September 6, 2019

Jiangsu Micsafe Medical Technology Co., Ltd.
Tony Yang
General Manager
Xituan Industrial Park, Dafeng District
Yancheng, 224125 Cn

Re: K183665
Trade/Device Name: Safety Needles, Sterile Syringe, Sterile Syringe with Safety Needle, Sterile Syringe with Needle, Hypodermic Needle for Single Use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG, FMF, FMI
Dated: July 30, 2019
Received: July 30, 2019

Dear Tony Yang:

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,

For 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183665

Device Name
Safety Needles, Sterile Syringe, Sterile Syringe with Safety Needle, Sterile Syringe with Needle, Hypodermic Needle for Single Use

Indications for Use *(Describe)*

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

Sterile Syringe
The sterile syringe is a sterile luer lock or luer slip syringe which is intended to be used with a hypodermic needle for the aspiration and injection of fluids for medical purpose.

Sterile Syringe with Safety Needle
The sterile 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.

Sterile Syringe with Needle
The sterile syringe with needle is intended for use the aspiration and injection of fluids for medical purpose.

Hypodermic Needles for Single Use
The hypodermic 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.

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510(k) Summary (K183665)

Submitter Information

Company: Jiangsu Micsafe Medical Technology Co., Ltd.
Address: Xituan Industrial Park, Dafeng District, Yancheng City,
Jiangsu Province, 224125, China
Phone: 086-13651929266 Contact: Tony Yang, General Manager
Date: Sept 3, 2018

Device Information

Trade/Device Name: Safety Needles
Sterile Syringe
Sterile Syringe with Safety Needle
Sterile Syringe with Needle
Hypodermic Needle for Single Use

Classification: Class II
Regulation Number: 880.5860
Regulation Name: Piston syringe
Product Code(s): MEG, FMF, FMI

Common Name(s):Syringe, Antistick
Syringe, Piston
Needle, Hypodermic, Single Lumen

Type of use: Prescription use only
Predicate Device: Sterile Disposable Syringe With Safety Needle, Sterile Disposable Syringe With Needle, Sterile Disposable Syringe, Sterile Disposable Safety Needle, Sterile Disposable Needle (K170651)

Device Description

(1)Safety Needles
The Safety Needles are intended for manual and single use only. They consist of a needle cap, needle tube and hub with protector. 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.

(2)Sterile Syringe
The Sterile Syringe is intended for manual and single use only. It consists of a Barrel, Plunger, and Piston. The syringes are available with luer slip and luer lock connector types and are available in different sizes. They are intended to be connected to a safety/hypodermic needle.

(3)Sterile Syringe with Safety Needle
This product is intended for manual and single use only. The Sterile Syringe with Safety Needle consists of a hypodermic needle with a safety sheath attached to the needle hub and a luer slip or luer lock syringe. The proposed device is available in a variety of syringe and needle sizes. The safety sheath will be manually activated to cover the needle immediately after use to minimize risk of accidental needle sticks.

(4)Sterile Syringe with Needle
The Sterile Syringe with Needle is intended for manual and single use only. It consists of a hypodermic needle and a luer slip or luer lock syringe. The proposed device is available in a variety of syringe and needle sizes.

(5)Hypodermic Needles for Single Use
The Hypodermic Needle is intended for manual and single use only. It consists of a hub, needle tube, needle cap. The proposed device is compatible for use with a luer slip or luer lock syringe.

