October 4, 2019

Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.
℅ Charles Mack
Principal Engineer
Irc
2950 E Lindrick Drive
Chandler, Arizona 85249

Re: K190183
Trade/Device Name: Hypodermic Safety Needle, Hypodermic Safety Needle with Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG, FMF, FMI
Dated: September 03, 2019
Received: September 06, 2019

Dear Charles Mack:

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 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)*
K190183

Device Name
Hypodermic Safety Needle, Hypodermic Safety Needle with Syringe

Indications for Use *(Describe)*

Hypodermic Safety Needle with Syringe

The Hypodermic Safety Needle with Syringe 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.

Hypodermic Safety Needle

The Hypodermic Safety Needle 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 shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

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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K190183 510(K) SUMMARY

Preparation Date:	October 3rd 2019
Manufacturer's Name:	Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd. No. 2 Guanyin Road, Economic Development Zone, Taihu, Anqing City Anhui Province China 246400
Corresponding Official:	Mr. Charles Mack Principal Engineer
Telephone Number:	931-625-4938
E-mail Address:	charliemack@irc-us.com
Trade Name:	Hypodermic Safety Needle with Syringe Hypodermic Safety Needle
Common Name(s):	syringe, antistick syringe, piston needle, hypodermic, single lumen
Regulation Name(s):	Piston syringe Hypodermic single lumen needle
Regulation Number(s):	21 CFR 880.5860 21 CFR 880.5570
Product Code:	MEG FMF FMI
Device Class:	Class II
Primary Predicate Device:	K113422; Terumo Surguard 3 Safety Needle Terumo Surguard 3 Hypodermic Syringe With Safety Needle
Secondary Predicate Device:	K051865, Teumo Surguard 2 Safety Needle

Device Description

The device is used for subcutaneous injection, intramuscular injection, intravenous injection of blood and preparation of liquid medicine. The needle tube will be pushed into safety cap after use. It is designed to aid in the prevention of needle stick injuries.
This device is a single use device, which is delievered sterile.

The device is a disposable anti-needle stick syringe made of the following components:

1. Needle cap: Covers the needle tube until the syringe is to be used.

2. Needle tube: The needle tube penetrates the patient's skin to inject/withdraw fluid from the body.
3. Safety shield: It is connected to the needle hub. The needle will be pushed into safety shield after use, it is designed to aid in the prevention of needle stick injuries. It is colored to distinguish the gauge of the needle.
4. Needle hub: The needle hub is connected to the syringe by 6% luer connector, and it is colored to distinguish the gauge of the needle.
5. Barrel: The barrel has a scale showing the capacity of the syringe. It is connected to the Hypodermic Safety Needle by 6% luer connector.
6. Plunger: Assembled with the plunger stopper to inject/withdraw fluid from the body.
7. Plunger stopper: Sealing when injecting/withdrawing fluid from the body.

Name	Material	Material Specification
Needle cap	Polypropylene	1100N
Needle tube	Stainless Steel	SUS304
Needle hub	Polypropylene	1100N
Safety shield	Polypropylene	1100N
Barrel	Polypropylene	R3260T
Plunger stopper	Rubber Piston	n/a
Plunger	Polypropylene	1100N
Hub colorant	Colorant	PP-S1003
Ink	Organic chemical ink	HBL-100 709-V Black
Lubricant of syringe	Silicone oil for syringe	Polydimethylsiloxane
Lubricant of needle	Silicone oil for needles	Polydimethylsiloxane
Adhesive	Epoxy Resin	ZS-H-623

Indications for Use

Hypodermic Safety Needle with Syringe:
The Hypodermic Safety Needle with Syringe 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.

Hypodermic Safety Needle:
The Hypodermic Safety Needle 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 shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

The device is prescription only.

Intended Use

This device is intended to be used in a clinical environment by a medical professional.

