SEP 24 1997 K973339

8.0 SUMMARY OF SAFETY AND EFFECTIVENESS

**"510(k) SUMMARY"**

8.1 Trade/Proprietary Name: Disetronic PenFine® Injection Pen Needle

8.2 Common/Usual Name: Injection Pen Needle

8.3 Classification Name: Hypodermic Single Lumen Needle

8.4 Comparison to Currently Marketed Devices
The Disetronic PenFine® Injection Pen Needles are substantially equivalent to the Novo Nordisk NovoFine 30 Injection Pen Needles and the Becton Dickinson B-D Micro-Fine, Ultra-Fine and Ultra-Fine II Injection Pen Needles.

8.5 Device Description
The Disetronic PenFine® Injection Pen Needles are sterile, non-pyrogenic, single use needles designed to be used with commercially available Injection Pens. They will be offered with a 29 and 30 gauge needle in an 8, 10 and 12 mm length.

The PenFine® Pen Needle is comprised of a siliconized stainless steel cannula welded into in a polyethyleneterapthalate (PETP) hub. A polyethylene protective cap snaps onto the hub over the needle. This assembly fits into a K-Resin outer protective container which provides the sterile barrier along with the peel tab.

The PenFine® has a patented design feature that differs from currently available pen needles. Existing pen needles must be screwed onto the threaded male extension of the injection pen. The PenFine® uses a single motion "snap on" mechanism.

The needles are used by peeling back the peel tab and snapping the hub onto the threaded end of the Injection Pen. The back end of the cannula punctures the rubber injection port on the drug reservoir in the Injection Pen. The outer protective cap is then removed. The inner protective cap will remain over the needle until the drug is ready to be injected.

When the injection is needed, the inner protective cap is removed and the needle is inserted into the chosen site. The Injector Pen automatically delivers the drug through the needle. The protective cap is replaced and the needle is then removed, safely discarded and replaced with a new needle.

8.6 Indications for Use
The Disetronic PenFine® Injection Pen Needles are intended for the hypodermic injection of fluids into the body when attached to an automatic injector pen.

8.7 Technological Characteristics
The technological characteristics are the same as the predicate devices.

8.8 Performance Data

Performance data has been generated in compliance with existing international standards and protocols and found equivalent to the predicate devices.

8.9 Conclusion

Based on the design equivalency and the functional and safety testing, Disetronic Medical Systems has determined that the PenFine® Injection Pen Needles are substantially equivalent to the devices currently marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 24 1997

Mr. Patrik De Haes
President and CEO
Disetronic Medical Systems, Incorporated
C/O P/L Biomedical
7690 Cameron Circle
Fort Myers, Florida 33912

Re: K973339
Trade Name: Disetronic Penfine™ Injection Pen Needle
Regulatory Class: II
Product Code: FMI
Dated: September 5, 1997
Received: September 5, 1997

Dear Mr. De Haes:

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4618. 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:

evice Name: Disetronic PenFine® Injection Pen Needle

Indications For Use: The Disetronic PenFine® Injection Pen Needles are intended for the hypodermic injection of fluids into the body when attached to an injector pen.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)** Patricia Cucanta
**Division of Dental, Infection Control,**
**and General Hospital Devices**
**510(k) Number** K973337

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

(Optional Format 1-2-96)