April 10, 2020

Gemtier Medical (Shanghai) Inc.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120 Cn

Re: K192679
Trade/Device Name: Sterile Syringe with Safety Needle for Single Use, Sterile Syringe for Single Use, Sterile Safety Needle for Single Use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG, FMF, FMI
Dated: February 26, 2020
Received: March 12, 2020

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,

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

510(k) Number *(if known)*
K192679

Device Name
Sterile Syringe with Safety needle for Single Use
Sterile Syringe for Single Use
Sterile Safety Needle for Single Use

Indications for Use *(Describe)*

Sterile Syringe with Safety 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 mechanism can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks.

Sterile Syringe for Single Use 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.

Sterile Safety Needle for Single Use is intended to be used with a luer lock syringe for aspiration and injection of fluids for medical purpose. 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.

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

The assigned 510(k) Number: __K192679_____

1. Date of Preparation: 04/09/2020

2. Sponsor Identification

Gemtier Medical (Shanghai) Inc.
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3. Designated Submission Correspondent

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

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Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Sterile Syringe with Safety needle for Single Use
Sterile Syringe for Single Use
Sterile Safety Needle for Single Use

Regulatory Information
Classification Name: Syringe Antistick
Classification: II;
Product Code: MEG
Regulation Number: 21CFR 880.5860
Review Panel: General Hospital;

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

Classification Name: Hypodermic single lumen needle
Classification: II
Product Code: FMI
Regulation Number: 21 CFR 880.5570
Review Panel: General Hospital

Indication for Use:

Sterile Syringe with Safety 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 mechanism can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks.

Sterile Syringe for Single Use 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.

Sterile Safety Needle for Single Use is intended to be used with a luer lock syringe for aspiration and injection of fluids for medical purpose. 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.

Device Description:

Sterile 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.
Syringe volume: 1ml, 2ml, 5ml, 10ml, 20ml, 30ml, and 50ml;
Needle specification:

Needle Gauge	Length	Wall type
18G	1", 1 1/4", 1 1/2"	Thin wall
21G	1/2", 5/8', 1",1 1/4", 1 1/2"	Thin wall
22G	1/2", 5/8', 1",1 1/4", 1 1/2"	Thin wall
23G	1/2", 5/8", 3/4", 1",1 1/4", 1 1/2"	Thin wall
25G	3/8", 1/2", 5/8", 3/4", 1", 1 1/4", 1 1/2"	Thin wall

The Sterile Syringe for Single Use 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, which is intended to be connected with a hypodermic needle.
Syringe volume: 1ml, 2ml, 5ml, 10ml, 20ml, 30ml, and 50ml;

Sterile 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 needle cap, needle tube, retractable cartridge, jointing medium and needle hub. The proposed device is available in variety of needle gauge and needle length. According to the needle length, the safety mechanism is available in 2-part cartridge (outer retractable cartridge and inner retractable cartridge) and 3-part cartridge (outer retractable cartridge, middle retractable cartridge and inner retractable cartridge). The proposed device is compatible for use with a luer lock syringe. After withdrawal of the needle from the body, the attached needle safety mechanism can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks. Needle specification is same as the needle size of Sterile Syringe with Safety needle for Single Use.

5. Identification of Predicate Device

510(k) Number: K170651
Product Name: Sterile Disposable Syringe With Safety Needle;
Sterile Disposable Syringe With Needle;
Sterile Disposable Syringe;
Sterile Disposable Safety Needle;
Sterile Disposable Needle

6. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device. The testing included the following items:

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

General requirements	Clause 5 of ISO 7886-1:2017
Extraneous matter	Clause 6 of ISO 7886-1:2017
Lubricant	Clause 7 of ISO 7886-1;2017
Tolerance on graduated capacity	Clause 8 of ISO 7886-1:2017
Graduated scale	Clause 9 of ISO 7886-1:2017
Barrel	Clause 10 of ISO 7886-1:2017
Piston/ plunger assembly	Clause 11 of ISO 7886-1:2017
Nozzle	Clause 12 of ISO 7886-1:2017
Performance	Clause 13 of ISO 7886-1:2017
Cleanliness	Clause 4.3 of ISO 7864:2016
Limits for acidity or alkalinity	Clause 4.4 of ISO 7864:2016
Limits for extractable metals	Clause 4.5 of ISO 7864:2016
Size designation	Clause 4.6 of ISO 7864:2016
Colour coding	Clause 4.7 of ISO 7864:2016
Needle hub	Clause 4.8 of ISO 7864:2016
Needle Cap	Clause 4.9 of ISO 7864:2016
Needle tube	Clause 4.10 of ISO 7864:2016
Needle point	Clause 4.11 of ISO 7864:2016
Bond between hub and needle tube	Clause 4.12 of ISO 7864:2016
Patency of lumen	Clause 4.13 of ISO 7864:2016
Surface finish and appearance	Clause 5.2 of ISO 9626:2016
Cleanliness	Clause 5.3 of ISO 9626:2016
Limits for acidity and alkalinity	Clause 5.4 of ISO 9626:2016
Size designation	Clause 5.5 of ISO 9626:2016
Dimensions	Clause 5.6 of ISO 9626:2016
Stiffness	Clause 5.8 of ISO 9626:2016
Resistance to breakage	Clause 5.9 of ISO 9626:2016
Resistance to corrosion	Clause 5.10 of ISO 9626:2016

