November 15, 2021

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

Re: K211329
Trade/Device Name: Sterile Disposable Syringe with Saftey Needle, Sterile Disposable Syringe with Needle, Sterile Disposable Syringe, 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: October 28, 2021
Received: October 29, 2021

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 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)*
K211329

Device Name
Sterile Disposable Syringe with Safety Needle, Sterile Disposable Syringe with Needle, Sterile Disposable Syringe, 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 Syringe is a sterile luer slip or luer lock syringe which is intended to be used with a hypodermic needle for 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: K211329

1. Date of Preparation: 11/03/2021

2. Sponsor Identification

Jiangsu Kangbao Medical Equipment Co., Ltd.
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3. Designated Submission Correspondent

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

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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 Syringe
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 Syringe is a sterile luer slip or luer lock syringe which is intended to be used with a hypodermic needle for 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 Syringe is intended for manual and single use only, which consists of piston, barrel, and plunger. The proposed device is available in a variety syringe volume. The syringe is available in luer lock and luer slip configurations, which are intended to be connected with a hypodermic needle.

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

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 length. The proposed device is compatible for use with a luer slip or 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 The Sterile Disposable Syringe with Safety Needle.

Needle specification: 23G*1/2", 23G*5/8", 23G*3/4", 23G*1", 23G*1-1/4" and 23G*1-1/2"

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

The Sterile Disposable Syringe with Safety Needle for Single Use is intended for manual and single use only to aspirate and inject of fluids for medical purpose, which 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.

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

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

510(k) Number: K193526
Product Name: Syringe with safety needle,
Safety needle

6. Non-Clinical Test Conclusion

Nonclinical 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 6009:2016 Hypodermic needles for single use – Colour coding for identification
- 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

Physical, Mechanical, Chemical testing listed in following table were performed on the proposed device. The test results show that the device meets 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
Color 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 80369-7:2016
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

Item	Standard
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
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.

Item	Standard
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,
- Intracutaneous,
- Acute Systemic Toxicity,
- Hemolysis,
- Pyrogen,

- In vivo thromboresistance,
- Complement activation.

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 test data of the proposed device is very close to the test data of the predicate device.

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 K193526		Remark
Product	Sterile Disposable Syringe with Safety Needle		Syringe with Safety Needle		/
Product Code	FMF FMI MEG		FMF FMI MEG		SE
Regulation Number	21 CRF 880.5860 21 CRF 880.5570		21 CRF 880.5860 21 CRF 880.5570		SE
Class	Class II		Class II		SE
Indication 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 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 stick.		SE
Configuration	Syringe	Barrel (luer lock/luer slip)	Syringe	Barrel (luer lock)	Analysis 1
		Plunger		Plunger	
		Piston		Piston	
	Needle	Needle hub	Needle	Needle hub	
		Needle tube		Needle tube	
		Needle cap		Needle cap	
		Safety mechanism		Safety shield	
Operation Mode	For manual use only		For manual use only		SE
Sterilized	Yes		Yes		SE
Single Use	Single Use		Single Use		SE
Label/Labeling	Complied with 21 CFR part 801		Complied with 21 CFR part 801		SE
Syringe Volume	1ml, 2ml, 3ml, 5ml, 10ml,		1ml, 3ml, 5ml, 10ml, 20ml, 30ml,		Analysis 2

		20ml, 30ml, 50ml, 60ml	60ml	
	Connector Type	Luer Lock and Luer Slip	Luer Lock	Analysis 1
Needle	Size	23G	16G,18G, 19G, 20G, 21G, 22G, 23G, 25G, 26G, 27G, 28G, 29G, 30G, 31G	Analysis 3
	Length	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"	13mm(1/2"), 16mm(5/8"), 20mm(3/4"), 25mm(1"), 32mm(1-1/4"), 38mm(1-1/2")	SE
Syringe Performance		Complied with ISO 7886-1	Complied with ISO 7886-1	SE
Needle Performance		Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	SE
Luer Connector Performance		Complied with ISO 80369-7	Complied with ISO 80369-7	SE
Patient-contact Materials				
Barrel		Polypropylene (PP)	Polypropylene (PP)	Analysis 4
Plunger		Polypropylene (PP)	Polypropylene (PP)	
Piston		Polyisoprene Rubber	Polyisoprene	
Needle hub		Polypropylene (PP) and blue pigment	Polypropylene (PP)	
Needle tube		Stainless Steel SUS 304	Stainless Steel 304	
Needle cap		Polypropylene (PP)	Polypropylene (PP)	
Safety mechanism		Polypropylene (PP) and blue pigment	Polypropylene (PP)	
Lubricants		Silicone oil	Polydimethylsiloxane	
Adhesive		UV adhesive	Epoxy adhesive	
Biocompatibility				
Cytotoxicity		No cytotoxicity	Conforms to ISO 10993 series standards	SE
Irritation		No intracutaneous reactivity		
Sensitization		No sensitization		
Systemic Toxicity		No systemic toxicity		
Hemolysis		No Hemolysis		
Pyrogen		No Pyrogen		
Complement Activation		Not show potentials to activate complete system		
In vivo Thrombogenicity		No thrombogenicity		

