January 12, 2024

Biocorp Production
Alexia Garin
Vice President & Regulatory Affairs
Zi Lavaur -La Béchade
Issoire, 63500, France

Re: K231820
Trade/Device Name: SoloSmart Injection Pen Adapter (SoloSmart®)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QOG
Dated: December 20, 2023
Received: December 20, 2023

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.

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, MS
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)*
K231820

Device Name
SoloSmart Injection Pen Adapter (SoloSmart®)

Indications for Use *(Describe)*
The SoloSmart 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:

DEVICE MODEL NAME	INSULIN BRAND NAME	MOLECULE NAME	MOLECULE CONCENTRATION
SoloSmart 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 +33mcg/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.

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"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)

1. Prepared By: Alexia Garin
2. Date Prepared: December 20, 2023
3. Trade/Proprietary Name: SoloSmart Injection Pen Adapter (SoloSmart®)
4. Common/Usual Name: Injection Data Capture Device
5. Classification Name: Piston Syringe
   21 CFR 880.5860
   Product Code: QOG
6. Predicate Device: K222689, Biocorp Production, Mallya Injection Pen Adapter
7. Applicant: Biocorp Production
   ZI Lavaur La Béchade
   63500 Issoire – France
8. Substantial Equivalence: The SoloSmart® device is substantially equivalent to the Mallya (K222689). The device has the same indication for use, intended use and same fundamental scientific technology.
9. Technological Characteristics: The Solosmart® Injection Pen Adapter 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 SoloSmart® 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 compatible app.
10. 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 21.4mm diameter & 23.3mm height. A USB cable, necessary to charge the SoloSmart® device is also provided in the package.
11. Indications for Use: The SoloSmart 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:

DEVICE MODEL	INSULIN BRAND NAME	MOLECULE NAME	MOLECULE CONCENTRATION
SoloSmart® 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

12. Substantial Equivalence discussion:

Attribute	*Subject Device*	*Predicate*	*Discussion/Comments*
Device Name	SoloSmart®	Mallya	-
Data Capture and Transmission Technology			
510(k) Number	K231820	K222689	-
Device Classification	Class 2 – QOG	Class 2 – QOG	same
Indication for Use	Indicated for the capture and wireless transmission of dosing information from compatible reusable and disposable pen injectors.	Indicated for the capture and wireless transmission of dosing information from compatible reusable and disposable pen injectors.	
Single patient Use	Yes	Yes	
Reusable Device	Yes	Yes	
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.	
Prescription use	No	No	
User Group	User of Compatible Injection Pens; includes diabetes patients	User of Compatible Injection Pens; includes diabetes patients	
User Feedback	Electronic – LED (light)	Electronic – LED (light) and Audible (Beeps)	Both provide visible feedback (light). Removal of audible feedback was confirmed as unnecessary in a HF Validation study
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	
Software controlled	Yes	Yes	same
Dose Recorded	Calculated based on dose set	Calculated based on dose set	Change from two-part to one part device necessitated and enabled changes to the hardware and software to capture, record and transmit the dose delivered, rather than
Information Transmitted	Dialed dose, and time and date of injection	Dialed dose, and time and date of injection	
Mechanism for Recording dose dialed	Sense dose dialed through rotation of dosing mechanism during dose administration	Sense dose dialed through rotation of dosing mechanism during dose setting	

Differentiates Prime vs. Dose	Yes	Yes	only the dose that was set (dialled).
Battery	Non-Replaceable; Rechargeable	Non-Replaceable; Rechargeable	Same type of battery with same design input specification regarding battery
Lifetime	Up to 3 years of use from manufacturing date	2 years of use	Extended lifetime

13. Performance Data

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

- Bench testing on performance, using ISO 11608-1 as a guide.
  - Dose accuracy of pen is not affected by SoloSmart®
  - Recording and transmission Accuracy
  - Dose Prime Differentiation
  - Complete Dose Notification
  - Incomplete Injection Identification
  - Physical Interaction with pen, including force to mount, maintain and remove SoloSmart®
- 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).
- Electrical safety, EMC and Radiocommunication – 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

14. Human factor validation

Biocorp performed a HF Validation study to confirm the usability of SoloSmart device form factor and associated instructions for use per FDA guidance.

15. Conclusion

Biocorp as concluded that the evidences documented during design control activities supports that the SoloSmart 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:
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