November 4, 2022

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

Re: K222124
Trade/Device Name: Sterile Hypodermic Syringe with/without Needle, Sterile Hypodermic Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI
Dated: August 3, 2022
Received: August 8, 2022

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,

Alan M. Stevens -S3

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)*

K222124

Device Name
Sterile Hypodermic Syringe with/without needle
Sterile Hypodermic Needle

Indications for Use *(Describe)*

Sterile Hypodermic Syringe with/without needle
The Sterile Hypodermic Syringe with/without needle is intended for use in the aspiration and injection of fluids for medical purposes.

Sterile Hypodermic Needle
The Sterile Hypodermic Needle is intended to be used with a syringe for fluids aspiration and injection for medical purposes.

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

K222124 510(k) SUMMARY

Preparation Date:	November 4, 2022
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:	Sterile Hypodermic Syringe with/without Needle Sterile Hypodermic Needle
Common Name(s):	syringe, piston
Regulation Name(s):	Piston Syringe
Regulation Number(s):	21CFR 880.5860
Product Code:	FMF, FMI
Device Class:	Class II
Predicate Device:	K060211 Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.

Device Description:

The Sterile Hypodermic Syringe with/without needle is intended for use in the aspiration and injection of fluids for medical purposes.

The Sterile Hypodermic Needle is intended to be used with a syringe for fluids aspiration and injection for medical purposes.

It is intended for the patient population, including adults, transitional adolescents, adolescents, and children.

The device is intended for use in a professional healthcare facility.
Warning: MR-unsafe!
Do not expose the device to a magnetic resonance (MR) environment.

- -The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.
- -Thermal injury and burns may occur due to the metal components of the device that can heat during MR scanning.
- -The device may generate artifacts in the MR image.
- -The device may not function properly due to the strong magnetic and radio frequency fields generated by the MR scanner.

The device is a disposable syringe made of the following components:

Needle cap: Covers the needle tube until the syringe is used.
Needle tube: The needle tube penetrates the patient's skin to inject/withdraw fluid from the body.
Needle hub: The needle hub is connected to the syringe by a 6% luer connector, which is colored to distinguish the gauge of the needle.
Barrel: The barrel has a scale showing the capacity of the syringe. It is connected to the Hypodermic Needle by a 6% luer connector.
Plunger: Assembled with the plunger stopper to inject/withdraw fluid from the body.
Plunger stopper: Sealing when injecting/withdrawing fluid from the body.

Indications for Use

Sterile Hypodermic Syringe with/without needle

The Sterile Hypodermic Syringe with/without needle is intended for use in the aspiration and injection of fluids for medical purpose.

Sterile Hypodermic Needle

The Sterile Hypodermic Needle is intended to be used with a syringe for fluids aspiration and injection for medical purposes.

Item	Subject Device	Predicate Device *(own)*	Discussion
510(k)	Pending	K060211	-
Manufacturer	Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.	Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.	-
Name	Sterile Hypodermic Syringe with/without needle Sterile Hypodermic Needle	Wuzhou Syringe with/without Needle	-
Product code	FMF, FMI	FMF, FMI	-
Indication for Use	**Sterile Hypodermic Syringe with/without needle** The Sterile Hypodermic Syringe with/without needle is intended for use in the aspiration and injection of fluids for medical purposes. **Sterile Hypodermic Needle** The Sterile Hypodermic Needle is intended to be used with a syringe for fluids aspiration and injection for medical purposes.	The Wuzhou Syringe, with/without a needle is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.	Note 0

