July 6, 2018

Companion Medical, Inc.
Jasper Benke
Vice President, RA/QA/CA
16486 Bernardo Center Drive, # 300
San Diego, California 92128

Re: K181327
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: June 19, 2018
Received: June 21, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alan M. Stevens -S

Digitally signed by Alan M. Stevens -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300189211, cn=Alan M. Stevens -S
Date: 2018.07.06 11:02:33 -04'00'

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*

K181327

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. 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.

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
InPen® Dose Calculator

I. SUBMITTER

Address: Companion Medical, Inc.
16486 Bernardo Center Drive, Suite 300
San Diego, California 92128
Phone: (858) 522-0252
Contact: Mr. Jasper Benke

Date Prepared: July 6, 2018

II. DEVICE

Name of Device: InPen® Dose Calculator
Common Name: Insulin Dose Calculator
Classification Name: Predictive pulmonary-function value calculator
Regulation: 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.

The predicate 510(k) submission for the InPen System was a bundled submission with a pen injector and insulin dose calculator. The K181327 submission is demonstrating equivalence to the predicate insulin dose calculator device cleared under K160629.

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. 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.

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 (InPen)	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. 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
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
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 platform	iOS platform
UI Standards	Android standards	iOS standards

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 related to the Android version of the InPen dose calculator. All design controls implemented to mitigate risks were verified and validated.

- Risk analysis was conducted according to ANSI/AAMI/ISO 14971:2007®2010 – Medical Devices – Application of risk management to medical devices

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.

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

Software information was provided as recommended in the following FDA guidance documents:

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Guidance for Industry and Food and Drug Administration Staff
- Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff

Human Factors

Human factors validation data was provided in K160629, consistent with the recommendations provided in FDA guidance document, Applying Human Factors and Usability Engineering to Medical Devices - Guidance for Industry and Food and Drug Administration Staff.

Changes to any user interface elements for all critical tasks were evaluated and it was determined that use-related risks associated with the changes are negligible.

VIII. CONCLUSIONS

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