K982399

AUG 6 1998

8.0 SUMMARY OF SAFETY AND EFFECTIVENESS

"510(k) SUMMARY"

8.1 Trade/Proprietary Name: 31 Gauge 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 31 gauge Disetronic PenFine® Injection Pen Needles are substantially equivalent to the 29 and 30 gauge Disetronic PenFine® Injection Pen Needles (K973339) and the Becton Dickinson B-D Ultra-Fine II Injection Pen Needles (K970737).

8.5 Device Description
The 31 gauge Disetronic PenFine® Injection Pen Needles are the same sterile, non-pyrogenic, single use needles designed to be used with commercially available Injection Pens as the 29 and 30 gauge Disetronic PenFine® Injection Pen Needles. The only difference is in the thickness of the cannula.

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

AUG 6 1998

Mr. Patrik De Haes
President and CEO
Disetronic Medical Systems, Incorporated
5201 East River Road, Suite 312
Minneapolis, Minnesota 55421-1014

Re: K982399
Trade Name: Disetronic PenFine® Injection Pen Needle
Regulatory Class: II
Product Code: FMI
Dated: July 2, 1998
Received: July 10, 1998

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 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). 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 requirements, 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) 594-4692. 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"(21CFR 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/dsma/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:

Device 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)

Patricia Cucenda

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K982399

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

(Optional Format 1-2-96)