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

Analysis 1- Configuration

The configuration of the proposed device is similar to the predicate device. The predicate device has luer lock connector, the proposed device has luer lock or luer slip connector. The difference in technological characteristics does not raise new questions of safety and effectiveness. Connectivity to the needle is assessed with performance data.

Analysis 2-Syringe Volume

The syringe volume for proposed device is different from the predicate devices. However, this difference is in dimension. Different volume device will be selected by physician per patient's condition. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device. Differences are assessed via performance data and conformance to the same ISO standards as the predicate device.

Analysis 3-Needle Size

The needle size for proposed device is different from the predicate devices. This difference is in dimension. Different size device will be selected by physician per patient's condition. Moreover, the needle size of the proposed syringe with safety needle is included in the range of the needle size of the predicate device. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device. Differences are assessed via performance data and conformance to the same ISO standards as the predicate device.

Analysis 4- Patient-contact Materials

Although the patient-contact material for proposed device is different from the predicate device. However, biocompatibility test has been performed on the proposed device and the results do not show any adverse effect. 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 K193526		Remark
Product		Sterile Disposable Syringe with Needle		Sterile Disposable Syringe with Safety Needle		/
Product Code		FMF FMI		FMF FMI MEG		Analysis 5
Regulation Number		21 CRF 880.5860 21 CRF 880.5570		21 CRF 880.5860 21 CRF 880.5570		Analysis 5
Class		Class II		Class II		SE
Indication for Use		The Sterile Disposable Syringe with Needle is intended for use in the aspiration and injection of fluids for medical purpose.		The 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 stick.		Analysis 6
Configuration		Syringe	Barrel (luer lock/luer slip)	Syringe	Barrel (luer lock	Analysis 7
			Plunger		Plunger	
			Piston		Piston	
		Needle	Needle hub	Needle	Needle hub	
			Needle tube		Needle tube	
			Needle cap		Needle cap	
			/		Safety Shield	
Operation Mode		For manual use only		For manual use only		SE
Sterilized		Yes		Yes		SE
Single Use		Single Use		Single Use		SE
Label/Labeling		Complied with 21 CFR part 801		Complied with 21 CFR part 801		SE
Syringe	Volume	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml		1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 60ml		Analysis 8
	Connector Type	Luer Lock and Luer Slip		Luer Lock		Analysis 7
Needle	Size	23G		16G, 18G, 19G, 20G, 21G, 22G, 23G, 25G, 26G, 27G, 28G, 29G,		Analysis 9

			30G, 31G	
	Length	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"	13mm(1/2"), 16mm(5/8"), 20mm(3/4"), 25mm(1"), 32mm(1-1/4"), 38mm(1-1/2")	SE
Syringe Performance		Complied with ISO 7886-1	Complied with ISO 7886-1	SE
Needle Performance		Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	SE
Luer Connector Performance		Complied with ISO 80369-7	Complied with ISO 80369-7	SE
Patient-contact Materials				
Barrel		Polypropylene (PP)	Polypropylene (PP)	Analysis 10
Plunger		Polypropylene (PP)	Polypropylene (PP)	
Piston		Polyisoprene Rubber	Polyisoprene	
Needle hub		Polypropylene (PP) and blue pigment	Polypropylene (PP)	
Needle tube		Stainless Steel SUS 304	Stainless Steel 304	
Needle cap		Polypropylene (PP)	Polypropylene (PP)	
Lubricants		Silicone oil	Polydimethylsiloxane	
Adhesive		UV adhesive	Epoxy adhesive	
Biocompatibility				
Cytotoxicity		No cytotoxicity	Conforms to ISO 10993 series standards	SE
Irritation		No intracutaneous reactivity		
Sensitization		No sensitization		
Systemic Toxicity		No systemic toxicity		
Hemolysis		No Hemolysis		
Pyrogen		No Pyrogen		
Complement Activation		Not show potentials to activate complete system		
In vivo Thrombogenicity		No thrombogenicity		
Sterilization				
Method		EO Sterilized	EO Sterilized	SE
SAL		10^{-6}	10^{-6}	SE
Endotoxin Limit		20 EU per device	20 EU per device	SE

