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: 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

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

[Signature]

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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