June 18, 2024

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

Re: K240774
Trade/Device Name: Pen Injector
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: March 19, 2024
Received: March 21, 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)*
K240774

Device Name
Pen Injector

Indications for Use *(Describe)*

The Pen Injector is a re-usable pen injector designed for single patient use by diabetics for the self-injection of a desired dose of insulin. The Pen Injector uses HUMALOG (insulin lispro) injection (U-100) available in 3 mL cartridges, and a single use detachable and disposable insulin pen needle (supplied separately, needle sizes including: 32G*4mm, 31G*4mm, 31G*5mm, and 31G*6mm).

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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510(k) Summary - K240774

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: Ryan Li
Position: Consultant
Tel.: + 86 13701581791
Email: IryryanO211@gmail.com
Date of Preparation: May 22, 2024

II. Proposed Device

Device Trade Name: Pen Injector
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 Pen Injector is a reusable mechanical pen-injector capable of injecting a dose of up to 80 units of insulin, in 1 unit increments. The Pen Injector consists of a pen injector body, a push block, a injection button, a dose display window, a dose adjustment knob, a reservoir and a pen injector cap. The intended dose is mechanically set by rotating a dose adjustment knob. The insulin is injected by depressing the knob which mechanical coupling causes the piston in the insulin cartridge to move forward thereby expelling the intended dose. The Pen Injector is intended for single user and provided for non-sterile.

V. Indication for use

The Pen Injector is a re-usable pen injector designed for single patient use by diabetics for the self-injection of a desired dose of insulin. The Pen Injector uses HUMALOG (insulin lispro) injection (U-100) available in 3 mL cartridges, and a single use detachable and disposable insulin pen needle (supplied separately, needle sizes including: 32G*4mm, 31G*4mm, 31G*5mm, and 31G*6mm).

VI. Comparison of technological characteristics with the predicate devices

Table 1 summarizes the proposed device technological characteristics with compared to the predicate device under K182387.

Item	Proposed Device	Primary Predicate Device (K182387)	Discussion
Product Name	Pen Injector	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 Pen Injector is a re-usable pen injector designed for single patient use by diabetics for the self-injection of a desired dose of insulin. The Pen Injector uses HUMALOG (insulin lispro) injection (U-100) available in 3 mL cartridges, and a single use detachable and disposable insulin pen needle (supplied separately, needle sizes including: 32G*4mm, 31G*4mm, 31G*5mm, and 31G*6mm).	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	Same
User Environment	Professional healthcare facilities and home environment	Unknown	Different **Note 1**
Reusable Device	Yes	Yes	Same
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 2**
Maximum Delivered Dose	80 Units	30 Units	Different **Note 3**
Shelf Life	5 years	5 years	Same
Service Life	3,000 times of reuse	Unknown	Different

			Note 4
Biocompatibility	Cytotoxicity Skin Sensitization Irritation	Unknown	Different **Note 5**
Sterility	Not a sterile device	Not a sterile device	Same

Discussion

Note 1

The user environment for the predicate device is unknown. However, this does not raise different questions of safety and effectiveness as both device are prescription use devices.

Note 2

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 comply with the ISO 11608-1 standard. Therefore, this difference would not affect the substantial equivalence.

Note 3

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

Note 4

A service life verification test was conducted to demonstrate that the proposed device is valid during its service life. Therefore, this difference would not affect the substantial equivalence.

Note 5

The biocompatibility tests were conducted to demonstrate the proposed device is biocompatible with intended users. Therefore, this difference would not affect the substantial equivalence.

VII. Performance Data

Non-Clinical Performance Test Conclusion

Biocompatibility

The proposed device, Pen Injector 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 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

Device Verification Tests confirm that the Pen Injector 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 Pen Injector is intended to be used with 3mL cartridges of HUMALOG (insulin lispro) injection (U-100). Therefore, the dose accuracy, injection force and injection time performance tests of the 3mL cartridges of HUMALOG (insulin lispro) injection (U-100) with Pen Injector was performed which meets the requirements of ISO 11608-1:2022. In addition, corresponding tests are conducted between the Pen Injector and the compatible pen needles to demonstrate the compatibility.

Shelf Life and Service Life

The Pen Injector has a five-year shelf life, as well as 3000 times of reuse service 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. In addition, a service life verification test was conducted on the proposed device to ensure its validity within its service 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, Pen Injector is as safe, as effective, and performs as well as the legally marketed predicate device NovoPen Echo® (K182387).