

K024109

510K SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Submitted By:**

DEC 30 2002

John Schalago
Manager, Regulatory Affairs

Becton Dickinson Consumer Healthcare
1 Becton Drive
Franklin Lakes, NJ 07417-1883

Phone: 201-847-5663
Fax: 201-848-0457

2. **Device Name:**

Trade Name: BD Ultra-Fine™ III Pen Needle

Common Names: Insulin Pen Needle

Classification Name: Hypodermic Single Lumen Needle

3. **Predicate Device:**

BD Ultra-Fine™ III Pen Needle

Manufactured by: Becton Dickinson Consumer Healthcare

4. **Device Description:**

The Becton Dickinson Ultra-Fine™ III Pen Needle is designed for use with a pen injector for subcutaneous injection of a desired dose of insulin. The pen needle consists of a needle, hub, and shield assembly. The Becton Dickinson Ultra-Fine™ III 31G pen needles are offered in two lengths, 5/16" and 3/16". The syringe fluid path is sterile (gamma irradiation sterilization), non-toxic, and non-pyrogenic. BD Pen Needles are disposable, single use devices.

5. **Intended Use:**

Becton Dickinson Pen Needle is intended for use with pen injector device for the subcutaneous injection of insulin.

510K Summary of Safety and Effectiveness (Continued)

6. Technological Characteristics:

The B-D ULTRA-FINE ® III 31G Pen Needle and the predicate device have the identical technological characteristics and perform equivalently.

The only difference between the ULTRA-FINE ® III 31G and the predicate device is the inner bore diameter.

7. Performance:

Bench tests relating to the performance of the pen needle were conducted. The tests performed included needle pull-out force, hub pull-off forces, needle angularity, needle break-off testing and dose accuracy. The results demonstrate that the BD Ultra-Fine III 31G Pen Needles perform equivalent to the predicate device and is safe and effective when used as intended.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E, under which a device can be marketed without pre-approval or classification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US patent Laws or their application by the courts.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 30 2002

Mr. John Schalago
Manager, Regulatory Affairs
Becton Dickinson & Company
1 Becton Drive
Franklin Lakes, New Jersey 07417-1883

Re: K024109

Trade/Device Name: BD Ultra-Fine™ III Pen Needle
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: December 10, 2002
Received: December 13, 2002

Dear Mr. Schalago:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

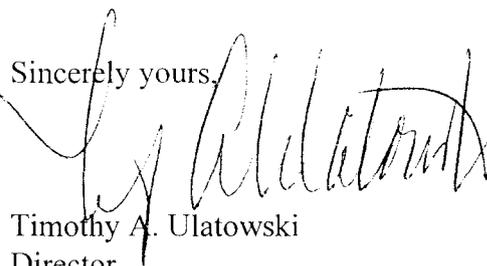
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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 Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K024109

Device Name: Becton Dickinson Pen Needle

Indications For Use:

Becton Dickinson Pen Needle is intended for use with pen injector device for the subcutaneous injection of insulin.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

*William M. Budick Sr.
Patricia Nicante*

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K024109

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