May 18, 2018

Jiangsu Shenli Medical Production Co., Ltd
c/o Mr. Charles Mack
IRC
2950 E Lindrick Drive
Chandler, Arizona 85249

Re: K180259
Trade/Device Name: Sterile Hypodermic Needle for Single Use
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: April 6, 2018
Received: April 17, 2018

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. 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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K180259

Device Name
Sterile Hypodermic Needle for Single Use

Indications for Use *(Describe)*
This device is intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

The assigned 510(k) number is: K180259
Date Prepared: 2018.05.15

I. Submitter:

Name: Jiangsu Shenli Medical Production Co., Ltd.
Address: No 20, Changzheng Road, Zhenglu,
Changzhou City, Jiangsu Province, China 213111
Tel: + 86-519-88731071
Fax: + 86-519-88737101
Contact: Ms. Tina Cai, General Manager

US Agent and Correspondent
Mr. Charles Mack
Principal Engineer
IRC
2950 E Lindrick Drive, Chandler, Arizona 85249 USA
Tel: 931-625-4938
Email: charliemack@irc-us.com

II. Device:

Trade/proprietary name: Sterile Hypodermic Needle for Single Use
Common Name: needle, hypodermic, single lumen
Classification Name: Hypodermic single lumen needle

Classification Information:
Product Code: FMI
Device Class: II
Regulation number: 21CFR880.5570

III. Predicate Device Information:

Manufacturer	Predicate Device	510(k) Number	Submitted Device
International Medsurg Connection	IMC Hypodermic Needle	K102584	Sterile Hypodermic Needle for Single Use

IV. Device Description:

The submitted device is a sterile hypodermic needle for single use. The device is a single lumen hypodermic needle offered in a 22 gauge x 1 ½ " length. The device is constructed of the material noted in the table below:

Name	Material	Material Specification
Needle tube	304 stainless steel	SUS304
Needle hub	Polypropylene (PP)	R307Y
Needle cap	Polypropylene (PP)	R307Y
Hub colorant	Black Masterbatch	Carbon Black
Lubricant	Medical Highly Activated Silicone	Highly Reactive Silicone Oil
Adhesive	Ultraviolet adhesive	AA 3311

The device is classified for patient contact as externally communicating circulating blood in a limited contact duration (<24h).

V. Intended use / Indication for Use:

This device is intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

VI. Comparison of Technological Characteristics with the Predicate Device

Feature	Subject Device	Predicate Device
Company	Jiangsu Shenli Medical Production Co., Ltd	International Medsurg Connections, Inc.
FDA510(K) Number	K180259	K102584
Device Name	Sterile Hypodermic Needle for Single Use	IMC Hypodermic Needle
FDA Classification	21CFR880.5570, Product code- FMI	21CFR880.5570, Product code- FMI
Indication for Use	This device is intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.	This device is intended for use to inject fluids into or withdraw fluids from parts of the body below the surface of the skin.
Needle Gauge and Length	22Gx1 1/2"	Gauge: 16G, 17G, 18G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G Length: 1/2", 5/8", 3/4", 7/8", 1", 1 1/4", 1 1/2"
Lubricant for needle	Medical Highly Activated Silicone	Medical Highly Activated Silicone
Adhesive	UV-cured Adhesive	Epoxy Resin
Needle Hub Colors	22G Black color	16G White color 17G Red-violet color 18G Pink color 20G Yellow color 21G Deep green color 22G Black color 23G Deep blue color 24G Medium purple color 25G Orange color 26G Brown color 27G Medium gray color 28G Blue-green color

		29G Red color 30G Yellow color
Cover Dimensions	1 1/2" size:54.3 (+1.5 -2.5) mm	1/2 " size:40mm 5/8" size:40mm 3/4" size:40mm 7/8" size:40mm 1" size:40mm 1 ¼ " size:56mm 1 ½ " size:56mm
Cover Color	Clear	Clear (for all gauges)
Hub/needle Bond Strength	Test Method: ISO 7894:1993 Meets Standard Criteria	Test Method: ISO 7894:1993 Meets Standard Criteria
Tip Configuration	Bevel	Bevel
Materials:		
Needle	Stainless Steel, SUS304	Stainless Steel, SUS304
Needle Hub	Polypropylene (PP)	Polypropylene (PP)
Needle cap	Polypropylene (PP)	Polypropylene (PP)

Summary of technological characteristics / performance

The sterile hypodermic needle for single use has substantially equivalent indications for use and technological characteristics as the predicate device.

