K982966

OCT 19 1998

510(K) SUMMARY

9.0 Summary of Safety and Effectiveness

9.1 Trade/Proprietary Name: Disetronic Pen

9.2 Common/Usual Name: Injection Pen

9.3 Classification Name: Piston Syringe

9.4 Substantial Equivalence: The Disetronic Injection Pen product line is substantially equivalent to the NovoPen Injection Pen (K942159), the B-D Injection Pen (K941567) the standard Piston Syringe (B-D Syringe - last submission K954064) and the Disetronic H-Tron plus Insulin Infusion Pump (K973044).

9.5 The Disetronic Injection Pen is a reusable devices that provides a method of accurately injecting a selected dose of insulin from a fluid cartridge 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 ball point pen, hence the description. 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 ball point pen beyond its housing.

The internal mechanisms used to set and activate the injection are identical 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 twisted 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.

The Pen models are differentiated in that different models of pens differ in the amount of drug represented by each incremental click of the dose setting mechanism. These differences are determined by differences in the threaded rod and nut mechanism of each model which determines the distance, and therefore the dose each click of the dosage knob represents.

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

9.8 Performance Data: The device conforms with the requirements when tested using the methods specified in the ISO standard, ISO 11608-1, "Pen-injectors for Medical Use - Part 1: Requirements and Test Methods".

9.9 Conclusion: Disetronic Medical Systems concludes based on the information presented that the 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

OCT 19 1998

Disetronic Medical Systems, Incorporated
C/O Mr. Lee H. Leichter
Consultant
P/L Biomedical
7690 Cameron Circle
Fort Myers, Florida 33912

Re: K982966
Trade Name: Disetronic Pen
Regulatory Class: II
Product Code: FMF
Dated: August 25, 1998
Received: August 25, 1998

Dear Mr. Leichter:

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

510(k) File Number: K982966

Device Name: Disetronic Pen

Indications For Use: The device 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)

Rebecca Cucerito

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K98 2966

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

(Optional Format 1-2-96)