March 11, 2022

Shandong Weigao Group Medical Polymer Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K212920
Trade/Device Name: Sterile Safety Syringe with Needle for Single Use, Sterile Safety Hypodermic Needle for Single Use,Sterile Auto-Disable Syringe with Needle for Single Use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI, MEG
Dated: February 9, 2022
Received: February 11, 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)*
K212920

Device Name
Sterile Safety Syringe with Needle for Single Use, Sterile Safety Hypodermic Needle for Single Use, Sterile Auto-Disable Syringe With Needle for Single Use

Indications for Use *(Describe)*
The Sterile Safety Syringe with Needle for Single Use 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 needlesticks.

The Sterile Safety Hypodermic Needle for Single Use 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 needlesticks.

The Sterile Auto-Disable Syringe with Needle for Single Use is intended for aspiration and injection of fluids.

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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K212920 510(k) Summary

1. Date of Preparation: March 11, 2022

2. Sponsor Identification:

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3. Designated Submission Correspondent:

Ms. Diana Hong (Primary Contact Person)
Ms. Jinlei Tang (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
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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 Safety Syringe with Needle for Single Use,
Sterile Safety Hypodermic Needle for Single Use
Sterile Auto-Disable Syringe with Needle for Single Use
Common Name: Piston syringe and antistick needle

Classification Name: Piston Syringe
Syringe Antistick
Classification: II
Product Code: FMF; MEG
Regulation Number: 21CFR 880.5860

Classification Name: Hypodermic Single Lumen Needle
Classification: II
Product Code: FMI
Regulation Number: 21 CFR 880.5570

5. Identification of Predicate Devices:

510(k) Number: K170651
Product Name: Sterile Disposable Syringe with Safety Needle (used as predicate device)
Sterile Disposable Syringe with Needle
Sterile Disposable Syringe
Sterile Disposable Safety Needle (used as predicate device)
Sterile Disposable Needle

510(k) Number: K201234
Product Name: BD SoloShot Mini Syringe/ BD Auto Disable Syringe

Indications for Use:

The Sterile Safety Syringe with Needle for Single Use 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 needlesticks.

The Sterile Safety Hypodermic Needle for Single Use 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 needlesticks.

The Sterile Auto-Disable Syringe with Needle for Single Use is intended for aspiration and injection of fluids.

Device Description:

The Sterile Safety Syringe with Needle for Single Use is intended for manual and single use only, which consists of a hypodermic needle with a safety shield attached to the needle hub and a luer slip or luer lock syringe. The proposed device is available in a variety combination of syringe volume and needle size. The safety shield will be manually activated to cover the needle immediately after use to minimize risk of accidental needle sticks.

The Sterile Safety Hypodermic Needle for Single Use is intended for manual and single use only, which consists of a hypodermic needle with a safety shield attached to the connector hub. The proposed device is available in variety combination of needle gauge and needle length. The proposed device is compatible for use with a luer slip or luer lock syringe. The safety sheath will be manually activated to cover the needle immediately after use to minimize risk of accidental needle sticks.

The Sterile Auto-Disable Syringe with Needle for Single Use is intended for aspiration and injection of fluids. The Sterile Auto-Disable Syringe with Needle for Single Use is available in various capacities of syringes.

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 three years.

The specifications of the proposed devices are provided in following table.

Table 1. Specifications of the Sterile Safety Hypodermic Needle for Single Use

Needle Gauge	Needle Length
30G	13mm, 16mm, 19mm
29G	13mm, 16mm, 19mm
28G	13mm, 16mm, 19mm
27G	13mm, 16mm, 19mm
26G	13mm, 16mm, 19mm
25G	16mm, 19mm, 25mm, 38mm
24G	16mm, 19mm, 25mm
23G	19mm, 25mm, 32mm, 38mm
22G	19mm, 25mm, 32mm, 38mm

21G	19mm, 22mm, 25mm, 32mm, 38mm
20G	19mm, 22mm, 25mm, 32mm, 38mm
19G	25mm, 32mm, 38mm
18G	19mm, 22mm, 32mm, 38mm

