February 10, 2020

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

Re: K192841
Trade/Device Name: InPen System
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: NDC, FMF
Dated: January 9, 2020
Received: January 13, 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); 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,

For CAPT Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192841

Device Name
InPen System

Indications for Use *(Describe)*

The InPen is a home-use reusable pen injector for single-patient use by people with diabetes age 12 and older for the self-injection of a desired dose of insulin. The pen injector is compatible with Lilly Humalog® U-100 3.0 mL cartridges, Novo Nordisk Novolog® U-100 3.0 mL cartridges, and Novo Nordisk Fiasp® U-100 3.0 mL cartridges and single-use detachable and disposable pen needles (not included). The pen injector allows the user to dial the desired dose from 0.5 to 30 units in one-half (1/2) unit increments.

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.

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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
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:	October 1, 2019

II. DEVICE

Name of Device:	InPen™ System
Common Name:	Pen Injector with Dose Calculator
Classification Name:	Piston Syringe
Classification Regulation:	21 CFR 880.5860; Class II
Product Codes:	FMF, NDC

III. PREDICATE DEVICES

InPen™ System (K160629)

IV. DEVICE DESCRIPTION

The InPen System consists of a manually-controlled pen injector and an app containing a logbook and a dose (bolus) 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 dose 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 the available U-100 insulin cartridges, i.e. Humalog®, Novolog®, and Fiasp®. The device is provided with Instructions For Use and a Quick Start Guide. The device is used with sterile needles and U-100 insulin cartridges (supplied separately).

The 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 is a home-use reusable pen injector for single-patient use by people with diabetes age 12 and older for the self-injection of a desired dose of insulin. The pen injector is compatible with Lilly Humalog® U-100 3.0 mL cartridges, Novo Nordisk Novolog® U-100 3.0 mL cartridges, and Novo Nordisk Fiasp® U-100 3.0 mL cartridges and single-use detachable and disposable pen needles (not included). The pen injector allows the user to dial the desired dose from 0.5 to 30 units in one-half (1/2) unit increments.

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 subject InPen pen injector is substantially equivalent to the predicate InPen pen injector (K160629) cleared on July 26, 2016. The InPen pen injector has the same intended use, technological characteristics, and principles of operation as the previously cleared predicate device. A substantial equivalence chart of the similarities and differences between the InPen pen injector and the predicate device is shown in Table 1. The differences in Indications for Use do not raise new questions of safety or effectiveness.
The additional insulin (Fiasp®) type does not change the intended use or raise new questions of safety and effectiveness, as the insulin types are the same concentration, and marketed as comparable therapeutically. Additionally, the labeling was updated to include the new insulin and warnings to mitigate medication errors. These differences are supported by verification and validation data to demonstrate substantial equivalence to the predicate. See Performance Data discussion in Section VII below.

Table 1

Attribute	Subject Device InPen Pen Injector	Predicate Device InPen Pen Injector (K160629)
Classification	(Class II - FMF - 21 CFR §880.5860)	Same

Indications For Use	The InPen is a home-use reusable pen injector for single-patient use by people with diabetes age 12 and older for the self-injection of a desired dose of insulin. The pen injector is compatible with Lilly Humalog® U-100, Novo Nordisk Novolog®, and Novo Nordisk Fiasp® 3.0 mL cartridges of insulin and single-use detachable and	The InPen is a home-use reusable pen injector for single-patient use by people with diabetes age 12 and older for the self-injection of a desired dose of insulin. The pen injector is compatible with Lilly Humalog® U-100 3.0 mL cartridges of insulin and single-use detachable and disposable pen needles (not included). The

	disposable pen needles (not included). The pen injector allows the user to dial the desired dose from 0.5 to 30 units in one-half (1/2) unit increments.	pen injector allows the user to dial the desired dose from 0.5 to 30 units in one-half (1/2) unit increments. The InPen is a home-use reusable pen injector for single-patient use by people with diabetes age 12 and older for the self-injection of a desired dose of insulin. The pen injector is compatible with Novo Nordisk Novolog® U-100 3.0 mL cartridges of insulin and single-use detachable and disposable pen needles (not included). The pen injector allows the user to dial the desired dose from 0.5 to 30 units in one-half (1/2) unit increments.
Cartridge Volume	3 ml (300 units)	Same
Drug	U-100 insulin	Same
Syringe Type	Piston Syringe	Same
Single Patient Use	Yes	Same
Reusable Device	Yes	Same
Dose Accuracy	Meets ISO 11608-1 requirements	Same
Biocompatibility	Meets ISO 10993-1 requirements	Same
Maximum Dose	30 Units	Same
User Feedback	Audible and tactile clicks per increment	Same
Dose Dialing	Two-way	Same
Battery	Non-rechargeable	Same
Electronics	Folded Flex Circuit	Same
Software	Yes	Same
Dose Delivery	Mechanical	Same
Unit Increments	Half-Unit increments after 0.5 Unit	Same
Dimensions	6.5” x ⌀0.6”	Same
Weight	35 grams	Same
Fluid Pathway Contact	None	Same
Dose Calculator Communication	Yes	Same

The subject InPen app is substantially equivalent to the predicate InPen app (K160629) cleared on July 26, 2016. The InPen app has the same intended use, technological characteristics, and principles of operation as the previously cleared predicate device. A substantial equivalence chart comparing the similarities and differences between the InPen pen injector and its predicate device is shown in Table 2. No changes were made to the InPen app. Therefore, there are no differences in Indications for Use, technological characteristics, or principles of operation.

Table 2

Attribute	Subject Device InPen App	Predicate Device InPen App (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
Meal Size Entry	Grams of carbohydrates	Same

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

The InPen pen injector has been determined to be compatible with Fiasp® cartridges by demonstrating conformance to ISO 11608-1, *Needle-Based Injection Systems For Medical Use - Requirements And Test Methods - Part 1: Needle-Based Injection Systems and Part 2:Needles* and demonstrating that the InPen remains appropriate for its intended use through the use of hazard analysis according to ISO 14971*, Medical devices — Application of risk management to medical devices.*. Additionally, the labeling changes were validated through human factors testing. The InPen dose calculator has been shown to be compatible with Fiasp drug product through clinical literature review of both the drug properties and clinical safety when used in place of Novolog and considering for insulin on-board based on the published study by Mudaliar et al (1999) for the duration of insulin action. Therefore, no changes have been made to the dose calculation algorithm.

VIII. CONCLUSIONS

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