K031200

JUN 2 4 2003

510K SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Submitted By:**

Cynthia Lacatena
Product Registration Coordinator

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

Phone: 201-847-6869
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2. **Device Name:**

Trade Name: BD Ultra-Fine™ Original Pen Needle
BD Ultra-Fine™ III Short Pen Needle
BD Ultra-Fine™ III Pen Needle

3. Common Names: Insulin Pen Needle

Classification Name: Hypodermic Single Lumen Needle

4. **Predicate Device:**

BD Ultra-Fine™ Pen Needle
BD Ultra-Fine™ III Pen Needle

Manufactured by: Becton Dickinson Consumer Healthcare

5. **Device Description:**

The Becton Dickinson Ultra-Fine™ 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, needle shield and outer needle shield assembly. The Ultra-Fine Pen Needles are offered in various needles sizes and lengths. 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 BD Ultra-Fine™ Original Pen Needle, BD Ultra-Fine™ III Short Pen Needle and BD Ultra-Fine™ III Pen Needle have the identical technological characteristics and perform equivalently as the predicate device.

The only difference from the predicate device is the outer needle shield material was changed from polyethylene to polypropylene enhancing the puncture resistance properties of the outer needle shield.

7. **Performance:**

Bench tests relating to the performance of the outer needle shield were conducted. The penetration force tests demonstrated that the polypropylene material had a greater penetration resistance capability then the polyethylene material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2003

Ms. Cynthia Lacatena
Product Registration Coordinator
Becton Dickinson Consumer Healthcare
1 Becton Drive
Franklin Lakes, New Jersey 07417-1883

Re: K031200
Trade/Device Name: Becton Dickinson Pen Needles
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: April 15, 2003
Received: May 28, 2003

Dear Ms. Lacatena:

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.

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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment XI .1

510(k) Number (if known): K031200

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)

Paloma Cuevas

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

510(k) Number: K031200