November 30, 2023

Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.
% Evan Hu
Technical and Regulatory Director
Shanghai Mind-link Consulting Co., Ltd.
1399 Jiangyue Road, Minhang
Shanghai, Shanghai 201114
China

Re: K230061
Trade/Device Name: Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: June 19, 2023
Received: November 28, 2023

Dear Evan Hu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K230061

Device Name
Insulin Syringe

Indications for Use *(Describe)*
Insulin syringes are intended for subcutaneous injection of U-100 insulin

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.

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K230061 510(k) Summary

1. Preparation date: 06/19/2023

2. Submitter
   Manufacturer: Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd
   Address: No.2 Guanyin Road, Taihu Economic Development Zone
   Contact person: Xiang Bingyi, 86-556 5129666, hwj1@hongyu-wuzhou.cn
   Submission correspondent: Evan Hu, 86-18616124827, Evan.ww.hu@outlook.com

3. Device
   Trading name: Insulin Syringe
   Common name: Insulin Syringe
   Regulation No.: 21 CFR 880.5860
   Classification name: Piston Syringe
   Classification: Class II
   Product code: FMF

4. Predicate device

   Predicate device: K220061-Safety Insulin Syringe

5. Device description
   The insulin syringe consists of needle cap, barrel, plunger, plunger stopper, needle tube and plunger cap. It is sterile disposable, non-pyrogenic, easy to use and meets all of the required standards. The plunger cap is optional. The single insulin syringe in unit package lacks the plunger cap compared with the product in the multi-unit package.
   The needle cap is used to protect physical protection of the needle prior to use. The needle tube penetrates the patient's skin to inject fluid into the body. The plunger stopper is the sealing assembly that encloses mandrel component and is used to inject fluid into the body. The barrel is a tube-like and cylindrical structure that holds insulin before the injection. The plunger is the rod pushed down or up depending on clinical use. The plunger cap is used to protect plunger before use.
   The capacity of the insulin device is 0.3 mL, 0.5 mL and 1 mL. The specification of needle tube is 26G, 27G, 28G, 29G, 30G, 31G, 32G and 33G. The needle length is 5 mm, 6 mm, 8 mm and 10 mm.

Table 1 Device specification

Syringe unit scale	Capacity (mL)	Needle gauge	Needle length					Wall type	Bevel angle
			5mm 3/16”	6mm 1/4”	8mm 5/16”	10mm 3/8”	13mm 1/2”	Regular wall and Thin wall	Long and short bevel
U-100 (Orange)	0.3	33G	√	√	√	√	√	√	√
		32G	√	√	√	√	√	√	√
		31G	√	√	√	√	√	√	√
		30G	√	√	√	√	√	√	√
		29G	√	√	√	√	√	√	√
		28G	-	√	√	√	√	√	√
		27G	-	√	√	√	√	√	√
		26G	-	√	√	√	√	√	√
	0.5	33G	√	√	√	√	√	√	√
		32G	√	√	√	√	√	√	√
		31G	√	√	√	√	√	√	√
		30G	√	√	√	√	√	√	√
		29G	√	√	√	√	√	√	√
		28G	-	√	√	√	√	√	√
		27G	-	√	√	√	√	√	√
		26G	-	√	√	√	√	√	√
	1	33G	√	√	√	√	√	√	√
		32G	√	√	√	√	√	√	√
		31G	√	√	√	√	√	√	√
		30G	√	√	√	√	√	√	√
		29G	√	√	√	√	√	√	√
		28G	-	√	√	√	√	√	√
		27G	-	√	√	√	√	√	√
		26G	-	√	√	√	√	√	√

“√” means that it is applicable in this configuration.