Substantial Equivalence Discussion

Intended Use Comparison

The table below includes a comparison of the intended use between the new device and those of the predicate device:

Characteristic	**Predicate Device** TERUMO® SurGuard®3 K133422	**Predicate Device** TERUMO® SurGuard2™ SAFETY NEEDLE K051865	**Subject Device** Hypodermic Safety Needle with/without Syringe K190183
Indications for Use	The TERUMO® SurGuard®3 Safety Needle device is intended for use in the aspiration and injection of fluids for medical purposes. The TERUMO® SurGuard®3 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® SurGuard2™ SAFETY NEEDLE device is intended for use in the aspiration and injection of fluids for medical purposes. The Terumo 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.	**Hypodermic Safety Needle with Syringe** The Hypodermic Safety Needle with Syringe 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. **Hypodermic Safety Needle** The Hypodermic Safety Needle 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 shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.
Prescription Only or Over the Counter	Prescription Use	Prescription Use	Prescription Use
Intended Population	Adult	Adult	Adult
Environment of Use	Clinical Use	Clinical Use	Clinical Use

Discussions of differences in Indications for Use statement
The major difference between the Subject Device's Indications for Use and the predicate deviices lies in the use of the syringe. The Subject device can be provided with a syringe, where this is not identified in the predicate devices. All other aspects of the Indications for Use are the same.

Discussions of differences in intended population
The intended population for the subject device is identical to the predicate device.

Discussions of differences in environment of use
The environment of use for the subject device is identical to the predicate device.

Technological Characteristics

The table below includes a comparison of the technological characteristics between the new device and those of the predicate device:

Technological Characteristic	**Predicate Device** TERUMO® SurGuard®3 Safety Needle TERUMO® SurGuard®3 Hypodermic Syringe with Safety Needle K113422	**Subject Device** Hypodermic Safety Needle with/without Syringe K190183	**Comments**
Principles of operation	The Hypodermic Needle is a device that is composed of a typical hypodermic needle with a one-piece hub/adapter and pivoting cover that is connected to the adapter. The pivoting cover can be manually rotated forward after use allowing for secure encapsulation of the needlepoint, making the product safe for disposal. These needles have a regular, short, or intradermal bevel type. The needle assembly is protected with a polypropylene shield. The Hypodermic Needle contains a mechanism that covers the needlepoint after use. In the activated position, the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/ syringe combination.	The Hypodermic Needle is a device that is composed of a typical hypodermic needle with a one-piece hub/adapter and pivoting cover that is connected to the adapter. The pivoting cover can be manually rotated forward after use allowing for secure encapsulation of the needlepoint, making the product safe for disposal. These needles have a regular, short, or intradermal bevel type. The needle assembly is protected with a polypropylene shield. The Hypodermic Needle contains a mechanism that covers the needlepoint after use. In the activated position, the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/ syringe combination.	Same
Safety feature	The attached needle safety shield can be manually activated to cover the needle immediately after use	The attached needle safety shield can be manually activated to cover	Same

Technological Characteristic	**Predicate Device** TERUMO® SurGuard®3 Safety Needle TERUMO® SurGuard®3 Hypodermic Syringe with Safety Needle K113422	**Subject Device** Hypodermic Safety Needle with/without Syringe K190183	Comments
Operation Mode	Manual use only	Manual use only	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Syringe Volume	3,5,10 ml	5 ml	Comment 1
Connector Type	Luer Lock and luer slip	Luer Lock	Comment 2
Syringe Performance	Complied with ISO 7886-1: 1993	Complied with ISO 7886-1: 2017	Same
Configuration	A hypodermic needle with a hinged safety sheath attached to the connector hub with or without an attached hypodermic syringe.	A hypodermic needle with a hinged safety sheath attached to the connector hub with or without an attached hypodermic syringe.	Same
Marking/ Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Material	Polypropylene, Stainless Steel, Rubber Piston	Polypropylene, Stainless Steel, Rubber Piston	Same
Operation Mode	Manual Use	Manual Use	Same
Lubricant for needle	None	Silicone oil	N/A
Adhesive	Epoxy Resin	N/A	N/A
Needle Hub colors	Complies with ISO 6009-2010	Complies with ISO 6009-2010	Same
Single Patient Use	Yes	Yes	Same
Needle Gauge and Length	18G-25G 1" – 2"	21G x 1 ½"	Comment 3
How Supplied	Sterile Single Patient Use	Sterile Single Patient Use	Same
Method of Sterilization	Rx	Ethylene Oxide	Comment 4
SAL	10^{-6}	10^{-6}	Same

