October 18, 2021

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

Re: K211555
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: August 13, 2021
Received: August 18, 2021

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,

CAPT Alan M. 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211555

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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安徽宏宇五洲医疗器械股份有限公司
ANHUI HONGYU WUZHOU MEDICAL MANUFACTURER CO., LTD

K211555 510(k) SUMMARY

Preparation Date:	August 25, 2020
Manufacturer's Name and Address:	Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd. No. 2 Guanyin Road, Economic Development Zone, Taihu, Anqing City, Anhui Province, China 246400
Corresponding Official:	Charles Mack
Telephone Number:	931-625-4938
Email Address:	charliemack@irc-us.com
Trade Name:	Hypodermic Safety Needle Hypodermic Safety Needle with Syringe
Common Name(s):	syringe, antistick syringe, piston needle, hypodermic, single lumen
Regulation Name(s):	Hypodermic single lumen needle Piston syringe
Regulation Number(s):	21CFR880.5570 21CFR880.5860
Product Code:	MEG FMI FMF
Device Class:	Class II
Predicate Device:	K190183 Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.

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 the safety cap after use. It is designed to aid in the prevention of needlestick injuries.

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 a safety shield after use, and it is designed to aid in the prevention of needlestick injuries. It is colored to distinguish the gauge of the needle.
4. Needle hub: The needle hub is connected to the syringe by a 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 a 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	Manufacturers
Needle cap	PP	1100N	Advanced Petrochemical Company
Needle tube	Stainless Steel	SUS304	Zhangjiagang Puxiang Stainless Steel Co., Ltd.
Needle hub	PP	1100N	Advanced Petrochemical Company
Safety shield	PP	1100N	Advanced Petrochemical Company
Barrel	PP	R3260T	Zhejiang Hongji Petrochemical Co., LTD.
Plunger stopper	Rubber Piston	/	Changzhou Huawei Medical Supplies Co., Ltd
Plunger	PP	1100N	Advanced Petrochemical Company
Colorant-green	PP green Masterbatch	2893657	Seyuan technology (Suzhou) Co., Ltd.

Name	Material	Material Specification	Manufacturers
Colorant-black	PP Black Masterbatch	PLK 001 Med3	Anhui Jingwei Medical Materials Technology Co. LTD
Colorant-blue	PP Blue Masterbatch	BLU 001 Med3	Anhui Jingwei Medical Materials Technology Co. LTD
Colorant-brown	PP Brown Masterbatch	Brown P608397BN	Anhui Jingwei Medical Materials Technology Co. LTD
Colorant-cream	PP Yellow Masterbatch	Cream P608369GN	Anhui Jingwei Medical Materials Technology Co. LTD
Colorant-medium grey	PP Medium grey Masterbatch	Medium grey	Anhui Jingwei Medical Materials Technology Co. LTD
Colorant-medium purple	PP Medium purple Masterbatch	Medium purple P608366PL	Anhui Jingwei Medical Materials Technology Co. LTD
Colorant-Orange	PP Orange Masterbatch	Orange P608370-10G	Anhui Jingwei Medical Materials Technology Co. LTD
Colorant-Pink	PP R3260T	Pink P608536 (197C)	Anhui Jingwei Medical Materials Technology Co. LTD
Colorant-Red	PP Red Masterbatch	Red P608539 (198C)	Anhui Jingwei Medical Materials Technology Co. LTD
Colorant-Yellow	PP Yellow Masterbatch	Yellow P608368YL	Anhui Jingwei Medical Materials Technology Co. LTD
Ink	Organic chemical ink	HBL-100 709-V Black	Hangzhou Hengji ink coating co., Ltd.
Lubricant of syringe	Silicone oil for syringe	Polydimethylsiloxane	Wuhan WuZhao Chemical Industry Limited Company
Lubricant of needle	Silicone oil for needles	Polydimethylsiloxane	Wuhan WuZhao Chemical Industry Limited Company
Adhesive	Epoxy Resin	ZS-H-623	Dongguan zhisheng industrial co., Ltd.

Patient contact classification: External Communicating Device - Blood Path, Indirect - Prolonged Contact Duration (24 hours -30 days).

Intended Use / Indications for Use

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.

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.

