December 5, 2022

Biocorp Production
℅ Lee Leichter
President
P/L Biomedical
5800 West State Road 80 - Lot 219
Labelle, Florida 33935

Re: K222689
Trade/Device Name: Mallya Injection Pen Adapter (Mallya® for Solostar®)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QOG
Dated: August 29, 2022
Received: September 6, 2022

Dear Lee Leichter:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Alan M. Stevens -S3

CAPT Alan M. Stevens
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K222689

Device Name

Mallya Injection Pen Adapter

Indications for Use *(Describe)*

The Mallya Injection Pen Adapter is indicated for the capture and wireless transmission of dosing information from compatible reusable and disposable pen injectors. The following Injection pens are compatible.

MALLYA MODEL	INSULIN BRAND NAME	MOLECULE NAME	MOLECULE CONCENTRATION
Mallya designed for **Solostar® SANOFI** injection pen	Lantus	GLARGINE	100 IU/mL
	Toujeo		300 IU/mL
	Admelog	LISPRO	100 IU/mL
	Apidra	GLULISINE	100 IU/mL
	Soliqua 100/33	GLARGINE AND LIXISENATIDE	100 IU/mL +33 mcg/mL

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."

Summary of Safety and Effectiveness (510(k) Summary)

1.	Prepared By:	Alexia Garin
2.	Date Prepared:	Dec 5, 2022
3.	Trade/Proprietary Name:	Mallya Injection Pen Adapter (Mallya® for Solostar®)
4.	Common/Usual Name:	Injection Data Capture Device
5.	Classification Name:	Piston Syringe 21 CFR 880.5860 Product Code: QOG
6.	Predicate Device:	K160629, Companion Medical, InPen
7.	Manufacturing Site:	Biocorp Production ZI Lavaur La Béchade 63500 Issoire – France
8.	Registration Number:	-

9. Substantial Equivalence: The Mallya device is substantially equivalent to the InPen (K160629). The InPen is classified as a Piston Syringe and indicated for the delivery Humalog and Novolog. Although the InPen is a full reusable Injection Pen, it contains electronics, a non-replaceable battery and a Bluetooth radio that facilitates capture and transmission of dosing information to a standalone software device. This function is the functionality added by the Mallya as an accessory to SoloStar® injection pens that are not so equipped.

10. Technological Characteristics: The Mallya Injection Pen Adapter has the same technological characteristics as the predicate device to capture and transmit dosing information. The information is captured through a translation of the rotation of the dosing knob of the pen into a value indicating the dose increment dialed. The Mallya senses the proximity of the dose knob at the end of the delivery to indicate that the dose has been completed. Both the Mallya and the predicate device use Low Energy Bluetooth (BLE) communication technology and protocol to pair and transmit the information to a mobile device with a compatible app.

11. Physical description: The device is made of two parts to be assembled onto a pen injector. The Mallya base part (about 6 x 3 x 2 cm) which clips around the body of the injection pen and the Mallya button (about 2.5 x Ø2 cm) that slips over the injection pen button. A USB cable, necessary to charge the MALLYA device, and a reset key are also provided in the package.

12. Mallya device is compatible with the SoloStar® injection pens available on the US market such as the insulin brand names, molecules and associated concentrations listed in the table below:

MALLYA MODEL	INSULIN BRAND NAME	MOLECULE NAME	MOLECULE CONCENTRATION
Mallya designed for **SoloStar® SANOFI** injection pen	Lantus	GLARGINE	100 IU/mL
	Toujeo		300 IU/mL
	Admelog	LISPRO	100 IU/mL
	Apidra	GLULISINE	100 IU/mL
	Soliqua 100/33	GLARGINE AND LIXISENATIDE	100 IU/mL +33 mcg/mL

13. Substantial Equivalence:

COMPARISONS TO PREDICATE DEVICE

Attribute	*Subject Device*	*Predicate*	*Discussion/Comments*
Device Name	Mallya	InPen (data capture and transmission technology only)	The InPen functions as a pen injector in addition to capturing and communicating information. The Mallya works only as a data capture and transmission device accessory to approved pen injectors
Information Capture and Transmission Technology			
510(k) Number	N/A	K160629	N/A
Device Classification	Class 2 - QOG	Class 2 - FMF	The InPen is classified as a Piston Syringe and not the new Procode of Injection Data Capture Device. Both are within the same classification
Indication for Use	Indicated for the capture and wireless transmission of dosing information from compatible reusable and disposable pen injectors.	The InPen is a home-use reusable pen injector for single-patient use	The InPen is indicated for use as an injection pen and dose calculator, but does not have a specific indication for use related to information capture and transmission
Single patient Use	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 people with diabetes age 12 and older for the self-injection of a desired dose of insulin.	The InPen is intended to deliver insulin whereas the Mallya will work with any compatible injection pen for which it is labeled.
Prescription use	No	Yes	injection pens are for use by prescription only, but a separate prescription is not required for the Mallya
User Group	User of Compatible Injection Pens; includes diabetes patients	Diabetes patients treated with multiple daily insulin injection (MDI) therapy	Same
User Feedback	Electronic - LED (light) and Audible (Beeps)	Mechanical - Audible and tactile clicks per increment	Feedback to user is for injection pen function
Wireless Connectivity	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)	Same
Control or impact Drug delivery	No	No	Same, the information recording and transmission function does not impact drug delivery
Software	Yes	Yes	The recording and transmission of information is controlled by software
Fluid Pathway Contact	None	None	Same
Dose Recorded	Calculated based on dose set	Calculated based on dose set	Same
Information Transmitted	Dialed dose, and time and date of injection	Dialed dose, and time and date of injection	Same
Mechanism for Recording	Sense dose dialed through rotation of dosing mechanism	Sense dose dialed through rotation of dosing mechanism	Although the technology is different (magnet vs. electronic rotational

Attribute	*Subject Device*	*Predicate*	*Discussion/Comments*
dose dialed	during dose setting	during dose setting	encoder), both use the rotation of the dose knob during dose setting to determine the dose that has been dialed. Accuracy of Mallya dose recording has been assessed and verified during Design Verification.,
Differentiates Prime vs. Dose	Yes	Yes	Same
Battery	Non-Replaceable; Rechargeable	Non-Replaceable; Non-Rechargeable	The InPen cannot be recharged.
Lifetime	2 years of use	1 year of use	The Mallya can be used for up to two years

14. Performance Data

Data on the following testing were generated verifying the design of the device:

- Electromagnetic Compatibility and Electrical Safety – IEC 60601-1 and appropriate collateral requirements from IEC 60601-2 and IEC 60601-1-11
- Bench testing on performance, using ISO 11608-1 as a guide.
    - Dose accuracy of pen is not affected by Mallya
    - Recording and transmission Accuracy
    - Dose Prime Differentiation
    - Complete Dose Notification
    - Incomplete Injection Identification
    - Physical Interaction with pen, including force to mount, maintain and remove Mallya
- Biocompatibility – ISO 10993-1 and FDA guidance; permanent contact with intact skin
- Lifetime – The product met test criteria to verify it will operate/function for 2 years (Use Lifetime) following storage for up to two years (Shelf Life).
- Cybersecurity Testing and Software Verification and Validation per FDA Guidelines
- Human Factors – HF Validation per FDA guidance

15. Conclusion

The data presented supports that the Mallya is substantially equivalent to the predicate for specific indications and technological characteristics of the predicate device with regards to the data recording and transmission.

16. Contact person:

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