K982842

SEP 25 1998

6.0 510(k) Summary of Safety and Effectiveness

1. Submitter's Name: Eli Lilly and Company
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Contact Person: LeeAnn Chambers, RAC
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Date Prepared: August 7, 1998

2. Device Name:
Proprietary Name: HumaPen and HumaPen Ergo
Common Name: Insulin Pen
Classification Name: Piston Syringe

3. Predicate Device:
HumaPen and HumaPen Ergo are substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed B-D Pen.

4. Device Description:
HumaPen and HumaPen Ergo are two versions of 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® (human insulin[rDNA origin]) or Humulin® (insulin lispro injection [rDNA origin]) and a single use, detachable and disposable pen needle (supplied separately). The pen-injector allows the user to dial the desired dose one unit at a time up to 60 units.

5. Intended Use:
Insulin delivery device.

6. Technological Characteristics:

Pen Feature	New Device	Predicate Device
Similarities:		
Syringe type	Insulin Pen-injector	Insulin Pen-injector
Intended use(s)	Insulin delivery device	Insulin delivery device
Specific drug use	Insulin	Insulin
Delivery accuracy	meets ISO/DIS 11608-1.2 requirements	meets ISO/DIS 11608-1.2 requirements
Unit increments	one Unit increments	one Unit increments
Audible clicks with each increment?	yes	yes
Can dial remaining insulin?	no	no

Pen Feature	New Device	Predicate Device
Differences:		
Volume	3.0 mL (300 Units)	1.5 mL (150 Units)
Maximum dose size	60 Units	30 Units
Dosing adjustment	two-way dose correction (can dial forward or backward to desired dose)	if incorrect dose is set, the patient needs to turn the dose knob as far as it will turn to the reset groove then push in the injection button and redial to the desired dose.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 1998

LeeAnn Chambers, RAC
Associate Regulatory Consultant
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

Re: K982842
Trade Name: HumaPen and HumaPen Ergo
Regulatory Class: II
Product Code: FMF
Dated: August 7, 1998
Received: August 12, 1998

Dear Ms. Chambers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):
Device Name:
Indications for Use:

The HumaPen and the HumaPen Ergo are two versions of 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® or Humulin®) and a single use, detachable and disposable pen needle (supplied separately). The pen-injector allows the user to dial the desired dose one unit at a time up to 60 units.

(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 Dental, Infection Control, and General Hospital Devices
510(k) Number K982842

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)