Sterile barrier packaging testing were performed on the proposed device, which include visual

inspection (ASTM F1886/F1886M-16), seal strength (ASTM F88/F88-15) and dye penetration test (ASTM F1929-15). The test result showed that the device package can maintain its integrity.

Sterilization and shelf life testing listed in following table were performed on the proposed device. EO ECH residue did not exceed the limit of ISO 10993-7. Endotoxin limit did not exceed 20EU/device. Shelf life test result showed that the device can maintain its performance during the claimed shelf life.

EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacteria Endotoxin Limit	USP 38-NF 33 <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 reactivity,
- Acute Systemic Toxicity,
- Hemolysis,
- Complement activation,
- Thromboresistance study
- 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 proposed device and predicate device meet the acceptance criteria.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics for Sterile Syringe with Safety needle for Single Use

ITEM	Subject Device K192679	Predicate Device K170651	Comments
Regulation No.	21CFR 880.5860	21CFR 880.5860	Same
Product Code	MEG	MEG	Same
Class	II	II	Same
Indication for Use	Sterile Syringe with Safety 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 mechanism 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 needlesticks	Same
Configuration and material	Barrel (Polypropylene, PP) Plunger (Polypropylene, PP) Piston (Polyisoprene, Carbon Black) Needle cap (Polypropylene, PP) Needle tube (Stainless steel) Retractable cartridge (Polycarbonate, PC) Jointing medium (Methyl methacrylate acrylonitrile butadiene styrene (MABS) Needle hub (Polycarbonate, PC) Needle tube (Stainless steel SUS304) Lubricant (Silicon plastic agent) Adhesive (UV Light Cure Adhesive) Colorants (MACROLEX Orange 3G, Heliogen Blue K 7090, BAYFERROX 318M, Heliogen Green K 8730, Ranbar red P1400)	Barrel (Polypropylene, PP) Plunger (Polypropylene, PP) Piston (Polyisoprene) Needle hub (Polypropylene, PP) Protective cap (Polypropylene, PP) Needle tube (Stainless steel) Safety sheath (Polypropylene, PP) Needle tube (stainless steel SUS304) Needle tube (Stainless Steel SUS304) Lubricant (Silicone oil) Adhesive (UV glue) Colorants (Yellow, Red, White, Black, Blue, Green)	See Comment #1

Operation Mode	For manual use only	For manual use only	Same
Safety Feature	The needle is withdrawn into safety mechanism, the safety mechanism is fixed via latch lock to prevent arbitrary moving.	Slide over the needle to prevent from needle sticks	See Comment #2
Label/labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same
Syringe Volume	1ml, 2ml, 5ml, 10ml, 20ml, 30ml, 50ml	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml	See Comment #3
Connect Type	Luer lock	Luer lock and Luer slip	See Comment #4
Needle Gauge	18G, 21G, 22G, 23G, 25G	16G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	See Comment #5
Needle Length	Available in 3/8'', 1/2", 5/8", 3/4", 1", 1 1/4", 1 1/2"	Available in 5/16", 1/2", 5/8", 3/4", 1 1/4", 1 1/2"	See Comment #6
Single Use	Single Use	Single Use	Same
Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20EU	20EU	Same

Discussion of Differences

Comment 1

The configuration between proposed device and predicate device is different. However, the basic configurations are same, both of them include barrel, plunger, piston, needle hub, protective or needle cap. The only different is retractable cartridge, jointing medium and safety sheath, which are parts of safety mechanism, and predicate device lubricant adhesive and colorant information unknown. Additionally, the safety mechanism does affect the indication for use. Therefore, this difference does not affect substantially equivalence.

The material of configuration is different between proposed device and predicate device. However, the mainly configurations such as barrel, plunger, piston, needle tube, needle/protective cap are made of same materials. The only differences are the material of needle hub, safety feature, lubricant, adhesive and colorant. And the MSDS for all related materials has been provided in this submission. Differences in materials of construction are addressed through ISO 10993-1: biocompatibility testing. Additionally, the material of configuration does not affect the indication for use. Therefore, this difference does not affect substantially equivalence.

