K210991 510(k) Summary

Date of Preparation: August 25, 2021

Sponsor Name:	Guangdong Antmed Co., Ltd.
Sponsor Address:	Rm 201, Bld 3, Hualian Ave, Songshanhu District, Dongguan, Guangdong, 523800, China
Contact Person:	Zhiying Zhong
Title:	Regulatory Officer
Telephone :	+86-769-82599182
Fax number:	+86-769-82599182
Email:	antqd@antmed.com
Designated Correspondent	Ms. Diana Hong (Primary Contact Person) Ms. Tingting Su (Alternative Contact Person)
Correspondent contacts	**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

Identification of Proposed Device

Trade Name: Disposable Sterile Syringe with Needle, Disposable Sterile Syringe
Classification Name: Piston Syringe
Device Class: II
Product Code: FMF
Secondary Product Code: FMI
Regulation Number: 21CFR 880.5860
Review Panel: General Hospital

Identification of Predicate Device

510(k) Number: K072739
Product Name: Sterile Hypodermic Syringe for single use (used as predicate device)
Sterile Insulin Syringe for single use
Retractable Auto-Disable Syringe for single use
Sterile Hypodermic Needle for single use

Indications for Use:

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

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.

Device Description

The proposed devices are provided in two types of configurations:

i. a disposable sterile syringe with sterile hypodermic needle contained in a blister packaging made of PP/PE composite film and coated paper sealed by hot sealing
ii. a disposable sterile syringe contained in a blister packaging made of PP/PE composite film and coated paper sealed by hot sealing

The disposable sterile syringe with needle is manually operated and intended for single use only, which consists of a needle and a luer lock syringe. The disposable sterile syringe consists of barrel, plunger and piston. The proposed device is available in various combination of syringe volume and needle size.

Summary of Technology Characteristics

Comparison of Disposable Sterile Syringe with Needle

ITEM	Proposed Device	Predicate Device K072739	Remark
Product	Disposable Sterile Syringe with Needle	Sterile Hypodermic Syringe for single use	/
Product Code	FMF FMI	FMF FMI MEG	Analysis 1A
Regulation Number	21 CRF 880.5860	21 CRF 880.5860	Same
Class	Class II	Class II	Same
Indication for Use	The Disposable Sterile Syringe with Needle is and intended for use in the aspiration and injection of fluids for medical purpose.	The Sterile Hypodermic Syringe for Single Use With/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	Analysis 2

Condition of Use		Prescription (Rx) Use only		Prescription (Rx) Use only		Same
Configuration		Syringe	Barrel (luer lock)	Syringe	Barrel (luer lock/luer slip)	Analysis 3
			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	1ml, 3ml, 5ml, 10ml, 20ml		Luer Slip: 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 100ml Luer Lock: 3ml, 5ml, 10ml, 20ml, 50ml, 100ml		Analysis 4
	Connector Type	Luer Lock				
Needle	Size	23G, 25G		16G,18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 29G		Analysis 5
	Length	0.75"(3/4"), 1", 1.25"(1-1/4"), 1.5"(1-1/2")		0.5”(1/2“) - 1.5"(1-1/2")		
Syringe Performance		Complied with ISO 7886-1:2017		Complied with ISO 7886-1:1993		Analysis 6A
Needle Performance		Complied with ISO 7864:2016 ISO 9626:2016 ISO 6009:2016		Complied with ISO 7864:1993 ISO 9626:1991 ISO 6009:1992		
Luer Connector Performance		Complied with ISO 80369-7:2016		Complied with ISO 594-1:1986 ISO 594-2:1998		Analysis 7
Patient-contact Materials						
Barrel		Polypropylene (PP)		Polypropylene (PP) and Stainless Steel		Analysis 8
Plunger		Polypropylene (PP)				
Piston		Polyisoprene				
Needle hub		Polypropylene (PP)				
Needle tube		Stainless Steel SUS 304				
Biocompatibility						

Cytotoxicity	No cytotoxicity	No cytotoxicity	Analysis 9
Irritation	No intracutaneous reactivity	No intracutaneous reactivity	
Sensitization	No sensitization	No sensitization	
Systemic Toxicity	No systemic toxicity	No systemic toxicity	
Subacute Toxicity	No Subacute toxicity	/	
Hemolysis	No Hemolysis	No Hemolysis	
Pyrogen	No Pyrogen	No Pyrogen	
Complement Activation	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

Comparison of Disposable Sterile Syringe

ITEM	Proposed Device	Predicate Device K072739	Remark
Product	Disposable Sterile Syringe	Sterile Hypodermic Syringe for single use	/
Product Code	FMF	FMF FMI MEG	Analysis 1B
Regulation Number	21 CRF 880.5860	21 CRF 880.5860	Same
Class	Class II	Class II	Same
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 Sterile Hypodermic Syringe for Single Use With/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	Analysis 2
Configuration	Barrel (luer lock)	Barrel (luer lock/luer slip)	Analysis 3
	Plunger	Plunger	
	Piston	Piston	

