DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 26, 2016

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

Re: K160629
Trade/Device Name: Inpen® System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, NDC
Dated: July 7, 2016
Received: July 8, 2016

Dear Mr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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)*
K160629

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 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.

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.

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
Companion Medical InPen® System

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 26, 2016

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 code: FMF, NDC

III. PREDICATE DEVICES

NovoPen® Echo (K123766)
ACCU-CHEK® Bolus Advisor (K150910)

These predicates have not been subject to a design-related recall.
No reference devices were used in this submission.

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® and Novolog®. 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 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.

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.

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 pen injector is substantially equivalent to other legally marketed pen injectors. Specifically, the InPen pen injector is substantially equivalent to the Novo Nordisk NovoPen Echo® (K123766) cleared on August 15, 2013. The InPen pen injector has the same intended use and similar indications, 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 1. The minor differences in technological characteristics do not raise new questions of safety or effectiveness. The differences in indications for use (patient age, insulin type) do not change the intended use, or raise new questions of safety and effectiveness; the subject patient age is a limitation of the predicate device patient age, thus the risk margin is decreased. The additional insulin 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.

Table 1

Attribute	Subject Device InPen Pen Injector	Predicate Device NovoPen Echo (K123766)
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® 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.	The Novo Pen Echo is a re-usable pen injector designed for single-patient use by diabetics for the self-injection of a desired dose of insulin. The pen injector uses PenFill 3.0 mL cartridges of Novo Nordisk insulin and a single use detachable and disposable pen needle (supplied separately). 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”	6.4” x ⌀0.7”
Weight	35 grams	51 grams
Fluid Pathway Contact	None	Same
Dose History	Full; Displayed on app	Last Dose; Displayed on device
Dose Calculator Communication	Yes	No

The InPen app is substantially equivalent to other legally marketed dose calculators. Specifically, the InPen app is substantially equivalent to the Roche ACCU-CHEK® Bolus Advisor (K150910) cleared on June 3, 2015. The InPen app has the same intended use and similar indications, 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. The minor differences in technological characteristics do not raise new questions of safety or effectiveness. The difference in indications for use (patient age) does not change the intended use, or raise new questions of safety and effectiveness, as the subject patient age is a limitation of the predicate device patient age, thus the risk margin is decreased.

Table 2

Attribute	**Subject Device** **InPen Dose Calculator**	**Predicate Device** **ACCU-CHEK® Bolus Advisor (K150910)**
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.	The ACCU-CHEK Bolus Advisor, as a component of the ACCUCHEK Connect Diabetes Management App, is indicated for the management of diabetes by calculating an insulin dose or carbohydrate intake based on user entered data. Before its use, a physician or healthcare professional must activate the bolus calculator and 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

Attribute	Subject Device InPen Dose Calculator	Predicate Device ACCU-CHEK® Bolus Advisor (K150910)
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	No
Tracking of residual bolus insulin to mitigate stacking	Yes	Same
Operating platform	iOS platform	Same
UI Standards	iOS standards	Same

VII. Performance Data

Biocompatibility

The InPen System has been evaluated for biocompatibility according to *ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing*. The InPen System does not contact any part of the insulin fluid path. The patient contacting materials were identified and tested as a limited duration (≤ 24 hours), surface device, with skin contact. The following assays were completed:

- Cytotoxicity
- Sensitization
- Irritation / Intracutaneous Reactivity

The InPen System is considered biocompatible and acceptable for use.

Electromagnetic Compatibility and Electrical Safety

The InPen System has been tested and shown to comply with the electrical safety and electromagnetic compatibility requirements in *IEC 60601-1 Medical Electrical Equipment, Part 1: General Requirements For Basic Safety And Essential Performance* and *IEC 60601-1-2 – Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests*.

Additionally, the InPen System complies with *IEC 60601-1-11 Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment*.

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.

Bench Testing

The InPen System has been shown to meet the requirements of *ISO 11608-1, Needle-Based Injection Systems For Medical Use - Requirements And Test Methods - Part 1: Needle-Based Injection Systems and Part 2:Needles.* Where appropriate, requirements were modified to reflect *ISO 11608-4, Pen-Injectors For Medical Use -- Part 4: Requirements And Test Methods For Electronic And Electromechanical Pen-Injectors*. Testing was completed for general design requirements, mechanical characterization, and dose accuracy. In all instances, the InPen System functioned as intended and met the acceptance criteria.

Clinical Evidence

Companion Medical has demonstrated the InPen System 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 series of Formative Studies and a comprehensive Human Factors Summative Study. In the Summative Study, patients with sufficient diabetes knowledge completed self-training and then completed a series of critical tasks using the InPen System. The Summative Study demonstrated that after self-training, patients are able to use the InPen System without making critical errors that could lead to a hazard. No new use-related hazards were identified during the study. The InPen System 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 study.

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.