510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K190487

B Applicant

Companion Medical, Inc.

C Proprietary and Established Names

InPen Dose Calculator

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NDC	Class II	21 CFR 868.1890 - Predictive Pulmonary-Function Value Calculator	Clinical Chemistry (75)

II Submission/Device Overview:

A Purpose for Submission:

Addition of new functionality to an existing bolus dose calculator for an existing device.

B Type of Test:

Insulin dose (bolus) calculation.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

B Indication(s) for Use:

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. The device is indicated for use with NovoLog® or Humalog® U-100 insulin.

For an insulin dose based on amount of carbohydrates, a healthcare professional must provide patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the software prior to use.

For an insulin dose based on fixed/variable meal sizes, a healthcare professional must provide patient-specific fixed doses/meal sizes to be programmed into the software prior to use.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

For use with the InPen System only.

The insulin dose calculations provided by this device are meant for patients undergoing multiple daily injection (MDI) therapy.

IV Device/System Characteristics:

A Device Description:

The InPen Dose Calculator is an insulin dosing calculator within the InPen app. The InPen app is used in conjunction with the InPen System, which consists of a manually-controlled pen injector and a smartphone app containing a data logbook and the InPen Dose Calculator. The InPen is a manual pen injector containing a non-replaceable battery and electronics to communicate via Bluetooth with the app on an iOS mobile device. The intended insulin dose of the InPen is manually set by the user by rotating a dose knob. The insulin is injected by manually depressing the dose knob which causes the piston in the insulin cartridge to expel the intended dose. The InPen is provided in two different models for compatibility with Humalog, Novolog, and Fiasp U-100 insulin cartridges.

Prior to use, the HCP (healthcare professional) must provide the patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the software. The dose calculator function is locked out from the user until an InPen has been paired with a mobile device and the user's insulin settings have been confirmed.

At initial use, the InPen and mobile device are paired. Once paired, the InPen and app communicate to ensure all doses from InPen have been sent to the app. The database records in the InPen and app are synchronized so that doses made while disconnected from the app, e.g. airplane mode, are updated in the app and incorporated into insulin-on-board (IOB) calculations upon reconnection. Instructions for re-pairing in the event of the user obtaining a new mobile device or a replacement InPen are included in the Instructions for Use.

The InPen dose calculator includes three modes for determining insulin dose; carb counting mode, meal estimation mode, and fixed dosing mode. Prior to use, the HCP will prescribe the appropriate dosing mode. For a description of the carb counting mode, as well as the algorithm for calculating insulin dose and insulin on board, see k160629. The carb counting mode is the same as was reviewed in the predicate device.

In fixed dosing mode, the InPen dose calculator will provide a fixed dose insulin recommendation at meal times. After choosing your meal, users enter BG for a dose recommendation.

In meal estimation mode, the InPen dose calculator will provide an insulin recommendation based on meal size at meal times. After choosing a meal and meal size, users enter BG for a dose recommendation.

The sponsor provided information only to support the use of NovoLog or Humalog U-100 insulin with the fixed dosing and meal estimation modes of the InPen dose calculator in this submission.

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

B Instrument Description Information:

Modes of Operation	**Yes**	**No**
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☒	☐
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

1. Instrument Name:

   InPen Dose Calculator

2. Specimen Identification:

   Not Applicable.

3. Specimen Sampling and Handling:

   Not Applicable.

4. Calibration:

   Not Applicable.

5. Quality Control:

   Not Applicable.

V Substantial Equivalence Information:

A Predicate Device Name(s):
InPen System

B Predicate 510(k) Number(s):
K160629

C Comparison with Predicate(s):

Device & Predicate Device(s):	K190487	K160629
Device Trade Name	Same	InPen Dose Calculator
General Device Characteristic Similarities		
Intended Use/Indications For Use	Same	Calculation of insulin dose or carbohydrate intake based on user entered data
User group	Same	Diabetes patients treated with multiple daily insulin injection therapy
General Device Characteristic Differences		
Dose calculation	Calculation based either on user entered carbohydrates, meal size estimation, or fixed meal doses	Calculation based on user entered carbohydrates

VI Standards/Guidance Documents Referenced:

IEC 60601-1-6: Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance- Collateral Standard: Usability, version 3.1

ISO 14971: Medical Devices- Application of risk management to medical devices

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Not applicable.

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

   Not applicable.

4. Accuracy (Instrument):

   Not applicable.

5. Carry-Over:

   Not applicable.

B Other Supportive Instrument Performance Characteristics Data:

The Carb Counting mode for calculating insulin dosage, including the method for determination of insulin on board are unchanged from the predicate device. These features were reviewed in k160629.

Usability:
The sponsor provided protocols and results from human factors testing to demonstrate that users can perform all critical tasks associated with the new device modes (fixed meal and meal estimation dosing). Subjects were representative of the device's intended use population, including pediatric and adult subjects with both Type 1 and Type 2 diabetes. The results of this study were adequate to demonstrate safe use of the device and support substantial equivalence to the predicate.

VIII Proposed Labeling:

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

IX Conclusion:

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