Technological Characteristic	**Predicate Device** TERUMO SURGUARD 2 SAFETY NEEDLE OR SIMILAR K051865	**Subject Device** Hypodermic Safety Needle with/without Syringe K190183	Comments
Principles of operation	The Terumo SurGuard2™ Safety Needle device with and without syringe manufactured by Terumo (Philippines) Corporation and Terumo Medical Corporation, USA (K040531 and K031453) and all referenced predicate devices are operated manually.	The Hypodermic Needle is a device that is composed of a typical hypodermic needle with a one-piece hub/adapter and pivoting cover that is connected to the adapter. The pivoting cover can be manually rotated forward after use allowing for secure encapsulation of the needlepoint, making the product safe for disposal. These needles have a regular, short, or intradermal bevel type. The needle assembly is protected with a polypropylene shield. The Hypodermic Needle contains a mechanism that covers the needlepoint after use. In the activated position, the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/ syringe combination.	Same
Safety feature	The attached needle safety shield can be manually activated to cover the needle immediately after use	The attached needle safety shield can be manually activated to cover	Same

Technological Characteristic	**Predicate Device** TERUMO SURGUARD 2 SAFETY NEEDLE OR SIMILAR K051865	**Subject Device** Hypodermic Safety Needle with/without Syringe K190183	Comments
Operation Mode	Manual use only	Manual use only	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Syringe Volume	1,3,5,10 ml	5 ml	Comment 5
Connector Type	Luer Lock and luer slip	Luer Lock	Comment 6
Syringe Performance	Complied with ISO 7886-1: 1993	Complied with ISO 7886-1: 2017	Same
Configuration	A hypodermic needle with a hinged safety sheath attached to the connector hub with or without an attached hypodermic syringe.	A hypodermic needle with a hinged safety sheath attached to the connector hub with or without an attached hypodermic syringe.	Same
Marking/ **Labeling**	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Material	Polypropylene, Stainless Steel, Rubber Piston	N/A	N/A
Operation Mode	Manual Use	Manual Use	Same
Lubricant for needle	None	Silicone oil	N/A
Adhesive	Epoxy Resin	N/A	N/A
Needle Hub colors	Complies with ISO 6009-2010	Complies with ISO 6009-2010	Same
Single Patient Use	Yes	Yes	Same
Needle Gauge and Length	18G-25G 1" – 2"	21G x 1 ½"	Comment 7
How Supplied	Sterile Single Patient Use	Sterile Single Patient Use	Same
Method of Sterilization	Rx	Ethylene Oxide	Comment 8
SAL	10^{-6}	10^{-6}	Same

Discussions of differences in technological characteristics

Comment 1

The predicate devices are offered with a wider variety of syringe volumes. This does not affect the operation of the device.

Comment 2

The subject is only offered in luer lock and the predicate is offered in luer lock and luer slip. This does not affect operation.

Comment 3
The submitted device is only offered in 21G x 1 ½", where the predicate is offered in a wider range of needle options.

Comment 4
The submitted device is sterilized by Ethylene Oxide, where the predicate is sterilized by radiation. The submitted device achieves the same level of sterility.

Comment 5
The predicate devices are offered with a wider variety of syringe volumes. This does not affect the operation of the device.

Comment 6
The subject is only offered in luer lock and the predicate is offered in luer lock and luer slip. This does not affect operation.

Comment 7
The submitted device is only offered in 21G x 1 ½", where the predicate is offered in a wider range of needle options.

