DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 2, 2017

Yangzhou Medline Industry Co., Ltd.
c/o Ms. Diana Hong
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai 200120
CHINA

Re: K170651
Trade/Device Name: Sterile Disposable Syringe With Safety Needle, Sterile Disposable Syringe With Needle, Sterile Disposable Syringe, Sterile Disposable Safety Needle, Sterile Disposable Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG, FMF, FMI
Dated: July 3, 2017
Received: July 5, 2017

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tara A. Ryan -S

for
Michael Ryan
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Change Control Table, Change History

Change Control Table

Version	Document Author	Document Approver	Date Approved
1.00	Name, Title, Office	Name, Title, Office	MM/DD/YYYY

Complete Change Control Table (all versions) retained in SWIFT Docs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170651

Device Name

Sterile Disposable Syringe with Safety Needle, Sterile Disposable Syringe with Needle, Sterile Disposable Syringe, Sterile Disposable Safety Needle, Sterile Disposable Needle

Indications for Use *(Describe)*

The Sterile Disposable Syringe with Safety Needle is intended for use in the aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle sticks.

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

The Sterile Disposable Syringe is a sterile luer 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 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.

The Sterile Disposable Needle is intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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

The assigned 510(k) Number: K170651

1. Date of Preparation: 8/2/2017

2. Sponsor Identification

Yangzhou Medline Industry Co., Ltd.
No. 108, Jinshan Road, Economic Development Zone Yangzhou, China 225000

Establishment Registration Number: Not yet registered

Contact Person: Jianzhong Qi
Position: General Manager
Tel: +86-514-87525631
Fax: +86-514-87525631
Email: President@cnmedical.net

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 240-238-7587
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Sterile Disposable Syringe with Safety Needle
Sterile Disposable Syringe with Needle
Sterile Disposable Syringe
Sterile Disposable Safety Needle
Sterile Disposable Needle

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

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

Additional Product Code: FMI, Hypodermic single lumen needle

Indications for Use Statement:

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.

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

The Sterile Disposable Syringe is a sterile luer 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 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 needlesticks.

The Sterile Disposable Needle is intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose.

Device Description

The Sterile Disposable Syringe with Safety Needle is intended for manual and single use only, which 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 combination of syringe volume and needle size. The safety sheath will be manually activated to cover the needle immediately after use to minimize risk of accidental needle sticks.

The Sterile Disposable Syringe with Needle is intended for manual and single use only, which consists of a hypodermic needle and a luer slip or luer lock syringe. The proposed device is available in a variety combination of syringe volume and needle size.

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

The Sterile Disposable Safety Needle is intended for manual and single use only, which consists of a hypodermic needle with a safety sheath 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 Disposable Needle is intended for manual and single use only, which is compatible for use with a luer slip or luer lock syringe. The proposed device is available in variety combination of needle gauge and needle length.

The syringe barrel sizes and needle gauges/ lengths of the subject device are provided in following table.

Table 1 Syringe barrel sizes and needle gauges/ lengths

	Syringe volume	Needle Gauge	Needle Length
Sterile Disposable Syringe with Safety Needle	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml	16G,18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	5/16", 1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"
Sterile Disposable Syringe with Needle	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml,	16G,18G, 19G, 20G, 21G, 22G, 23G, 24G,	5/16", 1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"

	50ml, 60ml	25G, 26G, 27G, 28G, 29G, 30G	
Sterile Disposable Syringe	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml	N.A.	N.A.
Sterile Disposable Safety Needle	N.A.	16G,18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	5/16", 1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"
Sterile Disposable Needle	NA.	16G,18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	5/16", 1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"

5. Identification of Predicate Device

Predicate Device 1
510(k) Number: K113422
Product Name: TERUMO® SurGuard® 3 Safety Needle
TERUMO® SurGuard® 3 Hypodermic Syringe with Safety Needle

Predicate Device 2
510(k) Number: K083514
Product Name: TERUMO® Syringe with/without Needle

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

Cleanliness	Clause 5 of ISO 7886-1:1993
Limits for acidity or alkalinity	Clause 6 of ISO 7886-1:1993
Limits for extractable metals	Clause 7 of ISO 7886-1:1993
Lubricant	Clause 8 of ISO 7886-1:1993
Tolerance on graduated capacity	Clause 9 of ISO 7886-1:1993
Graduated scale	Clause 10 of ISO 7886-1:1993
Barrel	Clause 11 of ISO 7886-1:1993
Piston/ plunger assembly	Clause 12 of ISO 7886-1:1993
Nozzle	Clause 13 of ISO 7886-1:1993
Performance	Clause 14 of ISO 7886-1:1993

Cleanliness	Clause 4 of ISO 7864:1993
Limits for acidity or alkalinity	Clause 5 of ISO 7864:1993
Limits for extractable metals	Clause 6 of ISO 7864:1993
Size designation	Clause 7 of ISO 7864:1993
Colour coding	Clause 8 of ISO 7864:1993
Needle hub	Clause 9 of ISO 7864:1993
Sheath	Clause 10 of ISO 7864:1993
Needle tube	Clause 11 of ISO 7864:1993
Needle point	Clause 12 of ISO 7864:1993
Performance	Clause 13 of ISO 7864:1993

Materials	Clause 3 of ISO 9626:1991/AMD-1:2001
Surface finish	Clause 4 of ISO 9626:1991/AMD-1:2001
Cleanliness	Clause 5 of ISO 9626:1991/AMD-1:2001
Limits for acidity and alkalinity	Clause 6 of ISO 9626:1991/AMD-1:2001
Size designation	Clause 7 of ISO 9626:1991/AMD-1:2001
Dimensions	Clause 8 of ISO 9626:1991/AMD-1:2001
Stiffness	Clause 9 of ISO 9626:1991/AMD-1:2001
Resistance to breakage	Clause 10 of ISO 9626:1991/AMD-1:2001
Resistance to corrosion	Clause 11 of ISO 9626:1991/AMD-1:2001

