August 14, 2026

Jiangsu Enjosim Medical Technology Co., Ltd.
% Ryan Li
Consultant
Elite Medical Technology Co., Ltd.
Rm. 102, # 30, Lane 3188, Xiupu Rd., Pudong New District
Shanghai, 201315, China

Re: K253747
Trade/Device Name: Disposable Pen Injector (KXYC-03C02, KXYC-03A03)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: July 15, 2026
Received: July 15, 2026

Dear Ryan Li:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

for KYRAN R. GIBSON -S

Shruti Mistry
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253747

Please provide the device trade name(s).

Disposable Pen Injector (KXYC-03C02, KXYC-03A03)

Please provide your Indications for Use below.

The Disposable Pen Injector is a disposable pen injector designed for single patient use by diabetics for the subcutaneous self-injection of a desired dose insulin. The disposable pen injector uses 3mL cartridge of HUMALOG (U-100, insulin lispro for injection) and a single use detachable and disposable insulin pen needle (supplied separately). The pen injector allows the user to dial the desired dose up to 80 units in 1-unit increments. It is intended for general population.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary- K253747

I. Submitter Information

Submitter Name: Jiangsu Enjosim Medical Technology Co., Ltd
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Date of Preparation: August 12, 2026

II. Proposed Device

Device Trade Name: Disposable Pen Injector (KXYC-03C02, KXYC-03A03)
Common Name: Pen-injector
Classification Name: Piston Syringe
Regulation Number: 21 CFR 880.5860
Regulatory Class: Class II
Product Code: FMF
Review Panel: General Hospital

III. Predicate Device

Primary predicate device
510(k) Number: K240961
Trade Name: Disposable Pen Injector Assembly

IV. Device Description

The Disposable Pen Injector is a disposable single-patient use pen injector capable of injecting a dose of up to 60 units (model: KXYC-03C02) or 80 units (model: KXYC-03A03) of insulin in 1-unit increments. The pen injector is intended for use with 3mL insulin cartridges and single-use, disposable insulin pen needles (supplied separately). After the intended insulin cartridge is used up, the Disposable Pen Injector should be disposed. The Disposable Pen Injector is intended for single user only and provided non-sterile.

V. Indication for use

The Disposable Pen Injector is a disposable pen injector designed for single patient

use by diabetics for the subcutaneous self-injection of a desired dose insulin. The disposable pen injector uses 3mL cartridge of HUMALOG (U-100, insulin lispro for injection) and a single use detachable and disposable insulin pen needle (supplied separately). The pen injector allows the user to dial the desired dose up to 80 units in 1-unit increments. It is intended for general population.

VI. Comparison of technological characteristics with the predicate devices

The following table summarizes the proposed devices technological characteristics compared to the predicate device (K240961).

Item	**Proposed Device**	**Primary Predicate Device (K240961)**	**Discussion**
Product Name	Disposable Pen Injector	Disposable Pen Injector Assembly	N/A
Product Code	FMF	FMF	Same
Regulation No.	21 CFR 880.5860	21 CFR 880.5860	Same
Class	Class II	Class II	Same
Indications for Use	The Disposable Pen Injector is a disposable pen injector designed for single patient used by diabetics for the subcutaneous self-injection of a desired dose insulin. The disposable pen injector uses 3mL cartridge of HUMALOG™ (U-100, insulin lispro for injection) and a single use detachable and disposable insulin pen needle (supplied separately). The pen injector allows the user to dial the desired dose up to 80 units in 1-unit increments. It is intended for general population.	The Disposable Pen Injector Assembly is a disposable pen injector designed for single patient use by diabetics for the subcutaneous self-injection of a desired dose insulin. The disposable pen injector assembly uses 3 mL cartridge of HUMALOG™ (U-100, insulin lispro for injection), and a single use detachable and disposable insulin pen needle (supplied separately). The pen injector allows the user to dial the desired dose up to 80 units in 1 unit increments. It is intended for general population.	Same
User Environment	Home environment	Home environment	Same
Reusable Device	No	No	Same
Compatible Cartridge Volume	3 mL (300 units of U-100 insulin)	3 mL (300 units of U-100 insulin)	Same
Dose Accuracy	Meets ISO 11608-1:2022 requirements	Meets ISO 11608-1:2022 requirements	Same
Dial Increments	0.01 mL per increment providing one unit (1U) dose increments	0.01 mL per increment providing one unit (1U) dose increments	Same
Device Model	KXYC-03C02, KXYC-03A03	N/A	Different