Analysis 5-Product Code

The predicate device has a syringe with safety needle and safety needle, so the corresponding product codes are MEG, FMF and FMI. The proposed syringe with needle consists of a syringe and needle, so the

corresponding product codes is FMF and FMI. Because the proposed syringe with needle has no safety mechanism, there is no MEG code, the product codes of proposed products are included in the codes of predicate device.

Based on above analysis, the difference on product code will not raise new questions on safety and effectiveness of the proposed device.

Analysis 6-Indication for Use

The indication for use of the proposed device and the predicate device differs in the verbal descriptions, and the actual indication for use of both devices is exactly the same. Both devices are intended for use in the aspiration and injection of fluids for medical purpose. The main difference in the indication for use is that there is no safety mechanism for the syringe with the needle, whether there is a safety mechanism or not will not affect the intended use of the equipment itself. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

Analysis 7- Configuration

The configuration of the proposed device is similar to the predicate device. The predicate device has luer lock connector, the proposed device has luer lock or luer slip connector. The difference in technological characteristics does not raise new questions of safety and effectiveness. Connectivity to the needle is assessed with performance data.

Analysis 8-Syringe Volume

The Syringe volume for the proposed device is different from the predicate devices. However, this difference is in dimension. Different volume device will be selected by physician per patient's condition. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device. Differences are assessed via performance data and conformance to the same ISO standards as the predicate device.

Analysis 9-Needle Size

The needle size for proposed device is different from the predicate devices. This difference is in dimension. Different size device will be selected by physician per patient's condition. Moreover, the needle size of the proposed syringe with needle is included in the range of the needle size of the predicate device. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device. Differences are assessed via performance data and conformance to the same ISO standards as the predicate device.

Analysis 10- Patient-contact Materials

Although the patient-contact material for proposed device is different from the predicate device. However, biocompatibility test has been performed on the proposed device and the results do not show any adverse effect. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed

device.

Table 3. Comparison of Sterile Disposable Syringe

ITEM		Proposed Device	Predicate Device K193526	Remark
Product		Disposable Sterile Syringe	Syringe with Safety Needle	/
Product Code		FMF	FMF FMI MEG	Analysis 11
Regulation Number		21 CRF 880.5860	21 CRF 880.5860 21 CRF 880.5570	Analysis 11
Class		Class II	Class II	SE
Indication for Use		The Disposable Sterile Syringe is a sterile luer lock syringe which is intended to be used with a hypodermic needle for the aspiration and injection of fluids for medical purpose.	The 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 stick.	Analysis 12
Configuration		Barrel (luer lock/luer slip)	Barrel (luer lock)	Analysis 13
		Plunger	Plunger	
		Piston	Piston	
Operation Mode		For manual use only	For manual use only	SE
Sterilized		Yes	Yes	SE
Single Use		Single Use	Single Use	SE
Label/Labeling		Complied with 21 CFR part 801	Complied with 21 CFR part 801	SE
Syringe	Volume	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml	1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 60ml	Analysis 14
	Connector Type	Luer Lock and Luer Slip	Luer Lock	Analysis 13
Syringe Performance		Complied with ISO 7886-1	Complied with ISO 7886-1	SE
Luer Connector Performance		Complied with ISO 80369-7	Complied with ISO 80369-7	SE
Patient-contact Materials				
Barrel		Polypropylene (PP)	Polypropylene (PP)	Analysis 15
Plunger		Polypropylene (PP)	Polypropylene (PP)	

