K993666

NOV 22 1999

510(K) SUMMARY

9.0 Summary of Safety and Effectiveness

9.1 Trade/Proprietary Name: Disetronic Pen P100

9.2 Common/Usual Name: Injection Pen

9.3 Classification Name: Piston Syringe

9.4 Substantial Equivalence: The Disetronic Pen P100 is substantially equivalent to the current Disetronic Insulin Injection Pen (K982966), the B-D 3 ml Injection Pen (K980755), the B-D 3 ml Ultra Injection Pen (K981797), the Eli Lilly and Company HumaPen and HumaPen Ergo (K982842) and the Owen Mumford Autopen 3ml (K983974).

9.5 The Disetronic Pen P100 is a reusable device that provides a method of accurately injecting a selected dose of insulin from an insulin cartridge supplied by other manufacturers, through a single lumen hypodermic needle. The device can be used by health professionals or for self-injection by the patient. The device is similar in appearance and size to a ballpoint pen. It is cylindrical in shape and has a retractable dosage knob at the top that resembles the 'clicker' used to extend and retract the tip of a ballpoint pen beyond its housing.

The internal mechanisms used to set and activate the injection are the same across the product line. Each pen operates in the following manner. After the cartridge is loaded into the barrel and the needle is attached, the user pushes a button on the side of the pen opposite the digital display. This releases a spring-loaded 'knob' at the top of the pen. The knob is then rotated in a clockwise direction which increments the digital display to show the dose to be delivered. The needle cap is removed and the needle is inserted into the injection site. The knob at the top of the pen is depressed which advances the plunger to displace the chosen dose. After the injection, the needle is removed from the pen and discarded.

9.7 Technological Characteristics: The technological characteristics of the Injection Pens are the same as products currently legally marketed in the USA.

9.8 Performance Data: The device conforms to the requirements when tested using the methods specified in the draft ISO standard, ISO 11608, "Pen-injectors for Medical Use."

9.9 Conclusion: Disetronic Medical Systems concludes based on the information presented that the Injection Pens are substantially equivalent to products currently legally marketed in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 1999

Mr. David E. Chadwick, Ph.D.
Director, Regulatory Affairs
Disetronic Medical Systems, Inc.
5151 Program Avenue
St. Paul, Minnesota 55112-1014

Re: K993666
Trade Name: Disetronic Pen
Regulatory Class: II
Product Code: FMF
Dated: October 25, 1999
Received: November 1, 1999

Dear Dr. Chadwick:

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,

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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) File Number: K993666

Device Name: Disetronic Pen P100 Insulin Infusion Pen

Indications For Use: The Disetronic Pen P100 is indicated for the injection of insulin into the body

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 K993666

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.19)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993666