DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 3, 2016

Eli Lilly and Company, Inc.
Ms. Kevin Bardonner
Research Scientist, Global Regulatory Affairs, CMC-Devices
Lilly Corporate Center
Indianapolis, Indiana 46285

Re: K160668
Trade/Device Name: HumaPen Savvio
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: March 8, 2016
Received: March 9, 2016

Dear Mr. Bardonner:

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,

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

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)*
K160668

Device Name
HumaPen Savvio

Indications for Use *(Describe)*
HumaPen Savvio 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K160668 – 510(k) Summary

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
Lilly Corporate Center
Indianapolis, IN 46285

Contact Person: Kevin Bardonner, P.E.
Research Scientist, Global Regulatory Affairs, CMC-Devices
Mobile: (317) 209-5585
bardonner_kevin_s@lilly.com

Date: 31 May 2016

807.92(a)(2) Proposed Device

Trade Name:	HumaPen Savvio
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 Savvio 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 Savvio 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 Savvio pen-injector is a modification of the predicate device cleared under K142518.

Pen Feature	**New Device: HumaPen Savvio (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[a] requirements	Meets ISO 11608-1:2014[b] 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
Use life	6 years	6 years
Sterility	Not a sterile device	Not a sterile device

Pen Feature	New Device: HumaPen Savvio (under review in this submission)	Predicate Device: HumaPen Luxura K142518
Differences		
Cartridge Holder attachment to the pen body	¼ turn bayonet fit	Screw threads that take 2 ½ turns to attach
Insufficient Remaining Dose (IRD) feature [c]	Patient cannot dial more than the deliverable amount of insulin remaining in the cartridge, prior to injection.	The pen-injector will allow a user to dial a dose that is greater than what is remaining in the insulin cartridge. Once the pen-injector has completed the delivery of the insulin available within the cartridge (i.e., empties the insulin cartridge), the portion of the dose that was not injected will be displayed on the dose dial; that is, the dose dial will not return to "0" as it would if the entire dose was delivered.
Exterior materials	Anodized aluminum and plated plastics and metals	Powder-coated and plated plastics and metals
Colors available	Red	Burgundy, Champagne

[a] ISO 11608-1:2014 testing was conducted using Becton-Dickinson needles, as recommended in the HumaPen Savvio instructions for use

[b] 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.

[c] ISO 11608-1:2014, Section 5.5 (General design requirements) lists four options for IRD features in paragraph j. HumaPen Savvio uses method (1), while HumaPen Luxura uses method (4).

The user interface of the HumaPen Savvio differs from the predicate in two minor aspects: cartridge holder attachment to pen body and the IRD feature (see above table). A risk analysis was conducted along with human factors testing to assess the user's ability to attach the HumaPen Savvio cartridge holder to the pen body and to properly use the IRD feature. The human factors validation testing showed that users were successfully able to attach the cartridge holder to the body of the HumaPen Savvio device (using the bayonet fit). It also showed that users were able to successfully dial and dose using the HumaPen Savvio IRD feature. During life-cycle testing that exposed these two features to 9 years of simulated use (1.5 x the number of doses anticipated over 6 years), there were no issues with dose accuracy or pen functionality (i.e. no broken components, no over-dialing beyond what remained in the cartridge, and no cartridge holder attachment/detachment issues). The new exterior material of construction for this device was tested and passed the international biocompatibility standard. Therefore, these minor differences of the user interface from the predicate do not raise new questions of safety or effectiveness or add risk.

807.92(b)(1) Nonclinical Performance Data

The HumaPen Savvio 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 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 6 year in-use life, the devices were operated the number of actuations (i.e. exhausting the full volume of 3 mL cartridges by expelling typical doses up to and including the IRD) expected for 9 years of operation prior to performing dose accuracy testing; this included the installation of a new needle to the cartridge holder for each injection as well as removal and installation of a new cartridge when the previous cartridge was exhausted.

The HumaPen Savvio 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 (including the cartridge holder) 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 two modifications related to the user interface of the HumaPen Savvio pen-injector did not adversely impact performance or usability of the device, demonstrating that the HumaPen Savvio 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 Savvio 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. The results of human factors studies demonstrated that the mitigations have reduced use-related risks as far as possible given the limits of conventional “dial-and-dose” technology used in the HumaPen Savvio pen-injector. Evaluation of the HumaPen Savvio indicates that the differences between the HumaPen Savvio and the predicate device, HumaPen Luxura, do not raise any new issues of safety or effectiveness. HumaPen Savvio is substantially equivalent to the predicate device.