Piston	Polyisoprene Rubber	Polyisoprene	
Lubricants	Silicone oil	Polydimethylsiloxane	
Biocompatibility			
Cytotoxicity	No cytotoxicity	Conforms to ISO 10993 series standards	SE
Irritation	No intracutaneous reactivity		
Sensitization	No sensitization		
Systemic Toxicity	No systemic toxicity		
Hemolysis	No Hemolysis		
Pyrogen	No Pyrogen		
Complement Activation	Not show potentials to activate complete system		
In vivo Thrombogenicity	No thrombogenicity		
Sterilization			
Method	EO Sterilized	EO Sterilized	SE
SAL	10^{-6}	10^{-6}	SE
Endotoxin Limit	20 EU per device	20 EU per device	SE

Analysis 11-Product Code

In the submission, the predicate device has syringe with safety needle and safety needle, so the corresponding product codes are MEG, FMF and FMI. The propose syringe consisting of barrel, piston, and plunger, so the corresponding product codes is FMF. Different product codes are caused by different applied products, but the product codes of applied products are included in the codes of predicate device.

Based on above analysis, the difference on product code will not raise new questions on safety and effectiveness of the proposed device.

Analysis 12-Indication for Use

The indication for use of the proposed device and the predicate device differs only in the verbal descriptions, and the actual indication for use of both devices is exactly the same. Both devices are intended for use in the aspiration and injection of fluids for medical purpose. Only the proposed syringe needs to be connected with the needle in order to fully achieve the intended use of aspiration and injection of liquid medicine. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

Analysis 13- Configuration

The configuration of the proposed device is similar to the predicate device. The predicate device has luer lock connector, the proposed device has luer lock or luer slip connector. The difference in technological characteristics does not raise new questions of safety and effectiveness. Connectivity to the needle is assessed with performance data.

Analysis 14-Syringe Volume

The Syringe volume for proposed device is different from the predicate devices. However, this difference is in dimension. Different volume device will be selected by physician per patient's condition. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device. Differences are assessed via performance data and conformance to the same ISO standards as the predicate device.

Analysis 15- Patient-contact Materials

Although the patient-contact material for proposed device is different from the predicate device. However, biocompatibility test has been performed on the proposed device and the results do not show any adverse effect. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

Table 4. Comparison of Sterile Disposable Safety Needle

ITEM		Proposed Device	Predicate Device K193526	Remark
Product		Sterile Disposable Safety Needle	Safety Needle	/
Product Code		FMI	FMI	SE
Regulation Number		21 CRF 880.5860	21 CRF 880.5860	SE
Class		Class II	Class II	SE
Indication 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 Safety Needle is intended for use with 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 stick.	SE
Configuration		Needle hub	Needle hub	SE
		Needle tube	Needle tube	
		Needle cap	Needle cap	
		Safety mechanism	Safety shield	
Operation Mode		For manual use only	For manual use only	SE
Sterilized		Yes	Yes	SE
Single Use		Single Use	Single Use	SE
Label/Labeling		Complied with 21 CFR part 801	Complied with 21 CFR part 801	SE
Needle	Size	23G	16G, 18G, 19G, 20G, 21G, 22G, 23G, 25G, 26G, 27G, 28G, 29G, 30G, 31G	Analysis 16
	Length	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"	13mm(1/2"), 16mm(5/8"), 20mm(3/4"), 25mm(1"), 32mm(1-1/4"), 38mm(1-1/2")	SE
Needle Performance		Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	SE
Patient-contact Materials				
Needle hub		Polypropylene (PP) and blue pigment	Polypropylene (PP)	Analysis 17
Needle tube		Stainless Steel SUS 304	Stainless Steel SUS 304	
Needle cap		Polypropylene (PP)	Polypropylene (PP)	
Safety mechanism		Polypropylene (PP) and blue	Polypropylene (PP)	

	pigment		
Lubricants	Silicone oil	Polydimethylsiloxane	
Adhesive	UV adhesive	Epoxy adhesive	
Biocompatibility			
Cytotoxicity	No cytotoxicity	Conforms to ISO 10993 series standards	SE
Irritation	No intracutaneous reactivity		
Sensitization	No sensitization		
Systemic Toxicity	No systemic toxicity		
Hemolysis	No Hemolysis		
Pyrogen	No Pyrogen		
Complement Activation	Not show potentials to activate complete system		
In vivo Thrombogenicity	No thrombogenicity		
Sterilization			
Method	EO Sterilized	EO Sterilized	SE
SAL	10^{-6}	10^{-6}	SE
Endotoxin Limit	20 EU per device	20 EU per device	SE

Analysis 16-Needle Size

The needle size for proposed device is different from the predicate devices. This difference is in dimension. Different size device will be selected by physician per patient's condition. Moreover, the needle size of the proposed syringe with safety needle is included in the range of the needle size of the predicate device. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device. Differences are assessed via performance data and conformance to the same ISO standards as the predicate device.