Configurations and Sizes

(1)Safety Needles	
18G; 20G; 21G; 22G; 23G; 25G; 26G	
(2)Sterile Syringe	
Luer Slip	1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml
Luer Slip Eccentric	20ml, 30ml, 50ml
Luer Lock	1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml
(3)Sterile Syringe with Safety Needle	
Luer Slip	1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml
Luer Slip Eccentric	20ml, 30ml, 50ml
Luer Lock	1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml
Needle Size:18G; 20G; 21G; 22G; 23G; 25G; 26G	
(4)Sterile Syringe with Needle	
Luer Slip	1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml
Luer Slip Eccentric	20ml, 30ml, 50ml
Luer Lock	1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml
Needle Size:18G ; 19G; 20G; 21G; 22G; 23G; 24G; 25G; 26G; 27G; 28G; 29G; 30G; 31G	

(5)Hypodermic Needles for Single Use
18G; 19G; 20G; 21G; 22G; 23G; 24G; 25G; 26G; 27G; 28G; 29G; 30G; 31G

Needle lengths

Safety Needle						
	1/2"	3/4"	1"	1 1/4"	1 1/2"	2"
18G	●	●	●	●	●	●
20G	●	●	●	●	●	●
21G	●	●	●	●	●	●
22G	●	●	●	●	●	●
23G	●	●	●	●	●	●
25G	●	●	●		●	
26G	●	●	●		●	

Hypodermic Needles for Single Use							
	1/2"	5/8"	3/4"	1"	1 1/4"	1 1/2"	2"
18G	●		●	●	●	●	●
19G	●		●	●	●	●	●
20G	●		●	●	●	●	●
21G	●		●	●	●	●	●
22G	●		●	●	●	●	●
23G	●		●	●	●	●	●
24G	●		●	●	●	●	●
25G	●	●	●	●		●	
26G	●	●	●	●		●	
27G	●	●	●	●			
28G	●	●	●	●			
29G	●	●	●				
30G	●	●	●				
31G	●	●	●				

Indications for Use

(1)Safety Needles

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

(2)Sterile Syringe

The sterile syringe is a sterile luer lock or luer slip syringe which is intended to be used with a

hypodermic needle for the aspiration and injection of fluids for medical purpose.

(3)Sterile Syringe with Safety Needle
The sterile 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.

(4)Sterile Syringe with Needle
The sterile syringe with needle is intended for use the aspiration and injection of fluids for medical purpose.

(5)Hypodermic Needles for Single Use
The hypodermic needle is intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose.

Comparison of Indications for Use and Technological Characteristics
(1)Safety Needles

Comparison Items	**Subject Device (K183665)**	**Predicate Device (K170651)**
Identification	Safety needle for single use	The sterile disposable safety needle-K170651
Classification	Product Code: FMI Class: 2	Product Code: MEG,FMF,FMI Class: 2
Intended Use	The safety needles are intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.	The sterile 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 needestick.
Configurations and Materials	Needle cap (Polypropylene)	Needle cap(Polypropylene)
	Needle tube (SUS304)	Needle tube (SUS304)

Comparison Items	Subject Device (K183665)	Predicate Device (K170651)
	Hub with protector (Polypropylene)	Needle hub with safety sheath(Polypropylene)
Size	18G, 20G, 21G, 22G, 23G, 25G, and 26G Needle length: 1/2"-2"	16G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, and 30G Needle length: 5/16"-1 1/2"
Sterile	Yes (EO)	Yes (EO)
Single Use	Yes	Yes
Biocompatibility	Conforms to the requirement of ISO 10993 series Standards	Conforms to the requirement of ISO 10993 series Standards
	No Cytotoxicity	No Cytotoxicity
	No Irritation to Skin	No Irritation to Skin
	No significant evidence of sensitization	No significant evidence of sensitization
	No systemic toxicity	No systemic toxicity
	No Hemolysis	No Hemolysis
	Non pyrogenic	Non pyrogenic
Performance safety & effectiveness	Conforms with the requirements of ISO 7864 and ISO 9626. Needle Safety Feature: Testing conducted per ISO 23908:2011. Force to activate safety mode: NMT 10N Force to disengage safety mode: NLT 20N Force to separate safety feature from needle hub: NLT 50N	Conforms with the requirements of ISO 7864 and ISO 9626. Needle Safety Feature: Specifications not provided.

