August 20, 2025

Comerge AG
Andreas Pedroni
Person Responsible for Regulatory Compliance
Bubenbergestrasse 1
Zurich, 8045
Switzerland

Re: K252104
Trade/Device Name: T1D1
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: NDC
Dated: July 3, 2025
Received: July 3, 2025

Dear Andreas Pedroni:

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 and Part 809); 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,

JOSHUA BALSAM -S

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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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)*
K252104

Device Name
T1D1

Indications for Use *(Describe)*
The T1D1 mobile application is indicated for the management of diabetes by people with Type 1 diabetes age 2 and older by calculating insulin doses based on user-entered data.

Prior to use, a healthcare professional must provide the patient target blood glucose values, insulin-to-carbohydrate ratios, and the correction factor (also known as the insulin sensitivity factor) to be programmed into the App software.

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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"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

T1D1

I. Submitter

Address: Comerge AG
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Zurich, 8045
Switzerland

Phone: (+41) 79 300 17 42
Contact: Mr. Andreas Pedroni

Date Prepared: August 1, 2025

II. Device

Name of Device: T1D1
Common Name: Insulin Dose Calculator
Classification Name: Regulation: Predictive pulmonary-function value calculator
21 CFR 868.1890, Class II
Product Codes: NDC

III. Predicate Device

- InPen® Dose Calculator (K181327)

IV. Device Description

The T1D1 application is a user-friendly mobile application designed for Android and Apple devices, specifically catering to individuals aged 2 and above who have Type 1 Diabetes Mellitus (T1DM) and undergo multiple daily injection (MDI) therapy. Its primary objective is to simplify insulin dosing management by providing essential features such as a bolus calculator, a convenient logbook, and various configurable user-specific settings. The T1D1 application is intended to be distributed free of charge and without advertisements while operating independently of any other diabetes care devices. The overarching aim of the app is to streamline the daily calculations required by individuals with T1DM, alleviating the time-consuming and error-prone task of manually calculating and keeping track of insulin dosing.

The key feature of the T1D1 application is the bolus calculator. This calculator implements the standard insulin bolus calculation, taking into account factors such as the user's current blood

glucose levels, carbohydrate intake, and target blood glucose levels. By considering these variables, the app provides users with an insulin dose recommendation, which assists in maintaining stable blood sugar levels.

The logbook feature allows users to record, track, and share their diabetes-related information. This information includes blood glucose levels, insulin doses, carbohydrate intake, and other relevant information. The ability to log and share this information with healthcare professionals or family members allows for improved communication and collaboration between individuals with T1DM and their support network.

The T1D1 application offers several presets to simplify the insulin dosing process. These presets can be customized based on individual preferences and needs. By providing preset options, the app eliminates the need for manual input of commonly used settings, saving time and reducing the likelihood of errors. In summary, the T1D1 application is a user-friendly mobile application that assists individuals with T1DM in managing their everyday insulin dosing from day one of their diagnosis.

V. Indications For Use

The T1D1 mobile application is indicated for the management of diabetes by people with Type 1 diabetes age 2 and older by calculating insulin doses based on user-entered data.

Prior to use, a healthcare professional must provide the patient target blood glucose values, insulin-to-carbohydrate ratios, and the correction factor (also known as the insulin sensitivity factor) to be programmed into the App software.

VI. Comparison of Technological Characteristics With The Predicate Device

T1D1 is similar in the indications for use to the primary predicate device, the InPen dose calculator (K181327). It differs in that lay caregivers can also use it for younger children starting at the age of two (2). Additionally, its use is restricted to patients with Type 1 Diabetes and is distributed over-the-counter.

To minimize the risk of use by unintended users, the device requires individuals to assess themselves as intended users. Furthermore, the predicate device allows the user to calculate an insulin dose or carbohydrate intake based on user-entered data, whereas the subject device focuses on insulin dose calculation only.

From a technological point of view, the subject device shares many similarities with the predicate devices. The T1D1 application runs on iOS and additionally on Android devices and implements the bolus dosing calculation as indicated by the American Diabetes Association (ADA) standards without modifications. To keep diabetes management as simple as possible

and make it as widely available to a broad population, the subject device is not dependent on nor connected to any diabetes care device.

In contrast to the predicate device, residual bolus insulin is not modeled and actively considered in the bolus insulin calculation. The T1D1 application informs the user about the last logged insulin bolus administration, leaving it up to the user to adjust the current insulin dose. Similar to the predicate devices, T1D1 offers a logbook feature where the user can keep track of their insulin dosing history. Because the T1D1 application is not connected to a blood glucose monitoring (BGM) device or a continuous glucose monitoring (CGM) device, it does not offer reports and graphs of current glucose or currently active insulin. However, users can select a date range of their logbook to create a CSV file export that can be shared via Email with their HCP or caretakers.