6. Indications for use
   Insulin syringes are intended for subcutaneous injection of U-100 insulin.

7. Comparison of technological characters between proposed and predicate device

   7.1 Comparison of technological characters
   Table 2 Comparison table

Characters	Proposed device (K230061, Insulin syringe)	Primary predicate device (K220061, Safety Insulin Syringe)	Remark
Product code	FMF	FMF, MEG	Different #1
Regulation No.	21CFR 880. 5860	21CFR 880. 5860	Same
Indications for use	Insulin syringes are intended for subcutaneous injection of U-100 insulin.	The Safety Insulin Syringe is a sterile, single use and non-reusable syringe intended for injection of U-100 insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse.	Different #2
Environment of use	Prescription use	Prescription use	Same
Specific drug use	U-100 Insulins	U-100 Insulins	Same
Single use	Yes	Yes	Same
Label/labeling	Conforming to 21 CFR part 801	Conforming to 21 CFR part 801	Same
Non-pyrogenic	Yes	Yes	Same
Gauge size	26G, 27G, 28G, 29G, 30G, 31G, 32G, 33G	26G to 34G	Different #3
Needle length	5 mm, 6 mm, 8 mm, 10 mm, 13 mm	4 mm, 5 mm, 6 mm, 8 mm, 9 mm, 10 mm, 12 mm, 13 mm	Different #4
Hub/Needle bond strength	Min force: 70~110N Conforming to ISO 8537: 2016	Conforming to ISO 8537: 2016	Same
Needle wall type	RW, TW	RW, TW, ETW	Different #5

Needle tip and bevel	Sharp tip Bevel: Long beveled, short beveled	Sharp tip Bevel: unknown	Different #6
Configuration and materials	Needle cap: Polyethylene; Needle tube: 304 Stainless steel; Barrel: Polypropylene; Plunger stopper: Synthetic rubber; Plunger: Polypropylene; Plunger cap: Polyethylene;	Needle cap: Polypropylene; Needle tube: 304 Stainless steel; Barrel: Polypropylene; Plunger stopper: Polyisoprene rubber; Plunger: Polypropylene; End cap: Polypropylene Safety protector: Polypropylene; Fixed hub: Polypropylene; Lubricant: Polydimethylsiloxane; Adhesive: UV Curing Adhesiv	Different #7
Capacity	0.3 mL, 0.5 mL, 1mL	0.3 mL, 0.5 mL, 1mL	Same
Sterilization method	Sterilized by EO gas SAL 10^{-6}	Sterilized by EO gas SAL 10^{-6}	Same
Safety feature performance	Not applicable	The force to activate the safety mechanism is less than 5 N. The force that the safety mechanism is destroyed is greater than 20 N.	Different #8
Needle performance	Conforming to the requirements of ISO 9626, ISO 7864	Conforming to the requirements of ISO 9626, ISO 7864	Same
Syringe performance	Conforming to the requirements of ISO 7886-1	Conforming to the requirements of ISO 7886-1	Same
Biocompatibility	Conforming to the requirements of ISO 10993 series standards	Conforming to the requirements of ISO 10993 series standards	Same
Shelf life	5 years	5 years	Same
Intended population	Adult and transitional adolescent	Adult and Pediatric	Different #9

7.2 Substantial equivalence analysis

#1
The proposed device, coded as FMF, features a permanently attached needle. The predicate device is classified as an insulin syringe with antistick function, denoted by the product code FMF and MEG. Therefore, the proposed device falls within the same category as the predicate device. Both the proposed and predicate devices are designed for subcutaneous injection of

U-100 insulins and are intended for use by healthcare professionals.
In conclusion, the proposed and the predicate device are substantially equivalent.

#2
The proposed device and predicate device are designed for the subcutaneous injection of U-100 insulins. The key distinction between them lies in the needle safety mechanism. The predicate device features a manually retractable needle for sharp injury protection and reuse prohibition, while the proposed device lacks a safety protection feature. However, this absence does not impact the functionality of the product.
In conclusion, the proposed and the predicate device are substantially equivalent.

#3 & #4 & #5
The proposed device exhibits gauge size, needle length and needle wall type that differs from the predicate device, but it falls within the range of the predicate device. Comprehensive performance testing has confirmed that the proposed device meets all the requirements stipulated by relevant standards or guidance, indicating a substantial equivalence. Any disparities in gauge size, needle length and needle wall type between the predicate and subject devices were effectively addressed through the execution of ISO 7864:2016 and ISO 9626:2016 performance testing protocols.
In conclusion, the proposed device and the predicate device are substantially equivalent.

