August 22, 2024

INSULCLOUD S.L.
% Dulciana Chan
Principal Consultant
RQM+
2790 Mosside Blvd, Suite 800
Monroeville, Pennsylvania 15146

Re: K241803
Trade/Device Name: INSULCLOCK® v2.0 PRO
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QOG
Dated: June 18, 2024
Received: June 21, 2024

Dear Dulciana Chan:

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.

Submission Number *(if known)*

K241803

Device Name

INSULCLOCK® v2.0 PRO

Indications for Use *(Describe)*

- Insulclock® is for use by patients using disposable insulin diagnosed with type I or type II diabetes mellitus.
- Insulclock® is for use by people from 18 to 65 years old.
Out of this age range, the Insulclock® must be used under supervision.
- Insulclock® is designed for use in any home environment.
- Using a compatible App.

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

DATE PREPARED
June 18, 2024

MANUFACTURER AND 510(k) OWNER
INSULCLOUD S.L.
Avenida Sabino Arana, #8, 48013
Telephone: +34674379320
Official Contact: Pilar Aranda, Quality Technician

REPRESENTATIVE/CONSULTANT
Allison C. Komiyama, Ph.D., R.A.C.
Dulciana Chan, MSE
RQM+
Telephone: +1 (877) 652-0830
Email: akomiyama@rqmplus.com
dchan@rqmplus.com

DEVICE INFORMATION

Proprietary Name/Trade Name:	INSULCLOCK® v2.0 PRO
Common Name:	Piston Syringe
Regulation Number:	880.5860
Class:	II
Product Code:	QOG
Premarket Review:	OHT3: Office of Gastrorenal, OBGyn, General Hospital, and Urology Devices, Office of Product Evaluation and Quality
Review Panel:	General Hospital and Personal Use Devices

PREDICATE DEVICE IDENTIFICATION
The INSULCLOCK® v2.0 PRO is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K212217	Tempo Smart Button	✓

The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION
The INSULCLOCK® v2.0 pro is a reusable data transmitter with Software Development Kit (SDK) that detects and stores insulin dose- related data when attached to a disposable insulin pen and then transfers information to a compatible mobile application via Bluetooth® wireless technology which can display the brand of insulin, dose amount, injection date, injection time, and ambient temperature.

Models:
- INSULCLOCK® v2.0 PRO for Kwikpen® (Lilly®)
- INSULCLOCK® v2.0 PRO for Flex-touch® (Novo Nordisk®)

INDICATIONS FOR USE

- Insulclock® is for use by patients using disposable insulin diagnosed with type I or type II diabetes mellitus.

- Insulclock® is for use by people from 18 to 65 years old.

Out of this age range, the Insulclock® must be used under supervision.

- Insulclock® is designed for use in any home environment.

- Using a compatible App.

INTENDED USE: INSULCLOCK® v2.0 pro is intended to detect, store and transfer insulin dose-related data, the time of injection and the temperature to which the disposable insulin pen has been exposed to. All this information is sent to a mobile app via integrated SDK.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

INSULCLOCK® v2.0 pro is substantially equivalent to the Tempo Smart Button (K212217) predicate device based on the similarities summarized in the following Table of Substantial Equivalence.

Attribute	*Subject Device*	*Predicate Device*	*Comparison*
	INSULCLOUD S.L. INSULCLOCK® v2.0 pro	Eli Lilly and Company Tempo Smart Button K212217	
Intended Use of Electronic Functionality	Detect, store, and transfer insulin dose- related data from the pen to a compatible application	Detect, store, and transfer insulin dose- related data from the pen to a compatible application	Same
Indications for Use	Insulclock® is for use by patients using disposable insulin diagnosed with type I or type II diabetes mellitus. - Insulclock® is for use by people from 18 to 65 years old. Out of this age range, the Insulclock® must be used under supervision. - Insulclock® is designed for use in any home environment.- Using a compatible App.	The Tempo Smart Button is intended to detect, store, and transfer insulin dose-related data from a Tempo Pen to a compatible application such as the myTempo App (App). The tempo Smart button is indicated for single-patient use by patients 18 years or older who are: ● Diagnosed with type 1 or 2 diabetes mellitus ● Using pre-filled insulin Tempo pens (Basaglar® Tempo Pen (insulin glargine) injection 100 units/mL, Lyumjev® Tempo Pen (insulin lispro-aabc) injection 100 units/mL, Humalog®Tempo Pen (insulin lispro injection) 100 units/mL] ● Using compatible application (APP)	Similar
Intended Users	Patients between the ages of 18 and 65 who are diagnosed with type 1 or type 2 diabetes mellitus. If the user is outside this age range, the device must be used under supervision.	People with diabetes age 18 and older	Similar
Single Patient Use	Yes	Yes	Same
Availability	Prescription only	Prescription only	Same
Classification	Class II – 21 CFR 880.5860	Class II – 21 CFR 880.5860	Same
Drug Contact	None	None	Same
Biocompatibility defined by ISO 10993-1	Meets requirements for intact skin contact	Meets requirements for intact skin contact	Same
Dose Accuracy	Meets ISO 11608-1 requirements when evaluated with compatible pens	Meets ISO 11608-1 requirements when evaluated with compatible pens	Same