Item	Subject Device	Predicate Device (own)	Discussion
Operation Mode	Manual use only	Manual use only	Identical
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	
Material	PP, Stainless Steel, Rubber Piston	PP, Stainless Steel, Rubber Piston	Identical
Needle Length	1/6”-2”	1/6’’ ~ 1 1/2’’	*Note 1*
Syringe Volume	1,2,2.5,3,5,10,20,30,50,60,100 ml	1,2, 5,10,20,30,50,60,100 ml	*Note 2*
Needle Gauge	15,16,17,18,19,20,21,22,23,24,25,26, 27,28,29,30G	16,18,20,21,22,23,24,25,26G	*Note 3*
Needle Hub	Color-coded per ISO 6009	Color-coded per ISO 6009	*Note 4*
Performance	Complied with the current applicable performance standards: - ISO 9626 - ISO 7864 - ISO 80369-7 - ISO 80369-20 - ISO 7886-1	Complied with the current applicable performance standards: - ISO 9626 - ISO 7864 - ISO 594-1 - ISO 594-2 - ISO 7886-1	*Note 5*
Single Patient Use	Yes	Yes	Identical
Biocompatibility	Conforms to ISO 10993-1	Conforms to ISO 10993-1	Identical
How Supplied	Sterile Single Patient Use	Sterile Single Patient Use	Identical
Sterilization	EO	EO	Identical
SAL	10^{-6}	10^{-6}	Identical

Note 0: Indication for Use

The Indications for Use for the subject device is slightly different from the predicate device. The intended use is the same for both devices.

Note 1: Needle Length

The needle length of the subject devices is available in more sizes than the predicate device. The difference does not raise new questions on the safety and effectiveness of the proposed device.

Note 2: Syringe Volume

The subject devices' syringe volume is different than the predicate device but is within the same range. The difference does not raise new questions about the safety and effectiveness of the proposed device.

Note 3: Needle Gauge

The needle gauge of the subject devices is a more different from the predicate device. T*he difference does not raise new questions about the safety and effectiveness of the proposed device.*

Note 4: Needle Hub

The needle hub's material and colorant of the subject device is identical to the predicate device and all conform to ISO 6009 and ISO 10993.

Note 5: Performance

The subject device conforms to the current FDA recognize standards ISO80369-7 and ISO80369-20, which will replace ISO594-1 and ISO594-2.

Performance Testing

To establish substantial equivalence to the identified predicate device, we performed the tests noted below on the subject devices. The testing results proved that the device complies with the applicable standards requirement and is substantially equivalent to the predicate devices.

Non-Clinical Performance Testing

Testing was performed to evaluate the functional performance and safety of the subject device with the following standards:

Performance:

- 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 80369-7 First edition 2016-10-15 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
- ISO 80369-20 First edition 2015-05-15, small-bore connectors for liquids and gases in healthcare applications part 20: standard test methods. (General I (QS/RM))
- ISO 6009 Fourth edition 2016-08-01 Hypodermic needles for single use - Colour coding for identification

Biocompatibility

The subject device is classified as an external communication device → Circulating Blood → Limited Contact Duration (≤24h).

ISO 10993-5: 2009 In Vitro Cytotoxicity

ISO 10993-10: 2010 Sensitization

ISO 10993-10: 2010 Intracutaneous Reactivity

ISO 10993-11: 2017 Acute Systemic Toxicity

ISO 10993-4:2017 Coagulation

ISO 10993-4: 2017 Complement activity

ISO 10993-4: 2017 & ASTM F756-17: Hemolytic Properties

Sterilization Validation:

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.

Package and Shelf Life:

Applicable Standards:

AAMI/ANSI/ISO 11137-1:2006/(R) 2010 Sterilization of health care products - Radiation - Part 1: 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, 3ed.

ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM D3078-02 (2021), Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission. (Sterility)
DIN58953-6: 2016 Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized.
ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials

The package integrity test noted below was conducted for the sterilization package of the subject devices by accelerated aging testing followed by simulated shipping distribution testing:

- Accelerated Aging Test
- Simulated shipping distribution testing
- Visual inspection
- Performance Inspection (Chemical performance and Physical performance)
- Sterile Test
- Vacuum Leak Test
- Dye penetration test
- Agar Contact-Attack Test
- Tensile Seal Strength Test

Clinical Performance Data
No clinical data was submitted in this submission.

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