



Food and Drug Administration
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December 30, 2015

Eli Lilly and Company, Inc.
Christine A. Phillips, PhD, RAC
Advisor – Global Regulatory Affairs - Devices
Lilly Corporate Center
Indianapolis, Indiana 46285

Re: K151686

Trade/Device Name: HumaPen Ergo II
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: FMF
Dated: November 19, 2015
Received: November 20, 2015

Dear Dr. Phillips:

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" (21CFR 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 -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,

Respiratory, Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151686

Device Name

HumaPen Ergo II

Indications for Use (Describe)

HumaPen Ergo II is a reusable insulin Pen intended for the self-injection of HUMALOG® (U-100, insulin lispro for injection) available in 3 mL Cartridges using disposable Pen Needles (sold separately).

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 K151686

The following 510(k) summary has been prepared pursuant to requirements specified in 21 CFR 807.92.

807.92(a)(1)

Submitter Information

Eli Lilly and Company
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Date: 29 December 2015

807.92(a)(2)

Proposed Device

Trade Name: HumaPen Ergo II
Common Name: Pen-Injector
Classification Name: Piston Syringe
Regulation: 21 CFR 880.5860
Product Code: FMF
Class: II

807.92(a)(3)

Predicate Device

Trade Name: HumaPen Luxura (K142518)
Common Name: Pen-Injector
Classification Name: Piston Syringe
Regulation: 21 CFR 880.5860
Product Code: FMF
Class: II

807.92(a)(4)**Device Description**

The HumaPen Ergo II is a reusable mechanical pen-injector designed for use for the self-injection of insulin. The pen-injector is intended for use with Eli Lilly and Company 3 mL insulin cartridges and single-use, detachable, and disposable pen needles (supplied separately). The pen-injector allows the user to dial the desired dose from 1 to 60 units, one unit at a time.

807.92(a)(5)**Intended Use(s)**

HumaPen Ergo II is a reusable insulin pen intended for the self-injection of HUMALOG® (insulin lispro for injection, U-100) available in 3 mL cartridges using disposable pen needles (sold separately).

807.92(a)(6)**Technological Characteristics**

The HumaPen Ergo II pen-injector is a modification of the predicate device cleared under K142518. Both devices have the same internal materials of construction, but different exterior components (two-toned blue plastic exterior components for the new device and burgundy and champagne colored metallic exterior components for the predicate device).

Pen Feature	New Device: HumaPen Ergo II (under review in this submission)	Predicate Device: HumaPen Luxura (K142518)
Similarities		
Intended Use	Delivery of Humalog (insulin lispro for injection, U-100) in 3 mL cartridges	Delivery of Humalog (insulin lispro for injection, U-100) in 3 mL cartridges
Cartridge Volume	3 mL (300 units of U-100 insulin)	3 mL (300 units of U-100 insulin)
Mechanism	Mechanical pen-injector/ needle-based injection system	Mechanical pen-injector/ needle-based injection system
Reusable device	Yes	Yes
Two-way dose dialing	Yes	Yes
Delivery Accuracy	Meets ISO 11608-1:2014 requirements	Meets ISO 11608-1:2014 ^a requirements
Dial Increments	0.01 mL per increment providing one unit (1U) dose increments	0.01 mL per increment providing one unit (1U) dose increments
Maximum Delivered Dose	60 Units	60 Units
Sterility	Not a sterile device	Not a sterile device
Differences		
Exterior Materials	Injection-molded plastics	Powder-coated and chrome-plated metals
Use life	3 years	6 years

^a Performance testing of the HumaPen Luxura pen-injector was performed in accordance with ISO 11608-1:2012. A newer version of the standard has been published that provides editorial changes and corrections that have no impact on test methods or requirements. Testing performed in accordance with the 2012 version also meets the requirements of the 2014 version.

807.92(b)(1)**Non-Clinical Performance Data**

The HumaPen Ergo II pen-injector meets the requirements specified in ISO 11608-1:2014 *Needle-based injection systems for medical use – Requirements and test methods – Part 1: Needle-based injection*

systems. The device design has passed the dose accuracy requirements, after preconditioning, in the following conditions defined in the ISO 11608-1:2014 standard:

- Standard Atmosphere
- Cool Atmosphere
- Warm Atmosphere
- Last-dose Accuracy
- Dry Heat
- Cold Storage
- Free Fall
- Vibration
- Damp Heat
- Temperature cycling (Cyclical)
- Life-cycle test
 - To support a 3 year in-use life, devices were operated the number of actuations expected for 4.5 years of operation prior to performing dose accuracy testing

The HumaPen Ergo II is a surface-contacting device that contacts intact skin only according to the definitions in ISO 10993-1:2009 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*. The exterior materials of the device were evaluated for in vitro cytotoxicity, skin irritation, and sensitization in accordance with this standard and meet the biocompatibility standard.

The results of Human Factors testing have demonstrated that the HumaPen Ergo II pen-injector is substantially equivalent to the predicate device.

807.92(b)(2) Clinical Performance Data

No clinical tests were performed.

807.92(b)(3) Conclusions

HumaPen Ergo II has met the standards for dose accuracy and functionality identified in the international standard for needle-based injection systems. The device materials meet the biocompatibility standard. Pen operation and pen function are unchanged from the currently cleared HumaPen Luxura. All the testing performed demonstrates that the new device is substantially equivalent to the predicate device.