Comment 2

The safety feature between proposed device and predicate device is different. The safety mechanism for proposed device is retractable cartridge, for predicate, that is safety sheath. Both of them are intended to prevent from needle stick injuries, and which does not affect indication for use. In addition, the safety feature for proposed device has been evaluated and the test result conforms to requirements of ISO 23908:2011 standard. Therefore, this difference does not affect substantially equivalence.

Comment 3

The predicate device has more specification of syringe volume compared predicate device. However, the different syringe volume will be selected by physician per injection requirement and this difference does not affect indication for use. Additionally, the performance of syringe has been evaluated and the test results met the requirements of ISO 7886-1. Therefore, this difference does not affect substantially equivalency on safety and effectiveness.

Comment 4

The connect type between proposed device and predicate device is different. For proposed device, only includes Luer lock, for predicate device, the connect type includes Luer lock and Luer slip. However, the connect type for proposed device is covered by predicate, and the connect type is only used to compatible with needle, and does not affect indication for use. Additionally, the performance of Luer lock has been evaluated and the test results met the requirements of ISO 80369-7.

Comment 5

The needle gauge of predicate device is more than proposed device, and for proposed device, the needle

gauge is covered by predicate device. However, this difference is just in needle size. In addition, all the needle gauge of proposed device has been tested. The test results comply with ISO 7864 and ISO 9626. The different specifications are selected by physician according to the patient's conditions. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

Comment 6

The needle length for proposed device is covered by predicate device. The different length of needles will be selected by physician according different patient's condition. In addition, the needle performance has been evaluated and test results comply with ISO 7864 and ISO 9626. This different does not affect the performance of the syringe. Therefore, this difference is considered not to affect substantially equivalency between proposed device and predicate device.

Table 2 Comparison of Technology Characteristics for Sterile Syringe for Single Use

ITEM	Subject Device K192679	Predicate Device K170651	Comments
Regulation No.	21CFR 880.5860	21CFR 880.5860	Same
Product Code	FMF	FMF	Same
Class	II	II	Same
Indication for Use	Sterile Syringe for Single Use 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 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.	See Comment #7
Configuration and material	Barrel (Polypropylene, PP) Plunger (Polypropylene, PP) Piston (Polyisoprene, carbon black) Lubricant (Silicon plastic agent) Adhesive (UV Light Cure Adhesive)	Barrel (Polypropylene, PP) Plunger (Polypropylene, PP) Piston (Polyisoprene) Needle tube (Stainless Steel SUS304) Lubricant (Silicone oil) Adhesive (UV glue)	See Comment #8
Operation Mode	For manual use only	For manual use only	Same
Label/labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same
Syringe Volume	1ml, 2ml, 5ml, 10ml, 20ml, 30ml, 50ml	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml	See Comment #9
Connect Type	Luer lock	Luer lock and Luer slip	See Comment #10
Single Use	Single Use	Single Use	Same
Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20EU	20EU	Same

Discussion of Differences

Comment 7

There are some subtle differences in indication for use between proposed device and predicated device. The difference is connect type. For proposed device, only has Luer lock, while for predicate device, has Luer lock and Luer slip (See Comment 10). And the type connect of proposed device is covered by predicate device. In addition, the connect type is only used to compatible with needle, and does not affect aspiration and injection of fluids. The results demonstrated that this difference does not raise new problem on the safety and effectiveness of the proposed device. Therefore, this difference does not affect substantially equivalence.

Comment 8

The configuration between proposed device and predicate device is different. However, the basic configurations are same, both of them include barrel, plunger, and piston. The material of configuration is different between proposed device and predicate device. However, the mainly configurations such as barrel, plunger and piston are made of same materials. And the MSDS for all related materials has been provided in this submission. Differences in materials of construction are addressed through ISO 10993-1: biocompatibility testing. Additionally, the material of configuration does not affect the indication for use. Therefore, this difference does not affect substantially equivalence.

Comment 9

The predicate device has more specification of syringe volume compared predicate device. However, the different syringe volume will be selected by physician per injection requirement and this difference does not affect indication for use. Additionally, the performance of syringe has been evaluated and the test results met the requirements of ISO 7886-1. Therefore, this difference does not affect substantially equivalency on safety and effectiveness.

Comment 10

The connect type between proposed device and predicate device is different. For proposed device, only includes Luer lock, for predicate device, the connect type includes Luer lock and Luer slip. However, the connect type for proposed device is covered by predicate, and the connect type is only used to compatible with needle, and does not affect indication for use. Additionally, the performance of Luer lock has been evaluated and the test results met the requirements of ISO 80369-7.