Table 2. Specifications of the Sterile Safety Syringe with Needle for Single Use

Syringe volume	Needle Gauge	Needle Length
1mL	30G	13mm, 16mm, 19mm
	29G	13mm, 16mm, 19mm
	28G	13mm, 16mm, 19mm
	27G	13mm, 16mm, 19mm
	26G	13mm, 16mm, 19mm
	25G	16mm, 19mm, 25mm, 38mm
	24G	16mm, 19mm, 25mm
	23G	19mm, 25mm, 32mm, 38mm
	22G	19mm, 25mm, 32mm, 38mm
	21G	19mm, 22mm, 25mm, 32mm, 38mm
	20G	19mm, 22mm, 25mm, 32mm, 38mm
	19G	25mm, 32mm, 38mm
	18G	19mm, 22mm, 32mm, 38mm
2mL	30G	13mm, 16mm, 19mm
	29G	13mm, 16mm, 19mm
	28G	13mm, 16mm, 19mm
	27G	13mm, 16mm, 19mm
	26G	13mm, 16mm, 19mm
	25G	16mm, 19mm, 25mm, 38mm
	24G	16mm, 19mm, 25mm
	23G	19mm, 25mm, 32mm, 38mm
	22G	19mm, 25mm, 32mm, 38mm
	21G	19mm, 22mm, 25mm, 32mm, 38mm
	20G	19mm, 22mm, 25mm, 32mm, 38mm
	19G	25mm, 32mm, 38mm
	18G	19mm, 22mm, 32mm, 38mm
2.5mL	30G	13mm, 16mm, 19mm
	29G	13mm, 16mm, 19mm
	28G	13mm, 16mm, 19mm
	27G	13mm, 16mm, 19mm
	26G	13mm, 16mm, 19mm
	25G	16mm, 19mm, 25mm, 38mm

	24G	16mm, 19mm, 25mm
	23G	19mm, 25mm, 32mm, 38mm
	22G	19mm, 25mm, 32mm, 38mm
	21G	19mm, 22mm, 25mm, 32mm, 38mm
	20G	19mm, 22mm, 25mm, 32mm, 38mm
	19G	25mm, 32mm, 38mm
	18G	19mm, 22mm, 32mm, 38mm
3mL	30G	13mm, 16mm, 19mm
	29G	13mm, 16mm, 19mm
	28G	13mm, 16mm, 19mm
	27G	13mm, 16mm, 19mm
	26G	13mm, 16mm, 19mm
	25G	16mm, 19mm, 25mm, 38mm
	24G	16mm, 19mm, 25mm
	23G	19mm, 25mm, 32mm, 38mm
	22G	19mm, 25mm, 32mm, 38mm
	21G	19mm, 22mm, 25mm, 32mm, 38mm
	20G	19mm, 22mm, 25mm, 32mm, 38mm
	19G	25mm, 32mm, 38mm
	18G	19mm, 22mm, 32mm, 38mm
5mL	30G	13mm, 16mm, 19mm
	29G	13mm, 16mm, 19mm
	28G	13mm, 16mm, 19mm
	27G	13mm, 16mm, 19mm
	26G	13mm, 16mm, 19mm
	25G	16mm, 19mm, 25mm, 38mm
	24G	16mm, 19mm, 25mm
	23G	19mm, 25mm, 32mm, 38mm
	22G	19mm, 25mm, 32mm, 38mm
	21G	19mm, 22mm, 25mm, 32mm, 38mm
	20G	19mm, 22mm, 25mm, 32mm, 38mm
	19G	25mm, 32mm, 38mm
	18G	19mm, 22mm, 32mm, 38mm
10mL	30G	13mm, 16mm, 19mm
	29G	13mm, 16mm, 19mm
	28G	13mm, 16mm, 19mm
	27G	13mm, 16mm, 19mm
	26G	13mm, 16mm, 19mm
	25G	16mm, 19mm, 25mm, 38mm