Comment 8
The submitted device is sterilized by Ethylene Oxide, where the predicate is sterilized by radiation. The submitted device achieves the same level of sterility.

Performance Testing

The following bench testing was performed and reviewed to support the substantial equivalence of the subject device:

- ISO 9626: 2016-08-01, Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods.
- ISO 7864: 2016-08-01, Sterile hypodermic needles for single use — Requirements and test methods.
- ISO 594-1:1986-06-15, Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements.
- ISO 594-2: 1998-09-01, Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings.
- ISO 23908: 2011-06-11, Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.
- ISO 7886-1: 2017-05, Sterile hypodermic syringes for single use — Part 1: Syringes for manual use.
- ISO 6009 Fourth edition 2016-08-01, Hypodermic needles for single use - Colour coding for identification.

Simulated Clinical Study

We conducted the simulated clinical study per the FDA Guidance titled "Medical Devices with Sharps Injury Prevention Features" (Issued on August 9, 2005) for the subject devices, and the testing result demonstrated that there were no failures of the safety feature of the Hypodermic Safety Needle with Syringe.

All of the pre-determined acceptance criteria were met.

Biocompatibility

The new device complies with the biocompatibility requirement defined in ISO10993-1 (Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process). Patient contact classification: External Communicating Device - Blood Path, Indirect - Prolonged Contact Duration (24 hours -30 days). The verification test shows that the new devices comply with the biocompatibility requirement defined in ISO10993-1, the same as the predicate devices.

- In Vitro Cytotoxicity (ISO10993-5: 2009)
- Skin Sensitization (ISO10993-10: 2010)
- Intracutaneous Reactivity Test (ISO10993-10: 2010)
- Acute Systemic Toxicity (ISO10993-11: 2006)
- Coagulation test (ISO10993-4: 2002Amd1:2006(E)
- Complement activity Test (ISO10993-4: 2002 Amd1: 2006(E)
- Hemolytic Properties Test (ASTM F756-13)
- Pyrogen Test (ISO 10993-11:2006)
- Subacute/Subchronic Toxicity Testing
- USP 788 Particulate Matter in Injections

All of the pre-determined acceptance criteria were met.

Sterility Information

The devices are EO sterilized. The sterilization validation conducted according to the standards noted below:

- ISO11135-1:Second Edition 2014, Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO11737-1: 2006, Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products
- ISO11737-2: 2009, Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ISO 10993-7: 2008(R) 2012, Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
- ANSI/AAMI ST72:2011 (R) 2016, Bacterial Endotoxins - Test Methods, Routine Monitoring, And Alternatives To Batch Testing

Package and Shelf Life:

We conducted the below package and shelf life verification test to support the shelf life claim according standards noted below::

- AAMI/ANSI/ISO 11137-1:2006/(R) 2010, Sterilization of health care products — Radiation — Part 2: Requirements for development, validation, and routine control of a sterilization process for medical devices.
- AAMI/ANSI/ISO 11737-2:2009, Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.

- AAMI/ANSI/ISO 11607-1:2006/(R) 2010, Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging systems.
- ASTM F1929-98 (2004), Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.
- ASTM F1980-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM D3078-02 (2008) , Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
- ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials

The test conducted as below:
- Product Performance Inspection (Chemical performance and Physical performance)
- Sterile Test
- Vacuum Leak Test
- Dye penetration test
- Agar Contact-Attack Test
- Tensile Seal Strength Test
- Accelerated Aging Test

The test result supports the 5 years shelf life claim for the subject device from the sterilization date.

All of the pre-determined acceptance criteria were met.

Clinical Tests

Not Applicable

Conclusions

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Hypodermic Safety Needle with Syringe and Hypodermic Safety Needle is substantially equivalent to the Terumo Surguard 3 Safety Needle Terumo Surguard 3 Hypodermic Syringe With Safety Needle cleared under K113422 and the Terumo Surguard 2 Safety Needle cleared under K051865 with respect to the indications for use, target populations, treatment method, and technological characteristics.