Discussion:

The indications for use statement for the subject device is identical to the predicate. Differences in needle lengths and gauges were addressed through ISO 7864 and ISO 9626 testing. Differences in needle safety specifications were addressed through simulated needle safety activation and verification of the specifications. The differences identified do not raise different questions of safety and effectiveness.

(2) Sterile Syringe

Comparison Items	Subject Device (K183665)	Predicate Device (K170651)
Identification	Sterile Syringe	The sterile disposable syringe-K170651
Classification	Product Code: FMF Class: 2	Product Code: MEG,FMF,FMI Class: 2
Intended Use	The sterile syringe is a sterile luer lock or luer slip syringe which is intended to be used with a hypodermic needle for the aspiration and injection of fluids for medical purpose.	The sterile disposable syringe is a sterile luer lock or luer slip syringe which is intended to be used with a hypodermic needle for the aspiration and injection of fluids for medical purpose.
Configurations and Materials	Barrel (Polypropylene)	Barrel (Polypropylene)
	Plunger (Polypropylene)	Plunger (Polypropylene)
	Stopper (Polyisoprene)	Stopper (Polyisoprene)
Size	1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, and 60ml Luer Lock/Luer Slip/Luer slip Eccentric	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, and 60ml Luer Lock/Luer Slip
Sterile	Yes (EO)	Yes (EO)
Single Use	Yes	Yes
Biocompatibility	Conforms to the requirement of ISO 10993 series Standards	Conforms to the requirement of ISO 10993 series Standards
	No Cytotoxicity	No Cytotoxicity
	No Irritation to Skin	No Irritation to Skin
	No significant evidence of sensitization	No significant evidence of sensitization
	No systemic toxicity	No systemic toxicity
	No Hemolysis	No Hemolysis
	Non pyrogenic	Non pyrogenic
Performance safety & effectiveness	Conforms with the requirements of ISO 7886 and ISO 80369-7.	Conforms with the requirements of ISO 7886 and ISO 594-1/-2.

Discussion:

The indications for use statement for the subject device is identical to the predicate. Differences

in connections (i.e., addition of eccentric luer slip models) were addressed through ISO 7886 and ISO 80369 testing. The technological differences do not raise different questions of safety and effectiveness.

(3) Sterile Syringe with Safety Needle

Comparison Items	**Subject Device (K183665)**	**Predicate Device (K170651)**
Identification	Sterile syringe with safety needles	The sterile disposable syringe with safety needle- K170651
Classification	Product Code: MEG,FMF,FMI Class: 2	Product Code: MEG,FMF,FMI Class: 2
Intended Use	The sterile 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 syringes 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.
Configurations and Materials	Barrel (Polypropylene)	Barrel (Polypropylene)
	Plunger (Polypropylene)	Plunger (Polypropylene)
	Stopper (Polyisoprene)	Stopper (Polyisoprene)
	Needle cap (Polypropylene)	Needle cap (Polypropylene)
	Needle tube (SUS304)	Needle tube (SUS304)
	Hub with protector (Polypropylene)	Needle hub with safety sheath (Polypropylene)
Size	1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, and 60ml Luer Lock/Luer Slip/Luer slip Eccentric 18G, 20G, 21G, 22G, 23G, 25G, and 26G Needle length: 1/2"-2"	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, and 60ml Luer Lock/Luer Slip 16G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, and 30G Needle length: 5/16"-1 1/2"
Sterile	Yes (EO)	Yes (EO)
Single Use	Yes	Yes

Comparison Items	Subject Device (K183665)	Predicate Device (K170651)
Biocompatibility	Conforms to the requirement of ISO 10993 series Standards	Conforms to the requirement of ISO 10993 series Standards
	No Cytotoxicity	No Cytotoxicity
	No Irritation to Skin	No Irritation to Skin
	No significant evidence of sensitization	No significant evidence of sensitization
	No systemic toxicity	No systemic toxicity
	No Hemolysis	No Hemolysis
	Non pyrogenic	Non pyrogenic
Performance safety & effectiveness	Conforms with the requirements of ISO 7864, ISO 9626, ISO 7886, and ISO 80369-7. Needle Safety Feature: Testing conducted per ISO 23908:2011. Force to activate safety mode: NMT 10N Force to disengage safety mode: NLT 20N Force to separate safety feature from needle hub: NLT 50N	Conforms with the requirements of ISO 7864, ISO 9626, ISO 7886, and ISO 594-1/-2. Needle Safety Feature: Specifications not provided.

