K100988

510(k) Summary

AUG 17 2010

1. Submitter's Name

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
(317) 276-2000

Contact Person

Steve Johnson, M.B.A, P.E.
Associate Regulatory Consultant
Phone: (317) 433-4685
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Date Prepared: April 2, 2010

2. Device Name

Proprietary Name:	HumaPen Luxura HD
Common Name:	Pen-Injector
Classification Name:	Piston Syringe
Regulation:	21 CFR 880.5860
Product Code:	FMF
Class:	II

3. Predicate Device

Manufacturer:	Eli Lilly and Company
Proprietary Name:	HumaPen Luxura HD®
Submission:	K063151

4. Device Description

HumaPen Luxura HD 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 3.0 mL insulin cartridges and single-use, detachable and disposable pen needles (supplied separately).

5. Intended Use

The HumaPen Luxura HD is a reusable pen injector designed for use by diabetics for the self-injection of a desired dose of insulin. The pen injector uses 3.0 mL cartridges of Lilly 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.

6. Technological Characteristics

Pen Feature	New Device	Predicate Device
Similarities		
Syringe Type	Piston Syringe	Piston Syringe
Intended Use	Delivery of Lilly insulins in 3 mL cartridges	Delivery of Lilly insulins in 3 mL cartridges
Reusable Device	Yes	Yes
Delivery Accuracy	Meets ISO 11608-1.2000 requirements	Meets ISO 11608-1.2000 requirements
Cartridge Volume	3 ml (300 units)	3 ml (300 units)
Maximum Delivered Dose	30 Units	30 Units
Audible Clicks with Each Increment	Yes	Yes
Two-Way Dose Dialing	Yes	Yes
Differences		
Unit Increments	Half-Unit increments after 0.5 Unit	Half-Unit increments after 1 Unit

7. Performance data

HumaPen Luxura HD was tested per ISO 11608-1 for dose accuracy and functionality. HumaPen Luxura. HumaPen Luxura HD components were evaluated for biocompatibility per ISO 10993-1.

8. Conclusion

HumaPen Luxura HD has met the standards for dose accuracy and functionality. HumaPen Luxura HD has also met tighter dose accuracy tolerance based on the dialing resolution of 0.5 units. Biocompatibility investigation of materials has shown that the materials used in the HumaPen Luxura HD are safe for patient contact. Pen operation and pen function are unchanged from the currently cleared HumaPen Luxura HD. The HumaPen Luxura HD is substantially equivalent to the currently cleared HumaPen Luxura HD.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Steven T. Johnson PE, MBA
Associate Regulatory Consultant
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

AUG 17 2010

Re: K100988
Trade/Device Name: HumanPen Luxura HD
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: July 26, 2010
Received: July 27, 2010

Dear Mr. Johnson:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

 K100988

Indications for Use

510(k) Number (if known): _____

Device Name: HumaPen Luxura HD

Indications for Use:

The HumaPen Luxura HD is a reusable pen injector designed for the self-injection of a desired dose of insulin. The pen injector uses 3.0 mL cartridges of Lilly 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.

Prescription Use ____X____ AND/OR Over –The –Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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