	24G	16mm, 19mm, 25mm
	23G	19mm, 25mm, 32mm, 38mm
	22G	19mm, 25mm, 32mm, 38mm
	21G	19mm, 22mm, 25mm, 32mm, 38mm
	20G	19mm, 22mm, 25mm, 32mm, 38mm
	19G	25mm, 32mm, 38mm
	18G	19mm, 22mm, 32mm, 38mm
20mL	30G	13mm, 16mm, 19mm
	29G	13mm, 16mm, 19mm
	28G	13mm, 16mm, 19mm
	27G	13mm, 16mm, 19mm
	26G	13mm, 16mm, 19mm
	25G	16mm, 19mm, 25mm, 38mm
	24G	16mm, 19mm, 25mm
	23G	19mm, 25mm, 32mm, 38mm
	22G	19mm, 25mm, 32mm, 38mm
	21G	19mm, 22mm, 25mm, 32mm, 38mm
	20G	19mm, 22mm, 25mm, 32mm, 38mm
	19G	25mm, 32mm, 38mm
	18G	19mm, 22mm, 32mm, 38mm
25mL	25G	16mm, 19mm, 25mm, 38mm
	24G	16mm, 19mm, 25mm
	23G	19mm, 25mm, 32mm, 38mm
	22G	19mm, 25mm, 32mm, 38mm
	21G	19mm, 22mm, 25mm, 32mm, 38mm
	20G	19mm, 22mm, 25mm, 32mm, 38mm
	19G	25mm, 32mm, 38mm
	18G	19mm, 22mm, 32mm, 38mm
30mL	25G	16mm, 19mm, 25mm, 38mm
	24G	16mm, 19mm, 25mm
	23G	19mm, 25mm, 32mm, 38mm
	22G	19mm, 25mm, 32mm, 38mm
	21G	19mm, 22mm, 25mm, 32mm, 38mm
	20G	19mm, 22mm, 25mm, 32mm, 38mm
	19G	25mm, 32mm, 38mm
	18G	19mm, 22mm, 32mm, 38mm
50mL	25G	16mm, 19mm, 25mm, 38mm
	24G	16mm, 19mm, 25mm
	23G	19mm, 25mm, 32mm, 38mm

	22G	19mm, 25mm, 32mm, 38mm
	21G	19mm, 22mm, 25mm, 32mm, 38mm
	20G	19mm, 22mm, 25mm, 32mm, 38mm
	19G	25mm, 32mm, 38mm
	18G	19mm, 22mm, 32mm, 38mm
100mL	25G	16mm, 19mm, 25mm, 38mm
	24G	16mm, 19mm, 25mm
	23G	19mm, 25mm, 32mm, 38mm
	22G	19mm, 25mm, 32mm, 38mm
	21G	19mm, 22mm, 25mm, 32mm, 38mm
	20G	19mm, 22mm, 25mm, 32mm, 38mm
	19G	25mm, 32mm, 38mm
	18G	19mm, 22mm, 32mm, 38mm

Table 3. Specifications of the Sterile Auto-Disable Syringe with Needle for Single Use

Syringe volume	Needle Gauge	Needle Length
0.2mL	30G	13mm, 16mm, 19mm
	29G	13mm, 16mm, 19mm
	28G	13mm, 16mm, 19mm
	27G	13mm, 16mm
	26G	16mm, 19mm
	25G	16mm, 19mm, 32mm, 38mm
	24G	16mm, 19mm
	23G	19mm, 25mm, 32mm, 38mm
0.5mL	30G	13mm, 16mm, 19mm
	29G	13mm, 16mm, 19mm
	28G	13mm, 16mm, 19mm
	27G	13mm, 16mm
	26G	16mm, 19mm
	25G	16mm, 19mm, 32mm, 38mm
	24G	16mm, 19mm
	23G	19mm, 25mm, 32mm, 38mm
1mL	30G	13mm, 16mm, 19mm
	29G	13mm, 16mm, 19mm
	28G	13mm, 16mm, 19mm
	27G	13mm, 16mm
	26G	16mm, 19mm
	25G	16mm, 19mm, 32mm, 38mm
	24G	16mm, 19mm

	23G	19mm, 25mm, 32mm, 38mm

6. Substantially Equivalent (SE) Comparison:

Table 4. General Comparison of Sterile Safety Syringe with Needle for Single Use

ITEM	Proposed Device		Predicate Device K170651		Comments
Product	Sterile Safety Syringe with Needle for Single Use		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
Indication for Use	The Sterile Safety Syringe with Needle for Single Use 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 needlesticks.		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)	Syringe	Barrel (luer lock/luer slip)	Same
		Plunger		Plunger	Same
		Piston		Piston	Same
	Needle	Hub	Needle	Hub	Same
		Needle tube		Needle tube	Same
		Needle cap		Needle cap	Same
		Safety shield		Safety shield	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
Syringe	1ml, 2ml, 2.5ml, 3ml, 5ml, 10ml, 20ml, 25ml, 30ml, 50ml, 100ml		1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml		Different Comment #1
Comment #1					