			Note 1
Maximum Delivered Dose	60 Units (KXYC-03C02) 80 Units (KXYC-03A03)	80 Units	Different **Note 2**
Shelf Life	5 years	5 years	Same
Biocompatibility	Cytotoxicity Skin Sensitization Irritation	Cytotoxicity Skin Sensitization Irritation	Same
Sterility	Not a sterile device	Not a sterile device	Same

Discussion

Note 1

The proposed device and the predicate device have different model designations. This difference is limited to product identification and does not represent a difference in the intended use, design, operating principle, materials, or other key technological characteristics of the devices. Therefore, the difference in model designation does not raise different questions of safety or effectiveness when compared to the predicate device and does not affect the substantial equivalence.

Note 2

The proposed device has two models with different maximum delivered doses: 60 units for model KXYC-03C02 and 80 units for model KXYC-03A03, while the maximum delivered dose of the predicate device is 80 units. Although model KXYC-03C02 has a lower maximum delivered dose (60 units), this difference does not change the intended use, fundamental design, operating principle, dose-setting mechanism, dose increment, or compatible cartridge volume of the proposed device. Dose accuracy testing in accordance with ISO 11608-1:2022 was conducted on both models KXYC-03C02 and KXYC-03A03, and all test results met the applicable acceptance criteria. Therefore, the difference in maximum delivered dose does not raise different questions of safety or effectiveness when compared to the predicate device, and the performance testing demonstrates that both proposed device models provide accurate and reliable dose delivery within their specified dose ranges. Accordingly, this difference does not affect the substantial equivalence.

VII. Performance Data

Non-Clinical Performance Test Conclusion

Biocompatibility

The proposed device, Disposable Pen Injector is categorized as skin contact with a duration of category B-prolonged (>24hrs to 30 days) according to FDA guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part1: Evaluation and testing within a risk management process". The Biocompatibility tests were conducted to verify that the proposed devices are not adverse to human tissue based on the following standards:

- ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Test for in vitro cytotoxicity
- ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation

Performance Testing

The Disposable Pen Injector meets the requirements specified in ISO 11608-1:2022 Needle-based injection systems for medical use – Requirement and test methods – Part 1: Needle-based injection systems. The device design has passed the dose accuracy requirements after preconditioning.

In addition, other device verification tests confirm that Disposable Pen Injector meets its design requirements including the following test items:

- Dial Torque
- Cap Removal Force
- Visual Inspection Testing
- Injection Resistance
- Needle Assembly Torque
- Dose Accuracy
- Needle Removal Torque
- Leakage inspection

Shelf Life

The Disposable Pen Injector has a five-year shelf life. For shelf life, in accordance with ASTM F1980:2022, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices, aging studies have been conducted to verify a five-year shelf life of the proposed device and ensure that its functionality is successfully maintained throughout the duration of this shelf life.

Simulated Transportation

A test is conducted according to ASTM D4169:2023e1 to demonstrate the proposed device could function as intended after transportation.

Human Factor Study

A human factors validation study was conducted for the proposed device under simulated-use conditions representative of the intended use environment. The study evaluated the safe and effective use of the devices, including the performance of critical tasks and users' understanding of important information provided in the labeling. The study results demonstrated that the user interface supports safe and effective use of the proposed devices by the intended users in the intended use

environment.

Clinical Test Conclusion
No clinical study is included in this submission.

VIII. Conclusion
The conclusion drawn from the non-clinical tests demonstrates that the proposed device, Disposable Pen Injector, is as safe, as effective, and performs as well as the legally marketed predicate device Disposable Pen Injector Assembly (K240961).