March 19, 2024

Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd
% Tanya Wang, Technical Manager
Shanghai Mind-Link Consulting Co., Ltd.
1399 Jiangyue Road, Minhang District
Shanghai, 201114, China

Re: K234024
Trade/Device Name: HWJECT Auto-disable syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: December 6, 2023
Received: December 20, 2023

Dear Tanya Wang:

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,

Shruti N. Mistry -S

Shruti Mistry
Assistant Director
Division of Drug Delivery and General
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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)*
K234024

Device Name
HWJECT Auto-disable syringe

Indications for Use *(Describe)*
The HWJECT Auto-Disable Syringe is intended for aspiration and injection of fluids. Additionally, it features auto-disable feature (no sharp injury protection feature) that involves a design where the syringe automatically becomes inoperable by locking the plunger with clip after injection to prevent syringe reuse.

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.**

# 510(k) Summary

1. **Preparation date: February 17, 2024**

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: Tanya Wang, 86-15216694647, tanya.wang@mind-link.net

3. **Device**

Trading name: HWJECT Auto-disable syringe
Common name: Auto-disable syringe
Regulation No.: 21 CFR 880.5860
Classification name: Piston Syringe
Classification: Class II
Product code: FMF

4. **Predicate device**

Predicate device: K210464, Auto Disable Syringe

5. **Device description**

The auto-disable syringe is intended for aspiration and injection of fluids. The subject device is composed of needle cap, barrel, plunger, clip, plunger stopper, and needle tube. The clip cooperates with plunger and barrel to complete self-destruction of the device. It is non-pyrogenic and intended for single use.

The auto-disable feature (no sharp injury) involves a design where the syringe automatically becomes inoperable by locking the plunger with the clip after injection to prevent syringe reuse. The capacity of the auto-disable syringe is available in 0.05 mL, 0.1 mL, 0.3 mL, 0.5 mL and 1 mL. The specification of needle tube ranges from 22G to 27G. The needle length ranges from 10 mm to 38 mm.

Table 1 Device specification

| Syringe volume | Needle Gauge | Needle Length |
|---|---|---|
| 0.05 mL | 27G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm |
| | 26G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm |
| 0.1 mL | 27G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |

| | | |
|---|---|---|
| | 26G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| | 25G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| | 24G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| | 23G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| | 22G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| 0.3 mL | 27G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| | 26G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| | 25G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| | 24G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| | 23G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| | 22G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| 0.5 mL | 27G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| | 26G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| | 25G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| | 24G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| | 23G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| | 22G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| 1 mL | 27G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| | 26G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| | 25G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| | 24G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| | 23G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |
| | 22G | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm |

## 6. Indications for use

The HWJECT Auto-Disable Syringe is intended for aspiration and injection of fluids. Additionally, it features auto-disable feature (no sharp injury protection feature) that involves a design where the syringe automatically becomes inoperable by locking the plunger with clip after injection to prevent syringe reuse.

## 7. Comparison of technological characters between proposed and predicate device

7.1 Comparison of technological characters

Table Characters comparison

| Characters | Subject device, (K234024, HWJECT Auto-disable syringe) | Predicate device, (K210464,Auto Disable Syringe) | Remark |
|---|---|---|---|
| **Product code** | FMF | FMF | Same |
| **Regulation No.** | 21 CFR 880.5860 | 21 CFR 880.5860 | Same |
| **Classification** | II | II | Same |
| **Indications for use** | The HWJECT Auto-Disable Syringe is intended for aspiration and injection of fluids. Additionally, it features auto-disable feature (no sharp injury protection feature) that involves a design where the syringe automatically becomes inoperable by locking the plunger with clip after injection to prevent syringe reuse. | The AUTO DISABLE SYRINGE is intended for use in the suction and injection of vaccine for medical purposes. Additionally, after injection to the body, the plunger can be automatically locked by the triggered mechanism to prevent the re-use of this syringe. | Different #1 |
| **Principle of operation** | The subject device has auto-disable feature that avoids reuse of syringe by locking the plunger with metal clip after injection. The metal clip cooperates with plunger and barrel to complete self-destruction of the auto-disable syringe. | The syringe consists of a calibrated hollow barrel, a movable plunger, a rubber stopper assembled at the end of the plunger, and a steel clip installed between the barrel and the plunger that functions to prevent re-use of the syringe. | Different #2 |
| **Single-use** | Single-use | Single-use | Same |
| **Labeling** | Meet the requirements of 21 CFR Part 801 | Meet the requirements of 21 CFR Part 801 | Same |
| **Non-pyrogenic** | Non-pyrogenic | Non-pyrogenic | Same |
| **Sterilization method** | EO sterilization | EO sterilization | Same |
| **SAL $10^{-6}$** | $10^{-6}$ | $10^{-6}$ | Same |
| **Capacity** | 0.05 mL, 0.10 mL, 0.3 mL, 0.5 mL, 1 mL | 0.05 mL, 0.10 mL, 0.20 mL, 0.25 mL, 0.30 mL, 0.40 mL, 0.50 mL, 1.0 mL | Same |

