JAN 0 9 2003

K024112

510K SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Submitted By:**

John Schalago
Manager, Regulatory Affairs

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

Phone: 201-847-5663
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2. **Device Name:**

Trade Name: BD Insulin Syringe – Ultra-Fine™ and Ultra-Fine™ II

Common Names: Insulin Syringe

Classification Name: Piston Syringe

3. **Predicate Device:**

BD Insulin Syringe – K941657 and K955235

Manufactured by: Becton Dickinson Consumer Healthcare

4. **Device Description:**

The BD Insulin Syringes – Ultra-Fine™ and Ultra-Fine™ II are designed for the subcutaneous injection of a desired dose of insulin. The syringe has a graduated barrel, a plunger rod and needle/hub assembly. The needle shield is colored orange. The Ultra-Fine™ Insulin Syringe has a 30g x 1/2" (12.7mm) needle and is available in 1cc (100 units), ½ cc (50 units), and 1/3 cc (30 units) sizes. The Ultra-Fine™ II 31g x 1/2" (8mm) needle and is available in 1cc (100 units), ½ cc (50 units), and 1/3 cc (30 units) sizes.

These devices operate on the principles of a piston syringe. The syringe fluid path is sterile (gamma irradiation sterilization), non-toxic, non-pyrogenic and single use, disposable.

Continued...

510K Summary of Safety and Effectiveness (*Continued*)

5. **Intended Use:**

BD Insulin Syringes are intended for the subcutaneous injection of insulins

6. **Technological Characteristics:**

The BD Ultra-Fine™ and Ultra-Fine™ II insulin syringes and the predicate devices have the identical technological characteristics and perform as piston syringes.

The only difference between the principal devices and the predicate device is the needle gauge.

7. **Performance:**

Bench tests relating to the performance of the needle length 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 Insulin Syringes performs equivalent to the predicate devices 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

JAN 0 9 2003

Mr. John Schalago
Manager, Regulatory Affairs
Becton Dickinson & Company
1 Becton Drive
Franklin Lakes, New Jersey 07417-1880

Re: K024112
Trade/Device Name: BD Insulin Syringe-Ultra-Fine™ and Ultra-Fine™ II
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: December 11, 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.

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) you may obtain. 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

Attachment XI.1

510(k) Number (if known): K024112

Device Name: Becton Dickinson Insulin Syringe

Indications For Use:

Becton Dickinson insulin syringes are intended for subcutaneous injection of insulins.

(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)

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

510(k) Number: K024112