April 24, 2025

GO-Pen ApS
% Paige Sutton-Smith
Quality and Regulatory Affairs Manager
Veranex
5420 Wade Park Blvd, Suite 204
Raleigh, North Carolina 27607

Re: K250262
Trade/Device Name: GO-PEN®
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: March 27, 2025
Received: March 27, 2025

Dear Paige Sutton-Smith:

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.

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,

Shruti N. Mistry -S

Shruti Mistry
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
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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)*
K250262

Device Name
GO-PEN®

Indications for Use *(Describe)*
GO-PEN® is a reusable insulin pen intended for the self-injection of NovoLog® (U-100, insulin aspart for injection) available in 10 ml vials.

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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GO-PEN® 510(K) SUMMARY

APPLICANT

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CONTACT PERSON

Ole Nielsen
CEO
GO-Pen ApS
Phone: +45 53772474

DATE PREPARED

April 18, 2025

DEVICE INFORMATION

Trade Name: GO-PEN®
Generic/Common Name: Insulin Pen Injector
Classification: II
Regulation: 21 CFR 880.5860
Regulation Name: Piston Syringe
Product Code: FMF

PREDICATE DEVICE(S)

HumaPen Savvio, (K160668)

DEVICE DESCRIPTION

GO-PEN® is an assembly of a durable pen-shaped dosing unit with a special disposable sterile reservoir that fits into the dosing unit. The GO-PEN® device can only be used with NovoLog® U-100 insulin aspart for injection. The user is intended to fill up the disposable reservoir with 1.3 mL of insulin from a 10 ml vial and mount it on the dosing unit. The GO-PEN® device allows the user to set the desired dose from 1 to 60 Units in 1 Unit increments using the dial feature. Once the GO-PEN® disposable reservoir is filled, it can be used over a period of up to 3 days at room temperature (max. 30°C/86°F) for multiple injections of precise doses of insulin. When the reservoir is empty or the time has been exceeded, the reservoir must be discarded, and a new sterile reservoir is used for the next filling. GO-PEN® is used with standard single-use hypodermic needles with a luer lock which are supplied separately by the user.

INDICATIONS FOR USE

GO-PEN® is a reusable insulin pen intended for the self-injection of NovoLog® (U-100, insulin aspart for injection) available in 10 ml vials.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Device Name	GO-PEN® (Subject Device)	HumaPen Savvio (Predicate Device)	Rationale for Substantial Equivalence
510(k) Number	**K250262**	**K160668**	N/A
Company	GO-Pen ApS	Eli Lilly and Company, Inc.	N/A
Classification	2	2	Same
Product Code	FMF	FMF	Same
Indications for Use	GO-PEN® is a reusable insulin pen intended for the self-injection of NovoLog® (U-100, insulin aspart for injection) available in 10 ml vials.	HumaPen Savvio is a reusable insulin pen intended for the self-injection of HUMALOG® (U-100, insulin lispro for injection) available in 3 mL cartridges using disposable pen needles (sold separately).	The proposed and predicate devices are intended to be used with the same strength of fast-acting insulin, but a different kind of insulin and that is provided in a different format – the predicate device requires a pre-filled pen cartridge while the proposed device requires the user to fill a reservoir from a vial. The proposed device allows for the use of a different type of fast-acting insulin, NovoLog®. These differences do not affect substantial equivalence. Both devices deliver U-100 rapid-acting insulin via reusable pens with disposable needles. The proposed device uses insulin from a vial, while the predicate uses pre-filled cartridges. This difference in insulin loading is addressed in the design and usability documentation. Once filled, the devices operate similarly. Although the insulins differ by brand (NovoLog® vs. HUMALOG®), both are rapid-acting and functionally equivalent for self-injection.
Reusable device	Yes	Yes	Same
Prescription/ Over-the-Counter	Rx only	Rx only	Same
Two-way dose dialing	Yes	Yes	Same

Device Name	GO-PEN® (Subject Device)	HumaPen Savvio (Predicate Device)	Rationale for Substantial Equivalence
Insufficient Remaining Dose feature	The pen-injector will allow a user to dial a dose that is greater than what is remaining in the reservoir. Once the pen-injector has completed the delivery of the insulin available within the reservoir (i.e., empties the reservoir), the portion of the dose that was not injected will be displayed on the dose dial; that is, the dose dial will not return to "0" as it would if the entire dose was delivered. This remaining dose is to be administered after replacing the reservoir.	Patient cannot dial more than the deliverable amount of insulin remaining in the cartridge, prior to injection.	ISO 11608-1:2022, §5.6(k) lists four options for IRD features. The GO-PEN® uses method (4) while the HumaPen Savvio uses method (1). This difference does not impact substantial equivalence as both pens comply with the standard and provide methods of completing a dose when the pen does not contain sufficient insulin.
Cartridge Volume	1.3 mL	3 mL	The GO-PEN® device holds less insulin than the predicate device. This difference does not impact substantial equivalence as both users must refill when empty.
Mechanism	Mechanical pen-injector/needle-based injection system	Mechanical pen-injector/needle-based injection system	Same
Delivery Accuracy	Meets ISO 11608-1:2022 requirements	Meets ISO 11608-1:2014 requirements	Same. Performance testing of the HumaPen Savvio was performed in accordance with ISO 11608-1:2014. A newer version of the standard has been published which has no impact on the test methods or requirements. Testing performed in accordance with the 2022 version also meets the requirements of the 2014 version.
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
Maximum Delivered Dose	60 Units	60 Units	Same
Use Life	Durable Pen – 2 years in packaging; 3 years once use begins Reservoir – 2 years in packaging; 3 days once filled Pull-rod – 12 uses or approximately 3 months	6 years	The GO-PEN® durable pen has a shorter use life than the predicate device which remains substantially equivalent as the use life difference does not impact the intended use or technological characteristics of the device.

