510(k) Summary

1. Submitter's Name

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

JAN - 9 2007

Contact Person

LeeAnn Chambers, M.S., RAC
Associate Regulatory Consultant
Phone: (317) 277-1813
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Date Prepared: October 11, 2006

2. Device Name

Proprietary Name:	HumaPen Luxura HD
Common Name:	Pen-Injector
Classification Name:	Piston Syringe

3 Predicate Devices

Manufacturer:	Novo Nordisk Pharmaceuticals, Inc.
Proprietary Name:	NovoPen® Junior
Submission:	NDA 20-986/S-004

Manufacturer:	Owen Mumford Inc.
Proprietary Name:	Autopen®
Submission:	K983874

4. Device Description

HumaPen Luxura HD is a reusable mechanical pen-injector designed 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).

5. Intended Use

HumaPen Luxura HD has been developed for the injection of insulin from Eli Lilly and Company 3 mL cartridges.

6. Technological Characteristics

Pen Feature	New Device HumaPen Luxura HD	Predicate Device NovoPen Junior	Predicate Device Autopen
Intended Use	Delivery of Lilly insulins in 3 mL cartridges.	Delivery of Novo Nordisk insulins from PenFill 3 mL cartridges.	Delivery of insulin from replaceable 3 mL cartridges.
Compatible drug products	HumaLog and Humulin	Novolog, Novolin R, Novolin N, Novolin 70/30	Eli Lilly 3 mL insulin cartridges
Reusable device	Yes	Yes	Yes
Cartridge Volume	3 mL (300 units)	3 mL (300 units)	3 mL (300 units)
Maximum Delivered Dose	30 Units	35 Units	42 Units
Unit increments	Half-Unit increments after 1 Unit	Half-Unit increments after 1 Unit	2 Unit increments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Eli Lilly and Company
Ms. LeeAnn Chambers
Regulatory Scientist
Pharmaceutical Delivery Systems
Lilly Corporate Center
Indianapolis, Indiana 46285

JAN - 9 2007

Re: K063151
Trade/Device Name: HumaPen Luxura HD
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: NSC
Dated: October 11, 2006
Received: October 18, 2006

Dear Ms. Chambers:

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.

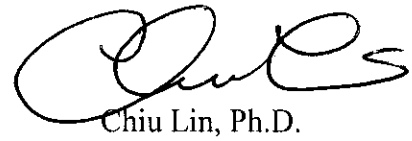
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K063151

1 of 1

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 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 1 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)

For HBV

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

(510(k) Number: K063151