Item	Subject Device	Predicate Device	Reference Device	Discussion
510(k)	K211555	K190183	K060211	-
510K Owner	Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.	Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.	Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd. (currently)	-
Name	Hypodermic Safety Needle with/without Syringe	Hypodermic Safety Needle with/without Syringe	Wuzhou Syringe with/without Needle	-
Product code	MEG, FMF, FMI	MEG, FMF, FMI	FMF, FMI	-
Indication for Use	**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. **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. **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.	The Wuzhou Syringe, with/without needle for single use only, is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.	Identical to the predicate device *(No change)*

Item	Subject Device	Predicate Device	Reference Device	Discussion
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 the needle immediately after use	There is no safety shield.	Identical to the predicate device *(No change)*
Operation Mode	Manual use only	Manual use only	Manual use only	Identical *(No change)*
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Identical *(No change)*
Material	PP, Stainless Steel, Rubber Piston	PP, Stainless Steel, Rubber Piston	PP, Stainless Steel, Rubber Piston	Identical *(No change)*
Operation Mode	Manual Use	Manual Use	Manual Use	Identical *(No change)*
Performance	Complied with the current applicable performance standards: - ISO 9626 - ISO 7864 - ISO 594-1 - ISO 594-2 - ISO 23908 - ISO 7886-1	Complied with the current applicable performance standards: - ISO 9626 - ISO 7864 - ISO 594-1 - ISO 594-2 - ISO 23908 - ISO 7886-1	Complied with the current applicable performance standards: - ISO 9626 - ISO 7864 - ISO 594-1 - ISO 594-2 - ISO 7886-1	Identical to the predicate device *(No change)*
Needle Length	1/6" ~ 1 1/2"	21 G x 1 1/2"	1/6" ~ 1 1/2"	*Note 1*
Syringe Volume	1,2,3,5,10,20,30,50,60,100 ml	5ml	1,2, 5,10,20,30,60,100 ml	*Note 2*
Needle Gauge	18,19,20,21,22,23,24,25,26,27,28,29,30G	21G	16,18,20,21,22,23,24,25,26G	*Note 3*
Needle Hub	Color-coded per ISO 6009	Color-coded per ISO 6009	Color-coded per ISO 6009	*Note 4*
Single Patient Use	Yes	Yes	Yes	*Identical (No change)*
Biocompatibility	Conforms to ISO 10993-1	Conforms to ISO 10993-1	*Conforms to ISO 10993-1*	*Identical (No change)*
How Supplied	Sterile Single Patient Use	Sterile Single Patient Use	Sterile Single Patient Use	Identical *(No change)*
Method of Sterilization	EO	EO	EO	Identical *(No change)*
SAL	10^{-6}	10^{-6}	10^{-6}	Identical *(No change)*

Note 1: Needle Length

The needle length of the subject devices is available in more sizes than the predicate device, but they conform to the same applicable performance standards as the predicate device. The difference does not raise new questions of safety and effectiveness.

Note 2: Syringe Volume

The subject devices' syringe volume is different than the predicate device and still conforms to the same applicable performance standards. The difference does not raise new questions of safety and effectiveness.

Note 3: Needle Gauge

The needle gauge of the subject devices has a wider range compared to the predicate device. However, the performance of the needle has been evaluated, and test results demonstrated compliance with the same applicable performance standards. The difference does not raise new questions on the safety and effectiveness of the proposed device.

Note 4: Needle Hub

The needle hub material of the subject device and predicate device all conform to ISO 6009 and ISO10993.

Performance Testing

Performance testing was provided to support the substantial equivalence determination and validate and verify that the Hypodermic Safety Needle with/without Syringe met all requirements of related international standards, including biocompatibility, sterility, and product specifications. The results of these tests demonstrate compliance with the requirements of the consensus standards noted below.

Non-clinical Testing

Performance Testing

For Hypodermic Safety Needle with/without Syringe, it meets all performance standards:

- ISO 7886-1 Second edition 2017-05 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
- 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 23908 First edition 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 6009 Fourth edition 2016-08-01 Hypodermic needles for single use - Color coding for identification

Biocompatibility

There was no change in the device components, which are subject to biocompatibility testing. Therefore no biocompatibility testing was performed. Patient contact classification: externally communicating devices, contact circulating blood for limited contact (<24 h) duration. This remains the same classification as the initial submission.

Sterility Information

There was no change in the sterilization process or materials involved with the sterilization, packaging materials, or product materials. The product adoption was done in accordance with ISO 11135:2014 Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices and AAMI TIR28:2016 Product adoption and process equivalence for ethylene oxide sterilization.

Clinical Test:

No clinical study is included in this submission.

Conclusions:

Based on the verification test results, the subject devices conform to the same applicable standards requirements such as performance, biocompatibility, and sterilization as the predicate device. The subject device uses the same fundamental scientific technology, same indications for use, same safety feature, the same method of sterilization, and the same shelf life and packaging. The differences do not raise new questions of safety and effectiveness, and the devices are substantially equivalent to the predicate.