Table 3 Comparison of Technology Characteristics for Sterile Safety needle for Single Use

ITEM	Subject Device K192679	Predicate Device K170651	Comments
Regulation No.	21CFR 880.5570	21CFR 880.5570	Same
Product Code	FMI	FMI	Same
Class	II	II	Same
Indication for Use	Sterile Safety Needle for Single Use is intended to be used with a luer lock syringe for aspiration and injection of fluids for medical purpose. 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.	The Sterile Disposable Safety Needle is intended for use 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	See Comment #11
Configuration and material	Needle cap (Polypropylene, PP) Needle tube (Stainless steel) Retractable cartridge (Polycarbonate, PC) Jointing medium (Methyl methacrylate acrylonitrile butadiene styrene (MABS) Needle hub (Polycarbonate, PC) Needle tube (Stainless Steel SUS304) Lubricant (Silicon plastic agent) Adhesive (UV Light Cure Adhesive) Colorants (MACROLEX Orange 3G, Heliogen Blue K 7090, BAYFERROX 318M, Heliogen Green K 8730, Ranbar red P1400)	Needle hub (Polypropylene, PP) Protective cap (Polypropylene, PP) Needle tube (Stainless steel) Safety sheath (Polypropylene, PP) Needle tube (Stainless Steel SUS304) Lubricant (Silicone oil) Adhesive (UV glue) Colorants (Yellow, Red, White, Black, Blue, Green)	See Comment #12
Operation Mode	For manual use only	For manual use only	Same
Safety Feature	The needle is withdrawn into safety mechanism, the safety mechanism is fixed via latch lock to prevent arbitrary moving.	Slide over the needle to prevent from needle sticks	See Comment #13

Label/labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same
Connect Type	Luer lock	Luer lock and Luer slip	See Comment #14
Needle Gauge	18G, 21G, 22G, 23G, 25G	16G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	See Comment #15
Needle Length and wall type	Available in 3/8'', 1/2", 5/8", 3/4", 1", 1 1/4", 1 1/2" Wall type: TW	Available in 5/16", 1/2", 5/8", 3/4", 1 1/4", 1 1/2" Wall type: TW or RW	See Comment #16
Single Use	Single Use	Single Use	Same
Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20EU	20EU	Same

Discussion of Differences

Comment11

The only difference for predicate device and proposed device is connect type. For proposed device, only has Luer lock, while for predicate device, has Luer lock and Luer slip (See Comment 14). The type connect of proposed device is covered by predicate device. In addition, the connect type is only used to compatible with syringe, and does not affect aspiration and injection of fluids. Additionally, both of them have safety feature, 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. The results demonstrated that this difference does not raise new problem on the safety and effectiveness of the proposed device. Therefore, this difference does not affect substantially equivalence.

Comment 12

The configuration between proposed device and predicate device is different. However, the basic configurations are same, both of them include, protective or needle cap, needle tube, and needle hub. The only different is retractable cartridge, jointing medium and safety sheath, which are parts of safety mechanism. Additionally, the safety mechanism does affect the indication for use and is just used to prevent from needle sticks. Therefore, this difference does not affect substantially equivalence.

The material of configuration is different between proposed device and predicate device. However, the mainly configurations such as needle tube, needle/protective cap are made of same materials. The only differences are the material of needle hub, safety feature, lubricant, adhesive and colorant. However, these configurations not contact with patient, and the materials are not novel materials. And the MSDS for all related materials has been provided in this submission. Differences in materials of construction are addressed through ISO 10993-1: biocompatibility testing. Additionally, the material of configuration does not affect the

indication for use. Therefore, this difference does not affect substantially equivalence.

Comment 13

The safety feature between proposed device and predicate device is different. The safety mechanism for proposed device is retractable cartridge, for predicate, that is safety sheath. Both of them are intended to prevent from needle stick injuries, and which does not affect indication for use. In addition, simulated clinical use testing per FDA guidance Medical Devices with Sharps Injury Prevention Features. The simulated clinical test demonstrated that the safety features were found to meet the predetermined requirements and were acceptable. .Therefore, this difference does not affect substantially equivalence

Comment 14

The connect type between proposed device and predicate device is different. For proposed device, only includes Luer lock, for predicate device, the connect type includes Luer lock and Luer slip. However, the connect type for proposed device is covered by predicate, and the connect type is only used to compatible with needle, and does not affect indication for use. Additionally, the performance of Luer lock has been evaluated and the test results met the requirements of ISO 80369-7.

Comment 15

The needle gauge of predicate device is more than proposed device, and for proposed device, the needle gauge is covered by predicate device. However, this difference is just in needle size. In addition, all the needle gauge of proposed device has been tested. The test results comply with ISO 7864 and ISO 9626. The different specifications are selected by physician according to the patient's conditions. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

Comment 16

The needle length and wall type for proposed device is covered by predicate device. The different length of needles and wall type will be selected by physician according different patient's condition. In addition, the needle performance has been evaluated and test results comply with ISO 7864 and ISO 9626. This different does not affect the performance of the syringe. Therefore, this difference is considered not to affect substantially equivalency between proposed device and predicate device.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.