Device Name	GO-PEN® (Subject Device)	HumaPen Savvio (Predicate Device)	Rationale for Substantial Equivalence
Sterility	Reusable pen is not a sterile device Empty Reservoirs – supplied sterilized with E-Beam	Reusable pen is not a sterile device Reservoirs are sterile, drug filled cartridges	Same. The durable pen portions of both devices are not sterile. The GO-PEN® includes a sterile reservoir component, while the predicate requires sterile drug filled cartridges. Both require sterile needles.
Nonclinical Bench Testing/In Vitro Bench Testing	The device design has passed the dose accuracy requirements after preconditioning in the following conditions defined in ISO 11608-1: - Standard Atmosphere - Cool Atmosphere - Warm Atmosphere - Last-dose Accuracy - Dry Heat - Cold Storage - Free Fall - Vibration - Damp Heat - Temperature cycling (Cyclical) - Life-cycle test (5 years) - Transport Test - Fluid Leakage (into dosing mechanism) test - Leakage (during injection) test	The device design has passed the dose accuracy requirements after preconditioning in the following conditions defined in ISO 11608-1: - Standard Atmosphere - Cool Atmosphere - Warm Atmosphere - Last-dose Accuracy - Dry Heat - Cold Storage - Free Fall - Vibration - Damp Heat - Temperature cycling (Cyclical) - Life-cycle test (9 years) - Transport test	Same, with the exception of the life-cycle test which has been completed for the GO-PEN® device for a shorter life-cycle than the predicate device.
Biocompatibility Testing	The durable pen portion of the GO-PEN® device is a surface contacting device that contacts intact skin only according to the definitions in ISO 10993.1:2018 and the exterior materials of the durable pen were tested accordingly and evaluated for in-vitro cytotoxicity. The materials excluded from Attachment G of the FDA biocompatibility guideline have also been evaluated for biocompatibility. The reservoir potion of the GO-PEN® is externally communicating device according to the definitions	The HumaPen Savvio is a surface contacting device that contacts intact skin only according to the definitions in ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. The exterior materials of the device (including the cartridge holder) were evaluated for in vitro cytotoxicity, skin irritation, and sensitization in accordance with this standard and meet the biocompatibility standard.	The GO-PEN® required more evaluation due to the included reservoir. However, both devices met the applicable ISO 10993 requirements.

Device Name	GO-PEN® (Subject Device)	HumaPen Savvio (Predicate Device)	Rationale for Substantial Equivalence
	in ISO 10993-1:2018 due to the storage of insulin and therefore the materials of construction evaluated for in-vitro cytotoxicity, skin irritation, material mediated pyrogenicity and sensitization in according with this standard.		
Usability Testing	Human factors testing confirmed that all critical tasks related to filling reservoirs with insulin and labelling them were passed without any mistakes. Other tasks related to filling, injecting and handling the device were passed, confirming that the user interface of the device did not adversely impact performance or usability of the device.	Human factors testing confirmed that the user interface of the device did not adversely impact performance or usability of the device.	The GO-PEN® required additional human factors testing due to the extra reservoir filling tasks, which were confirmed to not adversely impact the performance or usability of the device. All equivalent tasks of GO-PEN® and predicate device are equal in terms of overlapping functions, namely: injecting and handling.
Luer Testing	The device design has passed the luer lock testing requirements after preconditioning in the following conditions defined in ISO 80369-7 and 80369-20: - Dimensions - Fluid leakage - Sub-atmospheric pressure leakage - Stress cracking - Resistance to separation from axial load - Resistance to separation from unscrewing - Resistance to overriding	N/A - HumaPen Savvio does not include a luer feature.	The GO-PEN® features a standard luer, whereas the predicate device does not include this feature. The GO-PEN® testing was conducted to meet current requirements for the luer feature.

SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate device are substantially equivalent to the proposed indications for use for the GO-PEN®. Any differences in the technological characteristics between the devices do not raise any different questions of substantial equivalence. Thus, the GO-PEN® is substantially equivalent to the predicate device.

PERFORMANCE DATA

All necessary bench testing was conducted on the GO-PEN® to support a determination of substantial equivalence to the predicate device.

Nonclinical Testing Summary:

GO-PEN® meets the requirements specified in ISO 11608-1:2022 *Needle-based injection systems for medical use – Requirements and test methods – Part 1: Needle-based injection systems.* FDA guidance *Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products* was also considered to guide the nonclinical testing. The device design has passed the dose accuracy requirements after preconditioning in the conditions specific below as defined in the ISO 11608-1 standard.

The nonclinical bench testing included:

- Dose accuracy and Injection force
    - At Cool, standard, warm atmosphere
    - After Free fall preconditioning
    - After Dry heat preconditioning
    - After Cold storage preconditioning
    - After Damp heat preconditioning
    - After Cyclical preconditioning
    - After Vibration preconditioning
    - After In-Use lifetime test preconditioning
    - After Simulated Transport preconditioning
    - After Aging to Expiration (Functional Stability)
- Last dose accuracy
- Fluid leakage test
- Leakage
- Visible particles in reservoir
- Break loose and Glide force
- Usability
- Drug compatibility
- Luer testing

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the GO-PEN® meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the GO-PEN® does not raise different questions of safety or effectiveness for administering insulin when compared to the predicate devices.

Clinical Testing Summary:

No clinical testing was performed.

CONCLUSIONS

The conclusions drawn from the nonclinical tests demonstrate that the subject device is substantially equivalent to the predicate device.