

SUMMARY OF SAFETY AND EFFECTIVENESS

APR - 2 1998

1. Submitted By:

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2. Device Name: B-D 3 ml PEN**3. Predicate Device:** B-D MICRO-FINE PEN**4. Device Description:**

The B-D Insulin pen injector is designed for use by and for diabetics for the subcutaneous injection of a desired dose of insulin. The pen injector uses a cartridge of insulin (supplied by others) and a single use, detachable and disposable pen needle (sold separately).

The product consists of three main mechanical assemblies: A dosing mechanism, vial retainer, and cap/clip assembly. The dose set knob can be adjusted to any two (2) unit increments between two (2) and sixty (60) units by rotating the dose set knob counter clockwise until the desired dose is set. The pen needle can then be inserted into the body and by pushing in the dose set knob, the clutch assembly rotates in the opposite direction (clockwise) and the lead screw moves forward causing pressure to build up in the cartridge and insulin to be dispensed through the injector needle. After repeated injections, the insulin cartridge becomes depleted and must be replaced. During cartridge replacement, the lead screw is reset by unlocking the retracting mechanism and returning the lead screw to its start position. A new cartridge can then be inserted into the vial retainer.

5. Intended Use:

The B-D insulin pen injector is designed for use by and for diabetics for the subcutaneous injection of a desired dose of insulin.

6. Technological Characteristics:

The B-D 3 ml Pen and the predicate device (the B-D Micro-Fine Pen) have the same technological characteristics.

SEE ITEM 4 ABOVE FOR A DESCRIPTION

N.B. The B-D 3 ml Pen can deliver a maximum dose of 60 units in 2 (two) unit increments while the B-D Micro-Fine pen delivers a maximum of 30 units in 1 (one) unit increments. Also the BD 3 ml Pen uses a 3 ml insulin cartridge and the BD Micro-Fine pen uses a 1.5 ml insulin cartridge.

7. Performance Summary:

The design verification reflects the recommendations made in recent ISO/TC 84/WG 3. In general, testing of pen-injectors with replaceable cartridges encompassed dose accuracy and functional assessments in relation to various environmental and mechanical challenges.

The pens were tested for accuracy after sequential standard, cool, and hot atmosphere conditions and across a simulated life-time use (life-cycle). They were also tested for accuracy and examined for visual defects following exposure to dry heat, cold storage and cyclical atmosphere conditions and following three one-metre free falls onto a concrete surface.

In general, the 3 ml B-D Pen has proven to be robust, repeatable and consistent across a range of environmental and mechanical challenges. Relative to the overall dose accuracy (ALL data points collected across all test conditions) at each of the dose settings tested, the 3 ml B-D Pen has met the proposed ISO standards for dose accuracy and functionality.

Based on the results of the ISO testing, the B-D Pen is safe and effective when used as intended.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Peter Zurlo
Manager, Regulatory Affairs
BECTON DICKINSON CONSUMER PRODUCTS
1 Becton Drive
Franklin Lakes, New Jersey 07417-1883

Re: K980755
Trade Name: B-D 3 ml Pen
Regulatory Class: II
Product Code: FMF
Dated: February 23, 1998
Received: February 25, 1998

Dear Mr. Zurlo:

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 (Pre-market 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 pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of

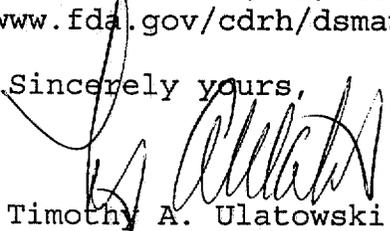
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

510(k) Number (if known): K970709

Device Name: B-D 3ml Pen

Indications For Use:

The B-D insulin pen injector is designed for use by and for diabetics for the subcutaneous injection of a desired dose of insulin in the treatment of diabetes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Salvatore Cicchetti

(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K980755

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ✓

(Optional Format I-2-96)