

## 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	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"

#### 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 Activation	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 &amp; 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	<p>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.</p> <p>The Sterile Disposable Syringe with Needle is intended for use in the aspiration and injection of fluids for medical purpose.</p> <p>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.</p> <p>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.</p> <p>The Sterile Disposable Needle is intended to be used with a luer</p>	<p>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.</p>	<p>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.</p>

	slip or luer lock syringe for aspiration and injection of fluids for medical purpose.			
Configuration and material	Barrel	Polypropylene (PP)	Barrel	Unknown
	Plunger	Polypropylene (PP)	Plunger	
	Piston	Polyisoprene	Piston	
	Needle hub	Polypropylene (PP)	Needle hub	
	Protective cap	Polypropylene (PP)	Protective cap	
	Needle tube	Stainless Steel (SUS304)	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 Activation	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.