#6
Both the proposed and predicate devices utilize typical sharp needles. The specific needle bevel of the predicate device is not disclosed. Healthcare professionals typically select the appropriate device based on clinical circumstances. This dissimilarity does not impact the intended functionality and has been accounted for through performance testing conducted in accordance with ISO 7864:2016 and ISO 9626:2016.
In conclusion, the proposed device and the predicate device are substantially equivalent.

#7
The materials used for the needle cap and plunger cap in the proposed device are not identical to those in the predicate device. The primary components share the same materials. However, it is important to note that the needle cap and plunger cap do not come into direct contact with patients. Despite this, comprehensive biocompatibility and performance tests have been conducted to verify the safety and effectiveness of all materials used in the device.
In conclusion, the proposed device and the predicate device are substantially equivalent.

#8
The proposed device is a conventional insulin syringe, whereas the predicate device is a safety insulin syringe. The non-safety syringe is commonly utilized in clinical settings. Performance tests have been conducted to validate the safety and efficacy of the proposed device.
In conclusion, the proposed device and the predicate device are substantially equivalent.

#9
The proposed device has a different intended population age (>18 years old), but fall within the population age range (Adult and pediatric) of the predicate device. Performance tests have been conducted to validate the safety and efficacy of the proposed device.
In conclusion, the proposed device and the predicate device are substantially equivalent.

8. Non-clinical testing

PERFORMANCE TESTING

The proposed device was tested and demonstrated to be in conformance with the following FDA recognized standards. The performance testing results met the standards' requirements to demonstrate the device's safety and effectiveness.

ISO 8537-2016: Sterile single-use syringes, with or without needle, for insulin

- Limits for acidity or alkalinity
- Limits for extractable metals
- Tolerance on the graduated capacity
- Graduation lines
- Numbering of scale
- Scale interval units
- Overall length of scale
- Barrel and plunger stopper
- Finger grips
- Fit of plunger stopper in barrel
- Dead space
- Freedom from leakage past plunger stopper
- Bond between hub and needle tube
- Needle cap

ISO 7886:1-2017: Sterile hypodermic syringes for single use – Part 1: Syringes for manual use

- Lubricant of syringe

ISO 9626-2016: Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods

- Stiffness
- Resistance to Breakage
- Resistance to Corrosion
- Needle O.D.
- Needle inner diameter

ISO 7864-2016: Sterile hypodermic needles for single use - Requirements and test methods

- Needle point

- Patency of lumen
- Cleanliness
- Needle length
- Lubricant of needle tube
- Penetration force and drag force for needles

BIOCOMPATIBILITY TESTING

The proposed device was tested in compliance with ISO 10993-1, as the Externally Communicating Device, Blood Path Indirect, prolonged Contact (>24hrs to 30 days).

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Hemocompatibility
- Pyrogen
- Subacute/Subchronic Toxicity
- Genotoxicity

Particulate testing was conducted in accordance with USP <787> and USP<790>. The testing results and met the USP acceptance criteria.

STERILE, PACKAGE AND SHELF-LIFE VALIDATION

The sterilization process of the proposed device has been validated in compliance with ISO 11135. The EO and ECH residual doesn't exceed the limit according to ISO 10993-7.

The Shelf-Life validation study was conducted under accelerated aging conditions in compliance with ASTM F1980-16 to verify the claimed shelf-life of 5 years.

Package integrity testing under simulated shipping conditions was conducted to satisfy the requirements in ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems. All packaging was deemed acceptable for protection of product and sterility maintenance.

Sterile barrier testing was conducted in compliance with the following FDA-recognized consensus standards.

- Vacuum Leak Test, ASTM D3078-02;
- Dye Penetration Test ASTM F1929-15;

- Microbial Barrier Properties Test DIN 58953-6: 2016;
- Seal Strength Test ASTM F88/F88M-21.

SIMULATED CLINICAL USE TESTING

Simulated clinical use testing of the proposed device has been conducted in compliance with the FDA Guidance for industry and FDA Stuff, Medical Devices with Sharps Injury Prevention Features, August 9, 2005.

9. Clinical testing

Not applicable for this submission.

10. Conclusion

The differences between the proposed and the predicate device do not raise any new or different questions of safety or effectiveness. The proposed device is substantially equivalent to the predicate device with respect to indications for use and technological characteristics.