

JUN 12 1998

4981797

## SUMMARY OF SAFETY AND EFFECTIVENESS

1. Submitted by:

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2. Device Name: B-D PEN ULTRA 1.5 ml and 3.0 ml Versions

3. Predicate Device: B-D PEN ULTRA

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 B-D Pen Ultra™ Assembly consists of three (3) main mechanical assemblies:

- A dose setting mechanism in the upper body,
- An injection mechanism in the center body, and
- An interlocking mechanism in the center body.

The B-D Pen Ultra™ Assembly also consists of three (3) sub-assemblies

- The window/upper body sub-assembly,
- The half-nut/plunger sub-assembly, and
- The cap/clip sub-assembly.

### Method of Use

The dose set knob (Adjusting Knob) can be adjusted to any single unit increment between one (1) and fifty-nine (59 for 1.5 ml pen) and sixty-nine (69 for 3.0 ml pen) by rotating the dose set knob clockwise (viewing Pen from Push Button end). The dose can also be corrected by dialing counter-clockwise (viewing Pen from Push Button end) if necessary. By rotating the dose set knob, the Leadscrew will move forward or backward to be positioned for the proper amount of displacement for the number of units dialed. After completing the dose setting procedure simply push in the rotating Push Button. This movement will cause the Leadscrew to push on the plunger of the cartridge and insulin to be dispensed through the injector needle. After repeated injections, the insulin cartridge becomes depleted and must be replaced. The pen needle is removed and discarded per instructions. The Vial Retainer is rotated 90° and removed. A new cartridge is set inside the Vial Retainer and the assembly is replaced. During cartridge replacement, the Leadscrew will be reset when the new cartridge/Vial Retainer assembly is replaced on the Center Body. This

replacement can only occur when the rotating Push Button is completely seated at the “injection completed” position. The cartridge replacement procedure will return the Leadscrew to its start position, which will be seated against the stopper in the cartridge.

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 Pen Ultra 1.5 and 3.0 ml and the predicate device (the B-D Pen Ultra) have the same technological characteristics.

SEE ITEM 4 ABOVE FOR A DESCRIPTION

N.B. The B-D Pen Ultra 1.5 ml can deliver a maximum dose of 59 units while the B-D Pen Ultra 3.0 ml delivers a maximum of 69 units.

7. Performance Summary:

The design verification reflects the recommendations made in the Draft ISO Standard ISO-11608-1. 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-meter free falls onto a concrete surface.

In general, the B-D Pen Ultra 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 B-D Pen Ultra 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.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Peter Zurlo  
Manager, Regulatory Affairs  
Becton Dickinson Consumer Products  
1 Becton Drive  
Franklin Lakes, New Jersey 07417-1883

Re: K981797  
Trade Name: B-D Pen Ultra  
Regulatory Class: II  
Product Code: FMF  
Dated: May 14, 1998  
Received: May 21, 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 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

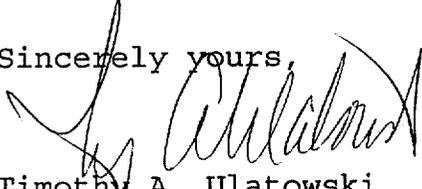
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 .....

510(k) Number (if known): K981797

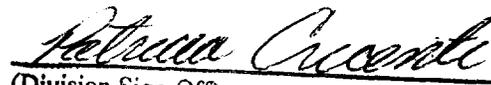
Device Name: B-D Pen Ultra 1.5 and 3.0 ml Versions

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)

  
(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K 981797

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)