February 18, 2020

Companion Medical, Inc.
Jasper Benke
Vice President, RA/QA/CA
11011 Via Frontera, Suite D
San Diego, CA 92127

Re: K190487
Trade/Device Name: InPen Dose Calculator
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: NDC
Dated: January 16, 2020
Received: January 17, 2020

Dear Jasper Benke:

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 and Part 809); 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,

Marianela Perez-Torres, Ph.D.
Acting Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K190487

Device Name
InPen Dose Calculator

Indications for Use *(Describe)*
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.

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.

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510(k) SUMMARY – K190487
InPen Dose Calculator

I. SUBMITTER

Address: Companion Medical, Inc.
11011 Via Frontera, Suite D
San Diego, California 92127
Phone: (858) 522-0252
Contact: Mr. Jasper Benke
Date Prepared: February 18, 2020

II. DEVICE

Name of Device: InPen Dose Calculator
Common Name: Insulin Dose Calculator
Classification Name: Predictive pulmonary-function value calculator (21 CFR 868.1890); Class II
Product Codes: NDC

III. PREDICATE DEVICES

InPen System (K160629)

This predicate has not been subject to a design-related recall. No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The InPen app is designed to manage the wireless transfer of insulin dose data from the InPen, log insulin dose data, and provide a dose calculator to aid mealtime insulin dose calculations. The insulin dose calculations provided by the app are meant for patients undergoing multiple daily injection (MDI) therapy. The InPen app is not intended to serve as an accessory to an insulin pump.

V. INDICATIONS 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The InPen dose calculator is substantially equivalent to other legally marketed dose calculators. Specifically, the InPen dose calculator is substantially equivalent to the InPen dose calculator (K160629) cleared on July 26, 2016. The InPen dose calculator has the same intended use and indications, technological characteristics, and principles of operation as the previously cleared predicate device. A substantial equivalence chart of the similarities and differences between the InPen dose calculator and the predicate device is shown in Table 1. The minor differences in technological characteristics do not change the intended use or raise new questions of safety or effectiveness.

Table 1

Attribute	Subject Device (K190487)	Predicate Device (K160629)
Classification	(Class II - NDC - 21 CFR §868.1890)	Same
Indications 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. 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.	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.

Prescription Use	Yes	Same
User Group	Diabetes patients treated with multiple daily insulin injection (MDI) therapy	Same
Communication with insulin pumps	No	Same
Software Level of Concern	Major	Same
Wireless Connectivity	Bluetooth Low Energy (BLE)	Same
Control or affect blood glucose measurements	No	Same
Control or affect insulin delivery	No	Same
Reports, graphs, and Electronic Log Book	Yes	Same
Meal Size Entry	Pre-specified meal/dose sizes (fixed or variable)	Grams of carbohydrates
Insulin Dose Calculator	Calculates insulin doses for meals and corrections while accounting for insulin on board	Same
Carbohydrate Calculator	Calculates carbohydrate intake based on user-entered data	Same
Manual Dose Entry	Yes	Same
InPen Dose Entry	Yes	Same
Tracking of residual bolus insulin to mitigate stacking	Yes	Same
Operating platform	Android and iOS platforms	Same
UI Standards	Android and iOS standards	Same

VII. Performance Data

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."* The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Clinical Evidence

Companion Medical has demonstrated the InPen dose calculator is appropriate for its intended use through the use of hazard analysis according ISO 14971. Verification and validation of the

user interface was completed through a comprehensive summative usability evaluation. In the summative evaluation, patients with sufficient diabetes knowledge completed self-training and then completed a series of critical tasks using the InPen dose calculator. The summative evaluation demonstrated that after self-training, patients were able to use the InPen dose calculator without making critical errors that could lead to a hazard. No new use-related hazards were identified during the study. The InPen dose calculator satisfies all functional performance and safety requirements, meets its intended use, and is safe for the intended user population. Substantial equivalence was based in part on the evaluation.

The dose calculator uses the standard approach using healthcare provider specified insulin-to-carbohydrate ratio and insulin sensitivity factors for making calculations. In addition, the calculator includes a consideration for insulin on-board based on the published study by Mudaliar et al (1999) for the duration of insulin action.

VIII. CONCLUSIONS

The subject device is substantially equivalent to the predicate devices, as demonstrated by performance data. It has the same intended use/indications for use, and substantially equivalent technological characteristics and principles of operation.