Needle is intended for use in the aspiration and injection of fluids for medical purpose.		The Sterile Disposable Syringe with Needle is intended for use in the aspiration and injection of fluids for medical purpose.		Same
Configuration		Syringe	Barrel (luer lock/ luer slip/ fixed needle)	Syringe	Barrel (luer lock/luer slip)	Different
			Plunger		Plunger	
			Piston		Piston	
		Needle	Needle hub	Needle	Needle hub	
			Needle tube		Needle tube	
			Needle cap		Needle cap	
Operation Mode		For manual use only		For manual use only		Same
Sterilized		Yes		Yes		Same
Single Use		Single Use		Single Use		Same
Label/Labeling		Complied with 21 CFR part 801		Complied with 21 CFR part 801		Same
Syringe	Volume	0.5ml, 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml		1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml		Different
	Connector Type	Luer Lock and Luer Slip		Luer Lock/ Luer slip		Same
Needle	Size	18G, 20G, 21G, 22G, 25G, 27G		16G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G		Different
	Length	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"		5/16", 1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"		
Syringe Performance		Complied with ISO 7886-1		Complied with ISO 7886-1		Same
Needle Performance		Complied with ISO 7864,		Complied with ISO 7864,		Same

	ISO 9626	ISO 9626	
Luer Connector Performance	Complied with ISO 80369-7	Complied with ISO 594-2	Different
Patient-contact materials			
Barrel	Polypropylene (PP)	Polypropylene (PP)	Same
Plunger	Polypropylene (PP)	Polypropylene (PP)	
Piston	Polyisoprene	Polyisoprene	
Needle hub	Polypropylene (PP)	Polypropylene (PP)	
Needle tube	Stainless Steel SUS 304	Stainless Steel SUS 304	
Lubricants	Silicone oil	Silicone Oil	
Adhesive	UV adhesive	UV glue	
Biocompatibility			
Cytotoxicity	No cytotoxicity	No cytotoxicity	Same
Irritation	No intracutaneous reactivity	No intracutaneous reactivity	
Sensitization	No sensitization	No skin sensitization	
Systemic Toxicity	No systemic toxicity	No systemic toxicity	
Hemolysis	No Pyrogen	No Pyrogen	
Pyrogen	Not show potentials to activate complete system	Not show potentials to activate complete system	
Complement Activation	No thrombogenicity	No thrombogenicity	
In-vivo Thrombogenicity	No thrombogenicity	No thrombogenicity	

Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	
Endotoxin Limit	20 EU per device	20 EU per device	

Different -Syringe Volume

The syringe volume for proposed device is similar to the predicate devices. The predicate device does not have a 0.5ml syringe. This difference will not raise new questions on safety and effectiveness of the proposed device.

Different -Needle Size and Length

The needle size and length for proposed device is different from the predicate device. This difference will not raise new questions on safety and effectiveness of the proposed device.

Different - Luer Connector Performance

The luer connector performance of proposed device is complied with ISO 80369-7, the predicate device is complied with complied with ISO 594-2. They are all the test standards of luer connector. At present, ISO 594-2 has been replaced by ISO 80369-7. The predicate device was tested according to ISO 594-2 because the application time was earlier. The proposed devices are tested according to the latest version of the standard ISO 80369-7. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

Table 3. Comparison of Sterile Disposable Safety Needle

ITEM		Proposed Device	Predicate Device K170651	Remark
Product		Sterile Disposable Safety Needle	Sterile Disposable Safety Needle	/
Product Code		FMI	FMI	Same
Regulation Number		21 CRF 880.5860	21 CRF 880.5860	Same
Class		Class II	Class II	Same
Indication for Use		The Sterile Disposable Safety Needle is 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 Disposable Safety Needle is 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		Needle hub	Needle hub	Same
		Needle tube	Needle tube	
		Needle cap	Needle cap	
		Safety machine	Safety sheath	
Operation Mode		For manual use only	For manual use only	Same
Sterilized		Yes	Yes	Same
Single Use		Single Use	Single Use	Same
Label/Labeling		Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Needle	Size	18G, 20G, 21G, 22G, 25G, 27G	16G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	Different
	Length	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"	5/16", 1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"	
Needle Performance		Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	Same
Patient-contact Materials				
Needle hub		Polypropylene (PP)	Polypropylene (PP)	Same
Needle tube		Stainless Steel SUS 304	Stainless Steel SUS 304	
Lubricants		Silicone oil	Silicone oil	
Adhesive		UV adhesive	UV glue	

Biocompatibility			
Cytotoxicity	No cytotoxicity	No cytotoxicity	Same
Irritation	No intracutaneous reactivity	No intracutaneous reactivity	
Sensitization	No sensitization	No skin sensitization	
Systemic Toxicity	No systemic toxicity	No systemic toxicity	
Hemolysis	No Hemolysis	No Hemolysis	
Pyrogen	No Pyrogen	No Pyrogen	
Complement Activation	Not show potentials to activate complete system	Not show potentials to activate complete system	
In vivo Thrombogenicity	No thrombogenicity	No thrombogenicity	
Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

Different -Needle Size and Length

The needle size and length for proposed device is different from the predicate device. This difference will not raise new questions on safety and effectiveness of the proposed device.

Table 4. Comparison of Sterile Disposable Needle

ITEM		Proposed Device	Predicate Device K170651	Remark
Product		Sterile Disposable Needle	Sterile Disposable Needle	/
Product Code		FMI	FMI	Same
Regulation Number		21 CRF 880.5860	21 CRF 880.5860	Same
Class		Class II	Class II	Same
Indication for Use		The Sterile Disposable Needle is intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose.	The Sterile Disposable Needle is intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose.	Same
Configuration		Needle hub	Needle hub	Same
		Needle tube	Needle tube	
		Needle cap	Needle cap	
Operation Mode		For manual use only	For manual use only	Same
Sterilized		Yes	Yes	Same
Single Use		Single Use	Single Use	Same
Label/Labeling		Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Needle	Size	18G, 20G, 21G, 22G, 25G, 27G	16G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	Different
	Length	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"	5/16", 1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"	
Needle Performance		Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	Same
Patient-contact Materials				
Needle hub		Polypropylene (PP)	Polypropylene (PP)	Same
Needle tube		Stainless Steel SUS 304	Stainless Steel SUS 304	
Lubricants		Silicone oil	Silicone oil	
Adhesive		UV adhesive	UV glue	
Biocompatibility				
Cytotoxicity		No cytotoxicity	No cytotoxicity	Same
Irritation		No intracutaneous reactivity	No intracutaneous reactivity	
Sensitization		No sensitization	No skin sensitization	
Systemic Toxicity		No systemic toxicity	No systemic toxicity	
Hemolysis		No Hemolysis	No Hemolysis	

Pyrogen	No Pyrogen	No Pyrogen	
Complement Activation	Not show potentials to activate complete system	Not show potentials to activate complete system	
In vivo Thrombogenicity	No thrombogenicity	No thrombogenicity	
Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

Different -Needle Size and Length

The needle size and length for proposed device is different from the predicate devices. This difference will not raise new questions on safety and effectiveness of the proposed device.

9. Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device in 510(k) submission, Sterile Disposable Syringe with Safety Needle, Sterile Disposable Syringe with Needle, Sterile Disposable Safety Needle and Sterile Disposable Needle is as safe and effective as the legally marketed predicate device cleared under K170651.