Attribute	Subject Device	Predicate Device (candidate)	Comments
Trade name	T1D1	InPen Dose Calculator	n/a
510(k) submitter / holder	Comerge AG	Companion Medical, Inc	n/a
510(k) number	K252104	K181327	n/a
Regulation number	21 CFR 868.1890	21 CFR 868.1890	Same
Regulatory class	Class II	Class II	Same
Product code	NDC	NDC	Same
Classification panel	Division of Chemistry and Toxicology Devices (DCTD)	Division of Chemistry and Toxicology Devices (DCTD)	Same

Indications for Use	The T1D1 mobile application is indicated for the management of diabetes by people with Type 1 diabetes age 2 and older by calculating insulin doses based on user-entered data. Prior to use, a healthcare professional must provide the patient target blood glucose values, insulin-to-carbohydrate ratios, and the correction factor (also known as the insulin sensitivity factor) to be programmed into the App software.	The InPen dose calculator, a component of the InPen app, is indicated for the management of diabetes by people with diabetes age 12 and older by calculating an insulin dose or carbohydrate intake based on user entered data. Prior to use, a healthcare professional must provide the patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the software.	Same, except for the type of diabetes and age.
Prescription / over-the-counter use	Over-the-counter use	Prescription use	Over-the-counter use
Intended Patient Population	Type 1 Diabetes patients treated with multiple daily insulin injections (MDI) therapy	Diabetes patients treated with multiple daily insulin injections (MDI) therapy	Same, except for the type of diabetes.
Communication with insulin pumps	No	No	Same
Software Level of Concern	Major	Major	Same

Wireless Connectivity	No wireless connectivity for device function of calculation of the insulin bolus and logging. WiFi/mobile data connection is used to synchronize the user data with the backend.	Bluetooth Low Energy (BLE)	Different. No connectivity for the device function is required.
Control or affect blood glucose measurements	No	No	Same
Control or affect insulin delivery	No	No	Same
Reports, graphs, and Electronic Logbook	Yes, electronic logbook: - Date and time - Insulin taken - Blood glucose - Carbohydrate ratio - Consumed carbohydrates - Personal notes	Yes	Subject device does not provide reports and graphs.
Carbohydrate Calculator	No	Calculates carbohydrate intake based on user-entered data	The subject device does not provide a CHO calculator.
Type of Insulin for calculation	fast-acting Insulin	Same	None
Manual Dose Entry	The user can edit the calculated dose	Yes	Same
Tracking of residual bolus insulin (RBI) to mitigate stacking	No	Yes	The subject device does not track the RBI but warns the

			user of recently logged insulin administration.
Operating platform	iOS and Android platform	Android platform	Similar. The subject device uses cross-platform technology using the iOS and Android standard UI.
UI Standards	iOS and Android standards	Android standards	Same

VII. Performance Data

Risk Analysis

A risk analysis was completed to account for potential new hazards associated with the device's intended use, including both hardware and software hazards. All design controls implemented to mitigate risks were verified and validated.

- Risk analysis was conducted according to ISO 14971:2019 – Medical Devices – Application of risk management to medical devices.

Software Verification and Validation Testing

Software Verification and Validation Testing per

- Content of Premarket Submissions for Device Software Functions - Guidance for Industry and Food and Drug Administration Staff (June 14, 2023) for the Enhanced Documentation Level
- Software development per IEC 62304 Medical device software – Software life cycle processes

Cybersecurity Evaluation

Cybersecurity Evaluation per

- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff (September 27, 2023).
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Guidance for Industry and Food and Drug Administration Staff (September 27, 2023)

- Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off the-Shelf (OTS) Software (January 14, 2005)

Human Factors / Labeling

Usability/Human Factors testing per

- Applying Human Factors and Usability Engineering to Medical Devices - Guidance for Industry and Food and Drug Administration Staff (February 3, 2016)
- Design Considerations for Devices Intended for Home Use - Guidance for Industry and Food and Drug Administration Staff (November 24, 2014)
- Guidance on Medical Device Patient Labeling - Final Guidance for Industry and FDA Reviewers (April 19, 2001)

VIII. Conclusions

Based on the equivalence of indications for use, technology characteristics, and operational principle, the substantial equivalence between the new and the predicate device has been demonstrated.