APR 7 2006

510(k) Summary

1. Submitter's Name

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

Contact Person
LeeAnn Chambers, M.S., RAC
Associate Regulatory Consultant
Phone: (317) 277-1813
FAX: (317) 276-1887

Date Prepared:

2. Device Name

Proprietary Name:	HumaPen Memoir
Common Name:	Pen-Injector
Classification Name:	Piston Syringe

3. Predicate Device

Manufacturer:	Novo Nordisk Pharmaceuticals
Proprietary Name:	Innovo®
Submission:	K010359

4. Device Description

HumaPen Memoir is a reusable mechanical pen-injector with electronic display designed for use for the self-injection of insulin. The pen-injector is intended for use with Eli Lilly and Company Humalog and Humulin 3.0 mL cartridges and single-use, detachable and disposable pen needles (supplied separately).

5. Intended Use

HumaPen Memoir has been developed for the injection of Humalog and Humulin from Eli Lilly and Company 3.0 mL cartridges.

6. Technological Characteristics

Pen Feature	New Device	Predicate Device
Similarities:		
Syringe Type	Piston Syringe	Piston Syringe
Intended Use	Delivery of Humalog and Humulin in Lilly 3 mL cartridges.	Delivery of Novolin in Novo Nordisk PenFill 3 mL cartridges.
Specific drug use	Insulin	Insulin
Reusable device	Yes	Yes
Delivery accuracy	Meets ISO 11608-1.2000 requirements	Meets ISO 11608-1 (Part 1) requirements
Cartridge Volume	3ml (300 units)	3ml (300 units)
Unit increments	One Unit increments	One Unit increments
Audible clicks with each increment	Yes	Yes
Dose Display	Electronic LCD	Electronic LCD
Display check when powered on	Yes	Yes
Last Dose Indication	Yes	Yes
Two-way dose dialing	Yes	Yes
Non-replaceable battery	Yes	Yes
Differences:		
Body Material	Metal	Plastic
Maximum dose units	60	70
Dose Memory	Last 16 doses	Last dose
Time and date of last dose	Yes	No
Pen life (battery)	3 yrs	5 yrs
Low battery display indication	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2006

Ms. LeeAnn Chambers
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

Re: K053563
Trade/Device Name: HumaPen Memoir
Regulation Number: 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: FMF
Dated: March 23, 2006
Received: March 27, 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 (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.

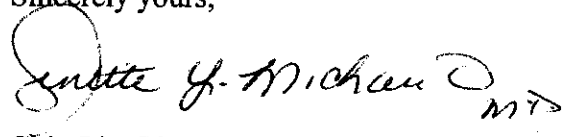
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

K053563

Indications For Use

510(k) Number (if known): K053563

Device Name: HumaPen Memoir

Indications For Use:

The HumaPen Memoir 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 insulin (Humalog® and Humulin®) and a single use detachable and disposable pen needle (supplied separately). The pen injector allows the user to dial the desired dose in one-unit increments up to 60 units.

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)

[signature]

[illegible] Cardiology, General Hospital
[illegible] Dental Devices

K053563