



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K25104

B Applicant

Comerge AG

C Proprietary and Established Names

T1D1

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NDC	Class II	21 CFR 868.1890 - Predictive Pulmonary-Function Value Calculator	Clinical Chemistry

E Purpose for Submission:

New Device

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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.

C Special Conditions for Use Statement(s):

You should not use the T1D1 application if you:

- have not received a diagnosis of T1D from a healthcare provider
- have not obtained a treatment plan from a healthcare provider (patient-specific target blood glucose, insulin-to-carbohydrate ratio, and the correction factor)
- are not using Multiple Daily Injections of rapid-acting insulin
- are caring for someone with Type 1 Diabetes that is younger than 2 years old
- are not monitoring your blood glucose (BG) levels as advised by a healthcare provider
- are taking any diabetes medications that are not prescribed by a healthcare provider
- are using a sliding scale or do not count carbs

III Device Description

The T1D1 application is a mobile application designed for Android and Apple devices, for individuals aged 2 and above who have Type 1 Diabetes Mellitus (T1DM) and undergo multiple daily injection (MDI) therapy. It is intended to be used for calculating doses of rapid acting insulin through use of a bolus calculator function. The app also has other functions, such as a logbook, and various configurable user-specific settings.

The medical device function under review for the T1D1 application is the bolus calculator. This calculator implements the standard insulin bolus calculation to calculate recommended insulin doses based on factors such as the user's current blood glucose levels, carbohydrate intake, target blood glucose levels, and patient-specific insulin therapy parameters (e.g., insulin sensitivity factor and carbohydrate ratio).

For a table of device characteristics, see Section V Comparison of Technology to Predicate Devices below.

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

InPen Dose Calculator

B Predicate 510(k) Number(s):

K181327

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K252104</u>	<u>K181327</u>
Device Trade Name	T1D1	InPen Dose Calculator
General Device Characteristic Similarities		
Intended Use	For the management of diabetes by people with diabetes, by calculating an insulin dose based on user entered data.	Same
General Device Characteristic Differences		
Prescription Use	No	Yes
User Group	Type 1 Diabetes patients treated with multiple daily insulin injection (MDI) therapy	Diabetes patients treated with multiple daily insulin injection (MDI) therapy
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)
Calculator Outputs	Recommended insulin dose	Recommended insulin dose Recommended carbohydrate intake
Tracking of insulin on board	No	Yes
Operating platform	iOS and Android	Android

V Standards/Guidance Documents Referenced:

- ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices

- AAMI TIR57:2016 - Principles for medical device security - Risk management
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes
- 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
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff (September 27, 2023)
- 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)

VI Performance Characteristics:

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 Documentation:

The level of software documentation for this software device is enhanced. Software documentation consistent with an enhanced level was provided as described in the FDA guidance for the content of premarket submissions for device software functions. Documentation included complete software requirements and design specification documentation, depiction of functional units and software modules, system diagrams and flowcharts, revision history of design changes for each version number, configuration management plan, traceability of verification and validation to test cases for requirements and improvements, and verification and validation of test cases with protocols, pass/fail criteria, and results.

Software testing was conducted per IEC 62304 and included the following:

- Software unit/item tests
- Software integration tests
- Software system tests

Cybersecurity Documentation:

Cybersecurity documentation as described in the FDA guidance for Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submission was provided. Cybersecurity risk analysis per ISO 14971 and AAMI TIR57-2016/(R)2019. Pre-market cybersecurity analysis has demonstrated that the device is cybersecure.

Human Factors Study:

A total of 161 people participated in the study through online open recruitment. 113 participants correctly self-identified as unintended users and 46 of 48 participants correctly identified as intended users based off the information presented during the self-selection phase during start-up of the T1D1 application. The remaining 46 participants were split across the following user groups:

- 1) Independent self-treating patients
- 2) Partially dependent pediatric patients and their caregivers
- 3) Fully dependent pediatric patients and their caregivers

All users had a mix of experience in using an insulin pump and multiple daily injection therapy. All users had a diagnosis of Type 1 Diabetes from a healthcare provider. Study staff observed minimal use errors, close calls, and use difficulties during the summative study. Patients were given appropriate clinical context that was neutrally worded and resulted in users being able to perceive the appropriate action with the T1D1 application. The results of the summative human factors study support that the T1D1 device is substantially equivalent to the predict device.

VII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

VIII Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.