Analysis 17- Patient-contact Materials

Although the patient-contact material for proposed device is different from the predicate device. However, biocompatibility test has been performed on the proposed device and the results do not show any adverse effect. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

Table 5. Comparison of Sterile Disposable Needle

ITEM		Proposed Device	Predicate Device K193526	Remark
Product		Sterile Disposable Needle	Safety Needle	/
Product Code		FMI	FMI	SE
Regulation Number		21 CRF 880.5860	21 CRF 880.5860	SE
Class		Class II	Class II	SE
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 Safety Needle is intended for use with 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 stick.	Analysis 18
Configuration		Needle hub	Needle hub	Analysis 19
		Needle tube	Needle tube	
		Needle cap	Needle cap	
		/	Safety shield	
Operation Mode		For manual use only	For manual use only	SE
Sterilized		Yes	Yes	SE
Single Use		Single Use	Single Use	SE
Label/Labeling		Complied with 21 CFR part 801	Complied with 21 CFR part 801	SE
Needle	Size	23G	16G, 18G, 19G, 20G, 21G, 22G, 23G, 25G, 26G, 27G, 28G, 29G, 30G, 31G	Analysis 20
	Length	1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"	13mm(1/2"), 16mm(5/8"), 20mm(3/4"), 25mm(1"), 32mm(1-1/4"), 38mm(1-1/2")	SE
Needle Performance		Complied with ISO 7864, ISO 9626	Complied with ISO 7864, ISO 9626	SE
Patient-contact Materials				
Needle hub		Polypropylene (PP) blue pigment	Polypropylene (PP)	Analysis 21
Needle tube		Stainless Steel SUS 304	Stainless Steel SUS 304	
Needle cap		Polypropylene (PP)	Polypropylene (PP)	

Lubricants	Silicone oil	Polydimethylsiloxane	
Adhesive	UV adhesive	Epoxy adhesive	
Biocompatibility			
Cytotoxicity	No cytotoxicity	Conforms to ISO 10993 series standards	SE
Irritation	No intracutaneous reactivity		
Sensitization	No sensitization		
Systemic Toxicity	No systemic toxicity		
Hemolysis	No Hemolysis		
Pyrogen	No Pyrogen		
Complement Activation	Not show potentials to activate complete system		
In vivo Thrombogenicity	No thrombogenicity		
Sterilization			
Method	EO Sterilized	EO Sterilized	SE
SAL	10^{-6}	10^{-6}	SE
Endotoxin Limit	20 EU per device	20 EU per device	SE

Analysis 18-Indication for Use

The indication for use of the proposed device and the predicate device differs in the verbal descriptions, and the actual indication for use of both devices is exactly the same. Both devices are intended for use in the aspiration and injection of fluids for medical purpose. Whether there is a safety mechanism or not will not affect the intended use of the equipment itself. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

Analysis 19- Configuration

The configuration of proposed device is similar as the configurations of predicate device. Whether there is a safety mechanism or not will not affect the intended use of the equipment itself. Based on above analysis, the difference on configuration will not raise new questions on safety and effectiveness of the proposed device.

Analysis 20-Needle Size

The needle size for proposed device is different from the predicate devices. This difference is in dimension. Different size device will be selected by physician per patient's condition. Moreover, the needle size of the proposed syringe with safety needle is included in the range of the needle size of the predicate device. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device. Differences are assessed via performance data and conformance to the same ISO standards as the predicate device.

Analysis 21- Patient-contact Materials

Although the patient-contact material for proposed device is different from the predicate device. However, biocompatibility test has been performed on the proposed device and the results do not show any adverse effect. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

9. Conclusion

The conclusion drawn from the comparison to the predicate device and the non-clinical tests demonstrates that the subject device in 510(k) submission, The Sterile Disposable Syringe with Safety Needle, The Sterile Disposable Syringe with Needle, The Sterile Disposable Syringe, The Sterile Disposable Safety Needle and The Sterile Disposable Needle are substantially equivalent to the legally marketed predicate device cleared under K193526.