June 9, 2025

Biocorp Production
Alexia Garin
QARA Director
Zi Lavaur -La Béchade
Issoire, 63500
France

Re: K251500
Trade/Device Name: Mallya^{G} Injection Pen Adapter (MallyaG)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QOG
Dated: May 14, 2025
Received: May 15, 2025

Dear Alexia Garin:

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, 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)*
K251500

Device Name
MallyaG Injection Pen Adapter (MallyaG)

Indications for Use *(Describe)*
The MallyaG Injection Pen Adapter is indicated for the capture and wireless transmission of dosing information of compatible reusable and disposable pen injectors.

The Novo Nordisk PDS290 Injection pens compatible for growth disorder treatment are:

- Sogroya (somapacitan-beco)
- Norditropin FlexPro

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.

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BIOCORP
a novo nordisk company

MALLYA^{G}

510(k) Summary - K251500

1 SUBMITTER

Applicant:	Biocorp Production ZI Lavaur La Béchade 63500 Issoire – France
Prepared By:	Alexia Garin
Date Prepared:	June 09, 2025

2 DEVICE

Trade/Proprietary Name:	Mallya^{G} Injection Pen Adapter (Mallya^{G})
Common/Usual Name:	Injection Data Capture Device
Classification Name:	21 CFR §880.5860 Piston Syringe
Product Code:	QOG
Class:	II
510(k) number:	K251500

3 PREDICATE DEVICE

K250555, Biocorp Production, Mallya^{D} Injection Pen Adapter (Mallya^{D}).

4 SUBSTANTIAL EQUIVALENCE

The Mallya^{G} Injection Pen Adapter device is substantially equivalent to the Mallya^{D} (K250555). The device has the same indication for use and same scientific technology.

4.1 DEVICE DESCRIPTION

The Mallya^{G} Injection Pen Adapter is a smart sensor composed of a button to be assembled onto a pen injector by covering the injection pen button. It is designed to be mounted on specific Novo Nordisk® PDS290 platform injection pens. A USB cable, necessary to charge the Mallya^{G} device, is also provided in the package.

4.2 TECHNOLOGICAL CHARACTERISTICS

The Mallya^{G} has the same technological characteristics as the predicate device to capture and transmit dosing information. The information is captured through the rotation of the dosing button of the pen into a value indicating the dose increment injected. Both the Mallya^{G} and the predicate device use same Low Energy Bluetooth (BLE) communication technology and same protocol to pair and transmit the information to a mobile device with a connectable app.

4.3 INDICATIONS FOR USE

The MallyaG Injection Pen Adapter is indicated for the capture and wireless transmission of dosing information of compatible reusable and disposable pen injectors.

The Novo Nordisk PDS290 Injection pens compatible for growth disorder treatment are:
- Sogroya (somapacitan-beco)
- Norditropin FlexPro

4.4 DEVICE PHYSICAL DESCRIPTION

The device is made of a cap to be assembled onto a pen injector by covering the injection pen button. The overall device size is 25.8 mm diameter and 40.1 mm height. A USB cable, necessary to charge the Mallya[G] device, is also provided in the package.

4.5 SUBSTANTIAL EQUIVALENCE DISCUSSION

Attribute	***Subject Device***	***Predicate device***	
Device Name/ Brandname	Mallya Injection Pen Adapter Mallya[G]	Mallya Injection Pen Adapter Mallya[D]	
	Data Capture and Transmission Technology		
510(k) Number	N/A	K250555	
Attribute	***Subject Device***	***Predicate device***	***Discussion/ Comments***
Device Classification-Product Code	Class 2 – QOG	Class 2 – QOG	Same
Indication for Use	The Mallya[G] Injection Pen Adapter is indicated for the capture and wireless transmission of dosing information of compatible reusable and disposable pen injectors. The Novo Nordisk PDS290 Injection pens compatible for growth disorder treatment are: - Sogroya (somapacitan-beco) - Norditropin FlexPro	The Mallya[D] Injection Pen Adapter is indicated for the capture and wireless transmission of dosing information of compatible reusable and disposable pen injectors. The Novo Nordisk PDS290 Injection pens compatible for diabetes treatment are: - insulin degludec molecule (Tresiba U-100 FlexTouch and Tresiba U-200 FlexTouch) - insulin aspart molecule (Fiasp FlexTouch) - insulin degludec and liraglutide molecules (Xultophy)	Same indication for use baseline Same pen platform compatibility (Novo Nordisk PDS290)

Attribute	*Subject Device*	*Predicate device*	
Single patient Use	Yes	Yes	Same
Reusable Device	Yes	Yes	Same
Intended Use	Intended to be used by patients in the same use environment as their compatible injection pen.	Intended to be used by patients in the same use environment as their compatible injection pen.	Same
Prescription use	No	No	Same
User Group	User of Compatible Injection Pens; includes patients or patient relatives/caregiver	User of Compatible Injection Pens; includes patients or patient relatives/caregiver	Same
User Feedback	Electronic – LED (light)	Electronic – LED (light)	Same light indication
Wireless Connectivity	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)	Same connectivity BLE protocol
Control or impact Drug delivery	No	No	Same
Fluid Pathway Contact	None	None	Same
Software controlled	Yes	Yes	Same
Dose Recorded	Calculated based on dose increment set	Calculated based on dose increment set	Same
Information Transmitted	Dialed dose increment, and time and date of injection	Dialed dose increment, and time and date of injection	
Mechanism for Recording dose dialed	Sense dose increment dialed through movement and rotation of dosing mechanism during dose setting	Sense dose increment dialed through movement and rotation of dosing mechanism during dose setting	
Differentiates Prime vs. Dose	Yes	Yes	Same
Battery	Non-Replaceable; Rechargeable	Non-Replaceable; Rechargeable	Same
Lifetime	Up to 3 years of use from manufacturing date	Up to 3 years of use from manufacturing date	Same

5 SIGNIFICANT PERFORMANCE CHARACTERISTICS

5.1 PERFORMANCE CLAIMS

Mallya[G] claims are based on the reported dose accuracy:

- Device accuracy: 99% of the recorded doses match the dialed doses with a margin of error of +/- 1 increment.

5.2 SUPPORTING PERFORMANCE DATA

Data from the following testing identified, as appropriate to assess the impact of the modifications, were generated verifying the design of the modified device:

- Bench testing on performance, using ISO 11608-1 as a guide.
  - Dose Prime Differentiation.
- Biocompatibility –FDA guidance; permanent contact with intact skin based on ISO10993-1.
- Electrical safety, EMC and Radiocommunication – per FDA Guidelines based on IEC 60601-1 and appropriate collateral requirements from IEC 60601-2 and IEC 60601-1-11.
- Cybersecurity Testing and Software Verification and Validation per FDA Guidelines.

5.3 HUMAN FACTOR VALIDATION

Biocorp performed a human factor impact assessment for performance and safety validation to confirm the usability of the device and associated instructions for use per FDA human factor guidance.

6 CONCLUSION

Biocorp as concluded that the evidence documented during design control activities supports that the Mallya[G] Injection Pen Adapter (Mallya[G]), is substantially equivalent to the predicate for specific indications and technological characteristics of the predicate device with regards to the data recording and transmission.

7 CONTACT PERSON

Alexia Garin, pms@biocorp.fr +33 473 557050