Discussion:
The indications for use statement for the subject device is identical to the predicate. Differences in needle gauges, needle lengths and addition of eccentric luer slip models were addressed through ISO 7864, ISO 9626, ISO 7886, and ISO 80369-7 testing. Differences in needle safety specifications were addressed through simulated needle safety activation and verification of the specifications. The differences identified do not raise different questions of safety and effectiveness.

(4) Sterile Syringe with Needle

Comparison Items	Subject Device (K183665)	Predicate Device (K170651)
Identification	Sterile syringe with needles	The sterile disposable syringe with needle- K170651
Classification	Product Code: MEG,FMF,FMI	Product Code: MEG,FMF,FMI

Comparison Items	Subject Device (K183665)	Predicate Device (K170651)
	Class: 2	Class: 2
Intended Use	The sterile syringe with needle is intended for use 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.
Configurations and Materials	Barrel (Polypropylene)	Barrel (Polypropylene)
	Plunger (Polypropylene)	Plunger (Polypropylene)
	Stopper (Polyisoprene)	Stopper (Polyisoprene)
	Needle cap (Polypropylene)	Needle cap (Polypropylene)
	Needle tube (SUS304)	Needle tube (SUS304)
	Needle hub (Polypropylene)	Needle hub (Polypropylene)
Size	1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, and 60ml Luer Lock/Luer Slip/Luer slip Eccentric 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, and 31G Needle length: 1/2"-2"	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, and 60ml Luer Lock/Luer Slip 16G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, and 30G Needle length: 5/16"-1 1/2"
Sterile	Yes (EO)	Yes (EO)
Single Use	Yes	Yes
Biocompatibility	Conforms to the requirement of ISO 10993 series Standards	Conforms to the requirement of ISO 10993 series Standards
	No Cytotoxicity	No Cytotoxicity
	No Irritation to Skin	No Irritation to Skin
	No significant evidence of sensitization	No significant evidence of sensitization
	No systemic toxicity	No systemic toxicity
	No Hemolysis	No Hemolysis
	Non pyrogenic	Non pyrogenic
Performance safety & effectiveness	Conforms with the requirements of ISO 7864, ISO 9626, ISO 7886, and ISO 80369-7.	Conforms with the requirements of ISO 7864, ISO 9626, ISO 7886, and ISO 594-1/-2.

Discussion:

The indications for use statement for the subject device is identical to the predicate. Differences in luer connection (i.e., addition of luer slip Eccentric), needle gauges and needle lengths were addressed through ISO 7864, ISO 9626, ISO 7886, and ISO 80369 testing. The differences identified do not raise different questions of safety and effectiveness.

(5) Hypodermic Needles for Single Use

Comparison Items	**Subject Device (K183665)**	**Predicate Device (K170651)**
Identification	Hypodermic needle for single use	The sterile disposable needle-K170651
Classification	Product Code: FMI Class: 2	Product Code: MEG,FMF,FMI, Class: 2
Intended Use	The hypodermic 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.
Configuration	Needle cap (Polypropylene)	Needle cap (Polypropylene)
	Needle tube (SUS304)	Needle tube (SUS304)
	Needle hub (Polypropylene)	Needle hub (Polypropylene)
Size	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, and 31G Needle length: 1/2"-2"	16G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, and 30G Needle length: 5/16"-1 1/2"
Sterile	Yes (EO)	Yes (EO)
Single Use	Yes	Yes
Biocompatibility	Conforms to the requirement of ISO 10993 series Standards	Conforms to the requirement of ISO 10993 series Standards
	No Cytotoxicity	No Cytotoxicity
	No Irritation to Skin	No Irritation to Skin
	No significant evidence of sensitization	No significant evidence of sensitization
	No systemic toxicity	No systemic toxicity
	No Hemolysis	No Hemolysis
	Non pyrogenic	Non pyrogenic
Performance safety	Conforms with the requirements of	Conforms with the requirements of

Comparison Items	Subject Device (K183665)	Predicate Device (K170651)
& effectiveness	ISO 7864 and ISO 9626.	ISO 7864 and ISO 9626.