Syringe Volume The Syringe volume for proposed device is different from the predicate device. This difference does not affect intended use and this technological difference does not raise new questions of safety and effectiveness.						
Syringe performance		Complied with ISO 7886-1		Complied with ISO 7886-1		Same
Needle	Connector Type	Luer Lock/Luer Slip		Luer Lock /Luer Slip		Same
	Size	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G		16G,18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G		Different Comment #2
	Length	13mm, 16mm, 19mm, 22mm, 25mm, 32mm, 38mm		8mm(5/16"), 13mm(1/2"), 16mm(5/8"), 20mm(3/4"), 25mm(1"), 32mm(1-1/4"), 38mm(1-1/2")		Different Comment #2
	Needle hub	Color-coded per ISO 6009		Color-coded per ISO 6009		Same
Comment #2 Needle Size and Length The needle size and length for proposed device is different from the predicate device. However, the needle size and length of the proposed device is included in the range of the needle size and length of the predicate device. Therefore, this difference does not affect safety and effectiveness of the proposed device.						
Needle Syringe Performance		Complied with ISO 7886-1 Iso 9626-1		Complied with ISO 7886-1 Iso 9626-1		Same
Material		Barrel	Polypropylene (PP)	Barrel	Polypropylene (PP)	Same
		Plunger	Polypropylene (PP)	Plunger	Polypropylene (PP)	Same
		Piston	Polyisoprene	Piston	Polyisoprene	Same
		Hub	Polypropylene (PP)	Hub	Polypropylene (PP)	Same
		Needle tube	Stainless Steel	Needle tube	Stainless Steel	Same
		Needle cap	Polypropylene (PP)	Needle cap	Polypropylene (PP)	Same
		Safety shield	Polypropylene (PP)	Safety shield	Polypropylene (PP)	Same
Cytotoxicity		No cytotoxicity		No cytotoxicity		Same
Irritation		No intracutaneous reactivity		No intracutaneous reactivity		Same
Sensitization		No skin sensitization		No skin sensitization		Same
Systemic Toxicity		No systemic toxicity		No systemic toxicity		Same
Hemolysis		No Hemolysis		No Hemolysis		Same
Pyrogen		No Pyrogen		No Pyrogen		Same
Sterilization		EO Sterilized		EO Sterilized		Same

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

Table 5. General Comparison of Sterile Safety Hypodermic Needle for Single Use

ITEM	Proposed Device	Predicate Device K170651	Comment
Product	Sterile Safety Hypodermic Needle for Single Use	Sterile Disposable Safety Needle	/
Product Code	FMI	FMI	Same
Regulation No.	21 CRF 880.5570	21 CRF 880.5570	Same
Class	Class II	Class II	Same
Indication for Use	The Sterile Safety Hypodermic Needle for Single Use 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 needlesticks.	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	Hub Needle tube Needle cap Safety shield	Hub Needle tube Needle cap Safety shield	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
Connector Type	Luer Lock/Luer Slip	Luer Lock /Luer Slip	Same
Needle Gauge	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	16G,18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	Different Comment #3
Needle Length	13mm, 16mm, 19mm, 22mm, 25mm, 32mm, 38mm	8mm(5/16"), 13mm(1/2"), 16mm(5/8"), 20mm(3/4"), 25mm(1"), 32mm(1-1/4"), 38mm(1-1/2")	Different Comment #3
Comment #3 Needle Gauge and length			

The needle gauge and length for proposed device is different from the predicate device. However, the needle gauge and length of the proposed device is included in the range of the needle size and length of the predicate device. Therefore, this difference does not affect safety and effectiveness of the proposed device.					
Needle Hub	Color-coded per ISO 6009		Color-coded per ISO 6009		Same
Needle Performance	Complied with ISO 7864 ISO 9626		Complied with ISO 7864, ISO 9626		Same
Safety mechanism	Similar safety shield and same manual activated mechanism.		Similar safety shield and same manual activated mechanism.		Same
Material	Needle hub	Polypropylene (PP)	Needle hub	Polypropylene (PP)	Same
	Needle tube	Stainless Steel	Needle tube	Stainless Steel	Same
	Safety Shield	Polypropylene (PP)	Safety Shield	Polypropylene (PP)	Same
	Needle Cap	Polypropylene (PP)	Needle Cap	Polypropylene (PP)	Same
Biocompatibility					
Cytotoxicity	No cytotoxicity		No cytotoxicity		Same
Irritation	No intracutaneous reactivity		No intracutaneous reactivity		Same
Sensitization	No skin sensitization		No skin sensitization		Same
Systemic Toxicity	No systemic toxicity		No systemic toxicity		Same
Hemolysis	No Hemolysis		No Hemolysis		Same
Pyrogen	No Pyrogen		No Pyrogen		Same
Sterilization					Same
Method	EO Sterilized		EO Sterilized		Same
SAL	10^{-6}		10^{-6}		Same
Endotoxin Limit	20 EU per device		20 EU per device		Same

