August 15, 2024

Wuxi NEST Biotechnology Co., Ltd.
℅ Ryan Li, Consultant
ICAS Group
No.155 Pingbei Road, Minhang District
Shanghai, 201109, China

Re: K240961
Trade/Device Name: Disposable Pen Injector Assembly
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: July 16, 2024
Received: July 16, 2024

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 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
Hospital Devices, and Human Factors
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)*
K240961

Device Name
Disposable Pen Injector Assembly

Indications for Use *(Describe)*
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 HUMALOGTM (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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary - K240961

I. Submitter Information

Submitter Name: Wuxi NEST Biotechnology Co., Ltd.
Submitter Address: No. 530, Xida Road, Meicun Industrial Park, Xinwu District, Wuxi, Jiangsu, China
Contact Person: Cheng Zhiwei
Position: Registration Director
Tel.: +86-0510-68006788-5021
Email: project01@nest-wuxi.com

Date of Preparation: August 12, 2024

II. Proposed Device

Device Trade Name: Disposable Pen Injector Assembly
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: K182387
Trade Name: NovoPen Echo®

IV. Device Description

The Disposable Pen Injector Assembly is a disposable single-patient use pen injector capable of injecting a dose of up to 80 units 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 Assembly should be disposed. The Disposable Pen Injector Assembly is intended for single user only and provided non-sterile.

V. Indication for use

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 HUMALOGTM (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 from 1 to 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 device technological characteristics

with compared to the predicate device under K182387.

Item	Proposed Device	Primary Predicate Device (K182387)	Discussion
Product Name	Disposable Pen Injector Assembly	NovoPen Echo®	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 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.	The NovoPen Echo® is a re-useable pen injector designed for single patient use by diabetics for the self-injection of a desired dose of insulin. The pen injector uses PenFill® 3 mL cartridge of NovoLog®, 100 units/mL (U-100) [insulin aspart injection], Fiasp® 100 units/mL (U-100) [insulin aspart injection], and a single use detachable and disposable pen needle (supplied separately). The pen injector allows the user to dial the desired dose from 0.5 to 30 units in 0.5 unit increments	Different **Note 1**
User Environment	Home healthcare environment	Home healthcare environment	Same
Reusable Device	No	Yes	Different **Note 2**
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 11608-1:2014 requirements	Same
Dial Increments	0.01 mL per increment providing one unit (1U) dose increments	0.005 mL per increment providing half unit (0.5U) dose increments	Different **Note 3**
Maximum Delivered Dose	80 Units	30 Units	Different **Note 4**
Shelf Life	5 years	5 years	Same
Biocompatibility	Cytotoxicity Skin Sensitization Irritation	Unknown	Different **Note 5**

Sterility	Not a sterile device	Not a sterile device	Same

Discussion

Note 1

The first difference in indications for use is that the proposed device is a disposable device while the predicate device is a reusable device. This difference does not affect the substantial equivalence because the risk of single use is lower compared to the multiple use risk of the predicate device. Another is the difference in maximum delivered dose and dial increments: The subject pen injector allows the user to dial the desired dose from 1 to up to 80 units in 1 unit increments, where the predicate pen injector allows the user to dial the desired dose from 0.5 to 30 units in 0.5 unit increments. The third difference is the intended insulin brand: The subject pen injector uses 3 mL cartridge of HUMALOG (U-100, insulin lispro for injection), where the predicate pen injector uses PenFill® 3 mL cartridge of NovoLog®, 100 units/mL (U-100) [insulin aspart injection] and Fiasp® 100 units/mL (U-100) [insulin aspart injection]. These differences do not affect the substantial equivalence because adequate performance of the subject device has been demonstrated by testing per ISO 11608-1: 2022.

Note 2

The proposed device is disposable while the predicate device is reusable. However, this difference does not affect the substantial equivalence because the risk of single use is lower compared to the multiple use risk of the predicate device.

Note 3

Although the dial increments between the proposed device and the predicate device are different, corresponding performance tests were conducted on the proposed device to demonstrate its compliance with the ISO 11608-1: 2022 standard. Therefore, this difference would not affect the substantial equivalence.

Note 4

Although the maximum delivered dose between the proposed device and the predicate device is different, corresponding performance tests were conducted on the proposed device to demonstrate that its dose accuracy performance complies with the ISO 11608-1: 2022 standard. Therefore, this difference would not affect the substantial equivalence.

Note 5

The biocompatibility tests were conducted to demonstrate the proposed device's biological safety for its intended use. Therefore, this difference would not affect the substantial equivalence.

VII. Performance Data

Non-Clinical Performance Test Conclusion

Biocompatibility

The proposed device, Disposable Pen Injector Assembly is categorized as skin contact with a duration of category A-limited (≤24hrs) 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 safe for contacting human skinbased 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

Device Verification Tests confirm that Disposable Pen Injector Assembly meets the requirements of ISO 11608-1:2022 Needle-based injection systems for medical use – Requirement and test methods – Part 1: Needle-based injection systems.

The Disposable Pen Injector Assembly is intended to be used with 3mL insulin cartridges. Therefore, the dose accuracy performance test of FDA clear insulin cartridges with Disposable Pen Injector Assembly was performed which meets the requirements of ISO 11608-1:2022.

Shelf Life

The Disposable Pen Injector Assembly has a five-year shelf life. For shelf life, in accordance with ASTM F1980-16, 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 D4169:2022 to demonstrate the proposed device could function as intended after transportation.

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 Assembly is as safe, as effective, and performs as well as the legally marketed predicate device NovoPen Echo® (K182387).