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	1ml, 3ml, 5ml, 10ml, 20ml	Luer Slip: 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 100ml Luer Lock: 3ml, 5ml, 10ml, 20ml, 50ml, 100ml	Analysis 4
	Connector Type	Luer Lock		
Syringe Performance		Complied with ISO 7886-1:2017	Complied with ISO 7886-1:1993	Analysis 6B
Luer Connector Performance		Complied with ISO 80369-7:2016	Complied with ISO 594-1:1986 ISO 594-2:1998	Analysis 7
Barrel		Polypropylene (PP)	Polypropylene (PP)	Analysis 8
Plunger		Polypropylene (PP)	Polypropylene (PP)	
Piston		Polyisoprene	Rubber	
Biocompatibility				
Cytotoxicity		No cytotoxicity	No cytotoxicity	Analysis 9
Irritation		No intracutaneous reactivity	No intracutaneous reactivity	
Sensitization		No sensitization	No sensitization	
Systemic Toxicity		No systemic toxicity	No systemic toxicity	
Subacute toxicity		No Subacute toxicity	Unknown	
Hemolysis		No Hemolysis	No Hemolysis	
Pyrogen		No Pyrogen	No Pyrogen	
Sterilization				
Method		EO Sterilized	EO Sterilized	Same
SAL		10^{-6}	10^{-6}	Same
Endotoxin Limit		20 EU per device	20 EU per device	Same

Analysis 1A -Product Code and Regulation Number

In the submission, the predicate device has syringe with/without needle, Auto-disable syringe with/without needle, insulin syringe with fixed needle and hypodermic needle, with the corresponding product codes as FMF, FMI and MEG. The proposed syringe with needle has product codes as FMF and FMI. The subject device does not include a sharps injury protection feature, which is covered by the predicate device product code MEG. The product code of subject device is included in the codes of predicate device. Based on above analysis, the difference on product code and regulation number will not raise new questions on safety and effectiveness of the proposed device.

Analysis 1B -Product Code and Regulation Number

In the submission, the predicate device has syringe with/without needle, Auto-disable syringe with/without needle, insulin syringe with fixed needle and hypodermic needle, with the corresponding product codes as FMF, FMI and MEG. The proposed disposable sterile syringe has product code as FMF. The subject device does not include a sharps injury protection feature, which is covered by the predicate device product code MEG. The product code of subject device is included in the codes of predicate device. Based on above analysis, the difference on product code and regulation number will not raise new questions on safety and effectiveness of the proposed device.

Analysis 2-Indication for Use

The indication for use of the proposed device and the predicative device differ 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. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

Analysis 3- Configuration

The configuration of the proposed device is similar to the configurations of the predicate device, except for the type of barrel connector. The predicate device has the configuration of barrel with luer lock or luer slip connector while the proposed device has the configuration of barrel with luer lock connector only - which is covered by the predicate device connector type. Based on above analysis, the difference on configuration will not raise new questions on safety and effectiveness of the proposed device.

Analysis 4-Syringe Volume and Connector Type

The Syringe volume for proposed device is different from the predicate devices. However, this difference is just in dimension. Moreover, the syringe volume of the proposed device is covered by the range of the syringe volume of the predicate device. The predicate device has the configuration of barrel with luer lock or luer slip connector while the proposed device has the configuration of barrel with luer lock connector only which is covered by the predicate device connector type. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

Analysis 5-Needle Size and Length

The needle size for proposed device is different in dimensions from the predicate device. Moreover, the needle size of the proposed device 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.

Analysis 6A -Syringe Performance and Needle Performance

The proposed and predicate device have been tested in accordance with ISO 7886,7864, 6009 and

9626, and the test results meet the requirements of the standards. Although the version numbers of the standard followed by the predicate devices and the proposed devices are different, the three standards followed by the proposed device are all FDA recognized consensus standards. Therefore, different version numbers of the standard do not raise new questions on safety and effectiveness of the proposed device.

Analysis 6B -Syringe Performance

The proposed and predicate device have been tested in accordance with ISO 7886-1 and the test results meet the requirements of the standards. Although the version numbers of the standard followed by the predicate devices and the proposed devices are different, this standard followed by the proposed device are all FDA recognized consensus standards. Therefore, different version numbers of the standard do not raise new questions on safety and effectiveness of the proposed device.

Analysis 7-Luer Connector Performance

The proposed device and the predicate device follow different luer connector standards - this is because ISO 594-1, ISO 594-2 is replaced by ISO 80369-7 according to current regulations. 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.

Analysis 8- Patient-contact Materials

Although the patient-contacting materials for the 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.

Analysis 9-Biocompatibility

The biocompatibility test items of proposed device are different from predicate device. Since the contact level of the proposed device is blood path, indirect, and the contact duration is prolonged contact (<30 days) therefore, the additional biocompatibility endpoints were also evaluated for the proposed device. The results for the biocompatibility testing showed that there are no negative impacts from the materials that are used in the proposed device. Therefore, this difference does not raise new safety and effectiveness issues for the device.

Performance testing (Non-Clinical)

Non clinical tests were conducted to verify that the proposed device met all design specifications and to demonstrate it is Substantially Equivalent (SE) to the predicate device. The test results

demonstrated that the proposed device complies with the following standards:

ISO 10993-5:2009 Biological evaluation of medical Devices-Part 5: Tests for in Vitro Cytotoxicity
ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Test for irritation and skin sensitization.
ISO 10993-11:2017 Biological evaluation of medical devices- Part 11: Tests for systemic toxicity
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 - Color 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
USP<85> Bacterial Endotoxins Test
USP<788> Particulate Matter in Injections

Sterility, Shipping and Shelf-Life

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.

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. In addition, after simulation transport of the aging sample, the test result also 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	Test Method

EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacteria Endotoxin Limit	USP <85>

Biocompatibility testing

In accordance with ISO 10993-1, contact level of the proposed device is blood path, indirect, and the contact duration is prolonged contact (<30 days). 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,
Subacute Toxicity,
Hemolysis,
Pyrogen,
Complement Activation,
In Vivo Thrombogenicity,
Particulate testing

Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Disposable Sterile Syringe with Needle and Disposable Sterile Syringe is substantially equivalent to the legally marketed predicative device cleared under K072739 with respect to the indications for use, target populations, treatment method, and technological characteristics.