Gauging	Clause 4.1 of ISO 594-1:1986
Liquid leakage	Clause 4.2 of ISO 594-1:1986
Air leakage	Clause 4.3 of ISO 594-1:1986
Separation force	Clause 4.4 of ISO 594-1:1986
Stress cracking	Clause 4.5 of ISO 594-1:1986

Gauging	Clause 4.1 of ISO 594-2:1998
Leakage	Clause 4.2 of ISO 594-2:1998
Separation force	Clause 4.3 of ISO 594-2:1998
Unscrewing torque	Clause 4.4 of ISO 594-2:1998
Ease of assembly	Clause 4.5 of ISO 594-2:1998
Resistance to overriding	Clause 4.6 of ISO 594-2:1998
Stress cracking	Clause 4.7 of ISO 594-2:1998

Sterile Barrier Packaging Testing performed on the proposed device:

Seal strength	ASTM F88/F88-09
Internal pressure	ASTM F1140/F1140M-13
Dye penetration	ASTM F1929-12

Sterilization and Shelf Life Testing performed on the proposed device:

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:

In Vitro Cytotoxicity	ISO 10993-5:2009
Intracutaneous Reactivity	ISO 10993-10:2010
Skin Sensitization	ISO 10993-10:2010
Acute Systemic Toxicity	ISO 10993-11:2006
Hemolysis	ASTM F756-13
Pyrogen	USP<151>
Complement Acitivation	ISO 10993-4:2002/A12006
In Vivo Thrombogenicity	ISO 10993-4:2002/A12006

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 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 the proposed device did not show a significant difference from predicate device.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 2 Comparison of Technology Characteristics of Proposed device & Predicate Devices

ITEM	Proposed Device K170651	Predicate Device 1 K113422	Predicate Device 2 K083514
Product Code	MEG, FMF, FMI	MEG, FMF	FMF, FMI
Regulation No.	21 CFR 880.5860, 21 CFR880.5570	21 CFR 880.5860, 21CFR 880.5570	21 CFR 880.5860
Class	CLASS II	CLASS II	CLASS II
Intended Use	The Sterile Disposable Syringe with Safety Needle is intended for use in the aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle sticks. The Sterile Disposable Syringe with Needle is intended for use in the aspiration and injection of fluids for medical purpose. The Sterile Disposable Syringe is a sterile luer 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 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. The Sterile Disposable Needle is intended to be used with a luer	The TERUMO® SurGuard® 3 Hypodermic Syringe with Safety Needle is intended for use in the aspiration and injection of fluids for medical purposes. The TERUMO® SurGuard® 3 Hypodermic Syringe with Safety Needle is compatible for use with standard luer slip and luer lock syringes. Additionally, 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 Terumo Syringe with/ without needle is a sterile hypodermic syringe for single use, intended for the aspiration of fluids and blood, or for the injection of fluids immediately after filling.

	slip or luer lock syringe for aspiration and injection of fluids for medical purpose.					
Configuration and material	Barrel	Polypropylene (PP)	Barrel	Unknown	Barrel	Unknown
	Plunger	Polypropylene (PP)	Plunger		Plunger	
	Piston	Polyisoprene	Piston		Piston	
	Needle hub	Polypropylene (PP)	Needle hub		Needle hub	
	Protective cap	Polypropylene (PP)	Protective cap		Protective cap	
	Needle tube	Stainless Steel (SUS304)	Needle tube		Needle tube	
	Safety sheath	Polypropylene (PP)	Safety sheath			
Operation Mode	For manual use only		Same		Same	
Label/Labeling	Complied with 21 CFR part 801		Complied with 21 CFR part 801		Complied with 21 CFR part 801	
Syringe Volume	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml		3ml, 5ml, 10ml		1ml, 2ml, 5ml, 10ml, 50ml	
Connector Type	Luer Lock/ Luer slip		Luer Lock/ Luer slip		Luer Lock/ Luer slip	
Syringe performance	Complied with ISO 7886-1: 1993		Complied with ISO 7886-1: 1993		Complied with ISO 7886-1: 1993	
Needle Gauge and length	16G,18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G Available in 5/16", 1/2", 5/8", 3/4", 1", 1-1/4", 1-1/2"		18G~25G Available in 1’’ to 2’’		20G~26G	
Biocompatibility	In Vitro Cytotoxicity	No cytotoxicity	Same		Same	
	Intracutaneous Reactivity	No intracutaneous reactivity				
	Skin Sensitization	No skin sensitization				
	Acute Systemic Toxicity	No systemic toxicity				
	Hemolysis	No Hemolysis				

	Pyrogen	No Pyrogen		
	Complement Acitivation	Not show potentials to activate complete system		
	In Vivo Thrombogenicity	No thrombogenicity		
Sterilization	EO Sterilization		Same	Same
SAL	10^{-6}		Same	Same
Single Use	Yes		Same	Same
Label/Labeling	Complied with 21 CFR part 801		Same	Same

The Sterile Disposable Syringe with Safety Needle, Sterile Disposable Safety Needle, Sterile Disposable Needle are similar to the predicate device K113422 in device design, Indications for use, materials, sterilization, method of operation and technological characteristics. The proposed device Sterile Disposable Syringe with Needle, Sterile Disposable Syringe are similar to the predicate device K083514 in device design, Indications for use, materials, sterilization, method of operation and technological characteristics. The differences are in needle lengths/gauges and barrel sizes. Through performance testing comparison the subject device and predicate device have demonstrated substantial equivalence.

9. Substantially Equivalent (SE) Conclusion

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