Discussion:
The indications for use statement for the subject device is identical to the predicate. Differences in needle gauges and lengths were addressed through ISO 7864 and ISO 9626 testing. The differences identified do not raise different questions of safety and effectiveness.

Performance Testing
The subject device was tested/analyzed according to the following standards in order to ensure its effectiveness and safety:
1) Biocompatibility:
Needle: Externally communicating, blood path indirect with limited patient contact
Syringe: Externally communicating, blood path indirect with prolonged patient contact
Testing according to:

- ANSI AAMI ISO 10993-5:2009/(R)2014, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity;
- ANSI AAMI ISO 10993-10:2010/(R)2014, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization;
- ANSI AAMI ISO 10993-11:2006/(R)2010, Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity;
- ISO 10993-4:Third Edition 2017-04, 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.

2) Performance testing according to ISO 7864 Fourth Edition 2016-08-01, Sterile Hypodermic Needles For Single Use - Requirements And Test Methods:

- Cleanliness
- Limits for acidity or alkalinity
- Limits for extractable metals
- Color coding
- Conical fitting
- Color of hub
- Needle cap
- Tolerances on length
- Freedom from defects
- Lubricant
- Needle point
- Bond between hub and needle tube

- Patency of lumen
- Sharps injury protection

3) Performance testing according to ISO 7886-1 Second Edition 2017-05, Sterile Hypodermic Syringes For Single Use - Part 1: Syringes For Manual Use:

- Limits for acidity or alkalinity
- Limits for extractable metals
- Lubricant
- Tolerance on graduated capacity
- Scale
- Numbering of scales
- Overall length of scale to nominal capacity line
- Position of scale
- Barrel flanges
- Minimum length between barrel flanges and plunger push-button
- Conical fitting
- Position of nozzle on end of barrel
- Nozzle lumen
- Dead space
- Freedom from air and liquid leakage past plunger stopper
- Force to operate the position
- Fit of plunger stopper/plunger in barrel

4) Performance testing according to ISO 80369-7 First Edition 2016-10-15, Small-Bore Connectors For Liquids And Gases In Healthcare Applications - Part 7: Connectors For Intravascular Or Hypodermic Applications:

- Leakage by pressure decay
- Positive pressure liquid leakage
- Sub-atmospheric pressure air leakage
- Stress cracking
- Resistance to separation from axial load
- Resistance to separation from unscrewing
- Resistance to overriding

5) Performance testing according to ISO 9626 Second Edition 2016-08-01, Stainless Steel Needle Tubing For The Manufacture Of Medical Devices - Requirements And Test Methods:

- Dimensions
- Stiffness
- Resistance to breakage
- Resistance to corrosion

6) Additional Performance testing for the Safety Needles/ Sterile Syringe/Sterile Syringe with Safety Needle/Sterile Syringe with Needle/Hypodermic Needle for Single Use:

- Conical fitting to ISO 80369-7
- Sharps Injury Protection Test Report to ISO 23908:2011
- Particulate Testing per USP <788>

Clinical Testing

Not applicable

Conclusion

The subject and predicate device have similar technological characteristics, are provided sterile, and are intended for single use. Differences in configurations and sizes have been evaluated by non-clinical bench testing per ISO 7864, ISO 9626, ISO 7886 and ISO 80369-7. Furthermore, both devices were tested for biocompatibility per ISO 10993-1. Hence, we conclude that the subject device was demonstrated to be substantially equivalent to the predicate device.