Table 6. General Comparison of Sterile Auto-Disable Syringe with Needle for Single Use

ITEM	Proposed Device	Predicate Device K201234	Comment
Product	Sterile Auto-Disable Syringe with Needle for Single Use	BD SoloShot™ Mini Syringe/BD Auto Disable Syringe	/
Product Code	FMF	FMF	Same
Regulation Number	21 CRF 880.5860	21 CRF 880.5860	Same
Class	Class II	Class II	Same

Indication for Use		The Sterile Auto-Disable Syringe with Needle for Single Use is intended for aspiration and injection of fluids.	The BD SoloShot™ Mini Syringe/ BD Auto Disable Syringe is intended for aspiration and injection of fluids.	Same
Configuration		Barrel Plunger Piston Integral needle Needle cap Card	Barrel One-piece plunger rod (without rubber stopper) Clip affixed to the plunger rod Integral needle Shield cover	Different Comment #4
Comment #4 Configuration The configuration for proposed device is different from the predicate device. The main difference is that the proposed device contains rubber stopper. This technological difference may impact performance or biocompatibility. However, these are not new questions of safety and effectiveness from the predicate device.				
Reuse Prevention (Safety) Feature		Auto-disabled (Miniature size), prevents syringe re-use	Auto-disabled (Miniature size), prevents syringe re-use	Same
Dose Saving Feature		Low Dead Space/Volume	Low Dead Space/Volume	Same
Integrated Needle		Yes	Yes	Same
Dose Setting/Volumes		Fixed doses: 0.2ml, 0.5 ml, 1ml	Fixed doses: 0.5 ml	Different Comment #5
Comment #5 Dose Setting/Volumes The dose volumes for proposed device is different from the predicate device. This technological difference does not raise new questions of safety and effectiveness of the proposed device.				
Single Use		Single Use	Single Use	Same
Label/Labeling		Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Syringe performance		Complied with ISO 7886-3	Complied with ISO 7886-3	Same
Needle	Gauge	23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	23G, 24G, 25G	Different Comment #6
	Length	13mm, 16mm, 19mm, 25mm, 32mm, 38mm	16mm(5/8"), 20mm(3/4"), 25mm(1")	Different Comment

				#6
Comment #6 Needle Gauge and Length The needle gauge and length for proposed device is different from the reference device. This difference does not affect intended use and the technological difference does not raise new questions of safety and effectiveness of the proposed device.				
Needle Hub		Color-coded per ISO 6009	Color-coded per ISO 6009	Same
Material		Barrel: Polypropylene (PP) Plunger: Polypropylene (PP) Piston: Polyisoprene Integral needle: Stainless Steel Card: Stainless Steel Needle Cap: Polypropylene (PP)	Barrel: Plastic Plunger: Plastic + Colorant (blue, violet, orange) Clip: Stainless Steel Integrated Cannula: Stainless Steel Shield: Plastic	Different Comment #7
Comment #7 Material The material for proposed device is different from the reference device. This difference does not raise new questions of safety and effectiveness.				
Cytotoxicity		No cytotoxicity	No cytotoxicity	Same
Irritation		No intracutaneous reactivity	No intracutaneous reactivity	Same
Sensitization		No skin sensitization	No skin sensitization	Same
Systemic Toxicity		No systemic toxicity	No systemic toxicity	Same
Hemolysis		No Hemolysis	No Hemolysis	Same
Pyrogen		No Pyrogen	No Pyrogen	Same
Sterilization Method		EO Sterilized	EO Sterilized	Same
SAL		10^{-6}	10^{-6}	Same

7. 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 and reference device.

Performance Test

The test results demonstrated that the proposed device complies with the following standards:

- 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 - Requirements and test methods
- 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 7886-3: 2020 Sterile hypodermic syringes for single use - Part 3: Auto-disabled syringes for fixed-dose immunization

Sterile Barrier Packaging Test

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 Test

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 Test

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
- Particulate testing

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.

Simulated Distribution

The simulated shipping distribution performed on proposed device according to ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems. The test results demonstrate that packing can protect the proposed device from damage during storage and distribution environments.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the differences between the subject devices and the predicate devices do not raise new or different questions of safety or effectiveness. The subject devices are Substantially Equivalent (SE) to the predicate devices with respect to indications for use, target population, and technological characteristics.