1) The sterile hypodermic needle for single use have the same intended use/indication for use as the predicate device.
2) The same technologies and test principles are used in sterile hypodermic needle for single use as the predicate device.
3) The identified differences in technological characteristics do not raise new or different questions of safety and effectiveness than the predicate devices.
4) Although some specifications are slightly different than the predicate device (adhesive and hub color additive), changes have been verified and validated as part of performance testing and are included as part of this submission. Performance information and evidence of compliance to recognized standards demonstrate the device is substantially equivalent to the predicate device.

Biocompatibility testing includes cytotoxicity, sensitization, irritation, acute systemic toxicity, coagulation, complement activity (C3a, SC5b-9), hemolytic properties tests, and material-mediated pyrogenicity.

For the package integrity and shelf life, tensile seal strength test, package verification test, vacuum leak

test, dye penetration test, agar contact-attack test as well as accelerated aging testing is included. The test results provide evidence that the subject device complies with the same applicable standards as predicate device and is substantially equivalent to the predicate device.

Feature	Subject Device	Predicate Device
Biocompatibility	Complies with ISO10993-1	Complies with ISO10993-1
Sterilization	EO	EO
Sterile	Yes	Yes
SAL	10^{-6}	10^{-6}
Disposable	Yes	Yes
Single Patient Use	Yes	Yes

Based upon the intended use, and upon the similarity of materials, product configuration and administration, it can be concluded the sterile hypodermic needle for single use is substantially equivalent to the identified predicate device.

VII. Performance Data

Performance testing was provided in support of the substantial equivalence determination and to validate and verify that sterile hypodermic needle for single use met all requirements of related international standards, including biocompatibility, sterility, and product specifications. Results of these tests demonstrate compliance to the requirements of the below consensus standards.

Performance Testing

The device meets all performance standards for Sterile Hypodermic Needle:

- ISO 9626 Second edition 2016-08-01 Stainless steel needle tubing for the manufacture of medical devices -Requirements and test methods
- ISO 7864 Fourth edition 2016-08-01 Sterile hypodermic needles for single use - Requirements and test Methods
- ISO 594-1 First edition 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 Second edition 1998-09-01 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
- ISO 6009 Fourth edition 2016-08-01 Hypodermic needles for single use - Colour coding for identification

For the finished device, it meets the defined performance requirements through bench testing.

Biocompatibility

The new device complies with the biocompatibility requirement defined in ISO10993-1. Patient contact classification: External Communicating Device - Blood Path, Indirect - Limited Contact Duration (<24h). The verification test shows that the new devices comply with the biocompatibility requirement defined in ISO10993-1 same as predicate device.

Verification Test	Standards/Method
In Vitro Cytotoxicity	ISO10993-5: 2009 MTT Method
Skin Sensitization	ISO10993-10: 2010 GPMT Method: Guinea Pig Maximization Test (0.9% Sodium Chloride and corn oil Extract)
Intracutaneous Reactivity Test	ISO10993-10: 2010 Intracutaneously inject the extract to rabbit (0.9% Sodium Chloride and corn oil Extract)
Acute Systemic Toxicity	ISO10993-11: 2006 Extract to cause acute systemic toxicity in mouse (0.9% Sodium Chloride and corn oil Extract)
Coagulation test	ISO10993-4: 2002Amd1:2006(E) Test the values of APTT, PT, TT, Fibrinogen after whole blood extracting.
Complement activity (C3a, SC5b-9) Test	ISO10993-4: 2002Amd1: 2006(E) Test the values of C3a, SC5b-9 after whole blood extracting.
Hemolytic Properties Test	ASTM F756-13. Calculate the values of blank corrected % hemolysis after calcium and magnesium-free PBS
Material- Mediated Pyrogenicity	ISO 10993-11 :2006. Rabbit pyrogen test; USP 40 <151> Pyrogen Test;

Sterility Information

Summary of Sterilization Validation is provided in the table below:

Sterilization Method:	Ethylene Oxide Sterilization
Standards:	ISO11135-1: Sterilization of health care products - ethylene oxide - part 1: requirements for the development, validation, and routine control of a sterilization process for medical devices. ISO11737-1: Sterilization of medical devices - Microbiological methods - Part 1: Determination of the population of microorganisms on product. ISO11737-2: Sterilization of medical devices - Microbiological methods -- Part 2: Tests of sterility performed in the validation of a sterilization process. ISO 10993-7: Biological evaluation of medical devices - Part 7: Test of Ethylene Oxide Residuals. AAMI / ANSI ST72: Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing.

VIII. Conclusions:

The non-clinical data demonstrate that the sterile hypodermic needle for single use perform as intended in the specified use conditions. Based on the information provided in this submission, Jiangsu Shenli Medical Production Co., Ltd. believes that the sterile hypodermic needle for single use is substantially equivalent to the predicate (K102584) IMC Hypodermic Needle (International Medsurg Connection).