| | | | |
|---|---|---|---|
| **Gauge size** | 22G, 23G, 24G, 25G, 26G, 27G | 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G | Different #3 |
| **Needle length** | 10 mm, 13 mm, 16 mm, 20 mm, 25 mm, 28 mm, 30 mm, 32 mm, 38 mm | 10 mm, 13 mm, 25 mm | Different #4 |
| **Tip Type** | Fixed Needle | Fixed Needle | Same |
| **Needle bonding strength** | 62-100 N<br>Conforming to the requirements of ISO 7864:2016 | Conforming to the requirements of ISO 7864:2016 | Same |
| **Configuration and materials** | Barrel: PP<br>Plunger: PP<br>Needle: stainless steel<br>Piston: Synthetic rubber(Polyisoprene Rubber)<br>Clip: stainless steel | Barrel: PP<br>Plunger: PP<br>Piston: Latex Free (Polyisoprene Rubber)<br>Needle: stainless steel<br>Clip: stainless steel | Same |
| **Reuse Prevention (Safety Feature)** | Activation force: 2-4 N<br>Auto-disabled, prevents syringe re-use | Auto-disabled, prevents syringe re-use | Same |
| **Lubricant for barrel** | Silicone oil | Silicone oil | Same |
| **Barrel transparency** | Clear | Clear | Same |
| **Graduation Legibility** | Bold Markings | Bold Markings | Same |
| **Performance** | Conforming to the requirements of ISO 7886-3, ISO 7886-1, ISO 9626, and ISO 7864 | Conforming to the requirements of ISO 7886-3, ISO 7886-1, ISO 9626, and ISO 7864 | Same |
| **Biocompatibility** | • Cytotoxicity<br>• Sensitization<br>• Irritation<br>• Acute Systemic Toxicity<br>• Pyrogenicity<br>• Hemocompatibility | • Cytotoxicity<br>• Sensitization<br>• Irritation<br>• Acute Systemic Toxicity<br>• Pyrogenicity<br>• Hemocompatibility | Same |
| **Shelf life** | 5 years | 5 years | Same |

7.2 Substantial equivalence analysis

Different #1
The indications for use are generally identical, while the predicate device provides additional details for vaccine injection. However, both the predicate device and the subject device have the same configuration. The non-clinical performance testing has been conducted to verify the similarity.
In conclusion, the subject device and the predicate device are substantially equivalent.

Different #2
The principle of operation for the subject device and predicate device are generally identical. The metal clip cooperates with the plunger and barrel to complete the self-destruction of the auto-disable syringe. This difference does not raise new questions of safety and effectiveness when compared to the predicate device.

Different #3
The 22G needle gauge of the subject device isn't within the range of the predicate device. The subject device of the above needle gauge is in accordance with ISO 9626. The performance of the 22G subject device has been conducted to verify that this difference does not raise new questions of safety and effectiveness when compared to the predicate device.
In conclusion, the subject device and the predicate device are substantially equivalent.

Different #4
The needle length of the subject device is different from the predicate device, that has extra specifications. Both of them fulfill the requirements of ISO 9626 and ISO 7864. The non-clinical performance testing has been conducted to verify that the subject device's extra specifications do not raise new questions of safety and effectiveness of the when compared to the predicate device.
In conclusion, the subject device and the predicate device are substantially equivalent.

## 8. Non-clinical testing

### Performance Testing

The subject device was tested and demonstrated to be in conformance with the following FDA-recognized standards. The performance testing results met the requirements of the following standards demonstrating that the device is substantially equivalent to the predicate device.

ISO 7886-3:2020: Sterile hypodermic syringes for single use Part 3: Auto-disabled syringes for fixed-dose immunization

- Limits for acidity or alkalinity
- Limits for extractable metals
- Lubricant
- Tolerance on nominal capacity
- Graduated scale
- Barrel
- Design
- Fit of the plunger stopper/plunger in the barrel
- Fiducial line
- Dead space
- Freedom from air and liquid leakage
- Auto-disable syringe feature

ISO 9626 Second edition 2016-08-01 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 Fourth edition 2016-08-01 Sterile hypodermic needles for single use-Requirements and test methods

- Needle point
- Bond between hub and needle tube
- Patency of lumen
- Cleanliness
- Needle length
- Testing for measuring the penetration force and drag force for needles

Particulate testing was conducted in accordance with USP <788>. The testing results met the USP acceptance criteria.

**Biocompatibility Testing**

The proposed device was tested in compliance with ISO 10993-1, as the Externally Communicating Device, Blood Path Indirect, Limited Contact (<24 hours).

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Hemocompatibility
- Pyrogen

**Sterility and Shelf life**

The sterilization process has been conducted to confirm that the subject device reached $10^{-6}$ sterility assurance level and the performance of the products and packaging are in line with expectations after sterilization requirements per ISO 11135:2014.

The shelf-life validation study was conducted under the accelerated aging condition according to ASTM F1980 to determine the auto-disable syringe maintain a complete sterile state within the five-year labeling period.

**Package Integrity**

Package integrity testing under simulated shipping conditions was conducted to satisfy the requirements in ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems. All packaging was deemed acceptable for the 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 subject device and the predicate device do not raise any new or different questions of safety or effectiveness. The subject device is substantially equivalent to the predicate device with respect to the indications for use and technological characteristics.