September 16, 2022

Eli Lilly and Company
Marcia Arentz
Sr. Director
Lilly Corporate Center
Indianapolis, Illinois 46285

Re: K212217
Trade/Device Name: Tempo Smart Button
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QOG, OCN
Dated: July 11, 2022
Received: July 12, 2022

Dear Marcia Arentz:

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,

CAPT Alan 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212217

Device Name

Tempo Smart Button

Indications for Use *(Describe)*

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 type 2 diabetes mellitus,
- using prefilled 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 a compatible application (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

I. Submitter

Name and Address: Eli Lilly and Company
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Indianapolis, IN 46285

Contact: Marcia Arentz, MBA, MS-RA/QA, RAC
Senior Director Global Regulatory Affairs –
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Date Prepared: September 16, 2022

II. Device

Trade Name: Tempo Smart Button

Classification Name: Injection Data Capture Device

Regulation 21 CFR §880.5860 Piston Syringe

Product Codes: QOG, OCN

Class: II

III. Predicate Device

InPen System (K160629)

IV. Device Description

The Tempo Smart Button is a reusable data transmitter that detects and stores insulin dose-related data when attached to a disposable Tempo Pen and then transfers information to a compatible mobile application via Bluetooth® wireless technology. The insulin dose-related data is used by the mobile application which can display the brand of insulin, dose amount, date, and time.

Additionally, the Tempo Smart Button is available as part of a Welcome Kit. The Tempo Welcome Kit and Refill Kit provide the convenience of having a single kit that contains devices needed for insulin administration and blood glucose monitoring.

V. Intended Use and Indications for Use

The Tempo Smart Button is intended to detect, store, and transfer insulin dose-related data from a Tempo Pen to a compatible application.

The Tempo Smart Button is indicated for single-patient use by patients 18 years or older who are:

- diagnosed with type 1 or type 2 diabetes mellitus,
- using prefilled 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 a compatible application (App).

VI. Comparison of Technological Characteristics

The Tempo Smart Button, when used with a Tempo Pen, is substantially equivalent to the InPen pen injector (K160629). A substantial equivalence chart comparing the subject and predicate attributes is shown in the following table.

Attribute	InPen pen injector electronic functionality (predicate device, K160629)	Tempo Smart Button (subject device)
Intended Use of Electronic Functionality	Detect, store, and transfer insulin dose-related data from the pen to a compatible application	Same
Indications for Use		
Intended Users	People with diabetes age 12 and older	People with diabetes age 18 and older
Single Patient Use	Yes	Same
Availability	Prescription only	Same
Preparation for Injection	User installs cartridge and attaches needle to pen	User attaches module and attaches needle to pen
Classification	Class II – 21 CFR 880.5860	Same
Drug Contact	None	Same
Biocompatibility defined by ISO 10993-1	Meets requirements for intact skin contact	Same
Dose Accuracy	Meets ISO 11608-1 requirements when evaluated with compatible pre-filled cartridges	Meets ISO 11608-1 requirements when evaluated with compatible pens
Reusable Device	Yes	Same
Digital Dose Display	No	Same
Electronically Controlled Dosing	No	Same
Battery	Non-rechargeable	Same
Electronic Structure	Folded flex circuit	Same
Electrical Safety	Meets IEC 60601-1 requirements	Same
Embedded Firmware	Meets IEC 62304 requirements; Major level of concern	Same
Electronic Data for Insulin Identification	Insulin Identification manually selected by user during setup and displayed on mobile application during dosing	Insulin Identification detected by system and displayed on mobile application
Electronic Data for Dose Information Capture	Nominal dose recorded	Dose-related data recorded; dose information displayed on mobile application
Dose History	Full; Displayed on mobile application	Same
Data Transfer	Bluetooth (proprietary profile)	Similar

When attached to a Tempo Pen, the Tempo Smart Button has the same intended use and similar indications, technological characteristics, and principles of operation as the predicate device. The intended user group of the subject module falls within the intended user group of the predicate pen. The minor differences in technological characteristics do not raise different questions of safety or effectiveness.

VII. Nonclinical Performance Data

Biocompatibility: The module was evaluated according to the criteria in ISO 10993-1:2018 *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing*. All patient-contact components passed the cytotoxicity, sensitization, and irritation testing requirements.

Electromagnetic Compatibility and Electrical Safety: The module was evaluated according to the electrical safety and electromagnetic compatibility criteria in IEC 60601-1 *Medical Electrical Equipment, Part 1: General Requirements For Basic Safety And Essential Performance* and IEC 60601-1-2 *Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests*. The module complies with IEC 60601-1-11 *Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment*.

Software Verification and Validation: Lilly conducted software verification and validation and provided documentation in accordance with FDA *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (2005).

Cybersecurity: Lilly evaluated cybersecurity in accordance with FDA *Guidance Content of Premarket Submissions for Management of Cybersecurity in Medical Devices* (2014 and 2018 Draft) and identified no unacceptable or uncontrolled security verification test findings.

Bench Testing: Testing confirms that the module does not impact Tempo Pen compliance to specifications for dialing torque, injection force, and dose accuracy, nor does it impact Tempo Pen compliance to ISO 11608-1, *Needle-Based Injection Systems For Medical Use – Requirements And Test Methods – Part 1: Needle-Based Injection Systems*.

Lilly completed module testing for general design requirements, mechanical characterization, and accuracy of electronic dose capture. In all instances, the module met the acceptance criteria.

Risk Management: Lilly's Quality System complies with the requirements of ISO 14971:2012 *Medical devices - Application of risk management to medical devices*. Lilly followed applicable procedures during development of the module and app.

VIII. Human Factors Performance Data

Lilly developed the user interface (UI) through a comprehensive Human Factors (HF) Engineering Process. In the HF Validation Test, intended users successfully completed a series of simulated use scenarios used to evaluate critical tasks, which demonstrated that the module is safe and effective for the intended use by the intended user population in the intended use

environments.

IX. Conclusions

The subject device is substantially equivalent to the predicate device because it has the same intended use, indications for use that fall within those of the predicate device, and minor differences in technological characteristics that do not raise different questions of safety and effectiveness. Performance data demonstrate substantial equivalence.