Attribute	*Subject Device*	*Predicate Device*	*Comparison*
	INSULCLOUD S.L. INSULCLOCK® v2.0 pro	Eli Lilly and Company Tempo Smart Button K212217	
Reusable Device	Yes	Yes	Same
Digital Dose Display	No	No	Same
Electronically Controlled Dosing	No	No	Same
Battery	Rechargeable battery meeting UNE-EN 62133-2:2017,UN 38.3 and UL 1642.	Non-rechargeable	Different
Electronic Structure	Foiled flex circuit	Foiled flex circuit	Same
Electrical Safety	Meets IEC 60601-1 Requirements	Meets IEC 60601-1 Requirements	Same
Embedded Firmware	Meets IEC 62304 requirements: Class B Enhanced documentation in accordance with Content of Premarket Submissions for Device Software Functions	Meets IEC 62304 requirements: Major level of concern	Same
Electronic Data for Insulin Identification	Insulin Identification manually selected by the user during setup.	Insulin Identification detected by system.	Different
	Insulin identification displayed on mobile application.	Insulin identification displayed on mobile application.	Same
Electronic Data for Dose Information Capture	Dose-related data recorded; dose information displayed on mobile application.	Dose-related data recorded; dose information displayed on mobile application.	Same
Dose History	Full; Displayed on mobile application.	Full; Displayed on mobile application.	Same
Data Transfer	Bluetooth.	Bluetooth.	Same
Insulin Disposable Pen compatibilities	• Kwikpen® model (Lilly) • Flextouch® model (Novo Nordisk)	Tempo Pens (Basaglar® U-100 Tempo Pen, Lyumjev® U-100 Tempo Pen, Humalog® U-100 Tempo Pen)	Different
Compatible Mobile Applications	Mobile applications for Android 8.0 or higher or iOS 15.0 or higher, using the INSULCLOCK® v2.0 pro Software Development Kit (SDK)	My Tempo App	Different
Temperature Measurement	Ambient temperature measurement	No	Different

The following technological differences exist between the subject and predicate devices:

- Tempo Smart Button is indicated for use in people with diabetes over 18 years of age and INSULCLOCK® v2.0 pro intended users are patients between the ages of 18 and 65 who are diagnosed with type 1 or type 2 diabetes mellitus. If the user is outside this age range, the device must be used under supervision.
- The INSULCLOCK® v2.0 pro battery is rechargeable, whereas the predicate battery is not rechargeable.
- Both INSULCLOCK® v2.0 pro and Tempo Smart Button display Insulin identification on the mobile application. However, with INSULCLOCK® v2.0 pro, insulin is identified by the user in the app during setup, while it is detected by the system when using Tempo Smart Button.
- The subject and predicate devices are compatible with different Insulin Disposable Pens. Tempo Smart Button is compatible with Tempo pens (i.e., Basaglar® U-100 Tempo Pen, Lyumjev® U-100 Tempo Pen, Humalog® U-100 Tempo Pen). INSULCLOCK® v2.0 pro features two device models, one compatible with the Kwikpen® model (Lilly) and one with the Flextouch® model (Novo Nordisk).
- Compatible Mobile Applications: Tempo Smart Button is only compatible with My Tempo App, whereas INSULCLOCK® v2.0 pro is compatible with Mobile applications for Android 8.0 or higher or iOS 15.0 or higher using the INSULCLOCK® v2.0 pro Software Development Kit (SDK).
- INSULCLOCK® v2.0 pro can measure ambient temperature whereas Tempo Smart Button cannot.

In summary, INSULCLOCK® v2.0 pro has the same intended use and similar indications, technological features, and operating principles to the predicate device. The minor differences in technological characteristics do not raise new or different questions of safety or effectiveness.

SUMMARY OF NON-CLINICAL TESTING

The INSULCLOCK® v2.0 pro was tested to evaluate its performance based on the following standards:

Standard	Version	Title
Biocompatibility		
ISO 10993-1	2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
Software and Cybersecurity		
IEC 62304	2006	Medical device software. Software Life Cycle Processes
UL 2900-1	2023	Software Cybersecurity for Networks-Connectable Products, Part 1: General Requirements
UL 2900-2-1	2023	Software Cybersecurity for Networks-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems
Electrical Safety and EMC		
IEC 60601-1	2005 +	Medical electrical equipment - Part 1: General requirements for basic safety

Standard	Version	Title
	Amd1:2012	and essential performance.
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests.
IEC 60601-1-2:2020 (4.1 Edition)	2020	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
ANSI C63.27	2017	American National Standard for Evaluation of Wireless Coexistence
AIM 7351731	N/A	Medical Electrical Equipment & System Electromagnetic Immunity Test for Exposure to RFID Readers
AAMI TIR69:2017 (R2020)	2017	American National Standard for Evaluation of Wireless Coexistence
Performance		
UNE-EN ISO 11608-1	2022	Needle-based injection systems for medical use - Requirements and test methods - Part 1: Needle-based injection systems

HUMAN FACTORS PERFORMANCE DATA

A human factors validation study was conducted on participants who were representative of intended users. The results of the study showed that intended users were able to operate the device as intended.

SUMMARY OF CLINICAL TESTING

Clinical testing was not required to demonstrate the substantial equivalence of the INSULCLOCK® v2.0 pro to its predicate device.

CONCLUSION

Based on the information presented in this 510(k) premarket notification, the INSULCLOCK® v2.0 pro is considered substantially equivalent to the predicate device, Tempo Smart Button (K212217). The differences noted between the INSULCLOCK® v2.0 pro and the predicate device do not impact substantial equivalence based on the successfully conducted testing of the subject device.