K051899

SEP 13 2005

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
Fax: 201-848-0457

2. **Device Name:**

Trade Name: BD Pen Needles

Common Names: Insulin Pen Needles

Classification Name: Hypodermic Single Lumen Needle

3. **Predicate Device:**

BD Pen Needles

Manufactured by: Becton Dickinson Consumer Healthcare

Disetronic PenFine Injection Pen Needles

Manufactured by: Dietronic Medical Systems, Incorporated

4. **Device Description:**

The BD Pen Needles are designed for use with a pen injector for subcutaneous injection of a desired dose of a drug, including insulin and exenatide. The pen needle consists of a needle, hub, and shield assembly. The Becton Dickinson pen needles are offered various gauges sizes (29G, 30G, and 31G) and lengths (5mm, 8mm, and 12.7mm). BD Pen Needles are sterile (gamma irradiation sterilization), non-toxic, and non-pyrogenic. The pen needles are disposable, single use devices.

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

5. **Intended Use:**

Becton Dickinson Pen Needle is intended for use with pen injector device for subcutaneous injection of drugs, including insulin and exenatide.

6. **Technological Characteristics:**

The BD Pen Needle and the predicate device have the identical technological characteristics and perform equivalently.

The only difference between the devices is that the principal device is indicated for delivery of exenatide.

7. **Performance:**

The perform equivalent to the predicate device and 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

SEP 13 2005

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

Re: K051899
Trade/Device: BD Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: July 8, 2005
Received: July 13, 2005

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.

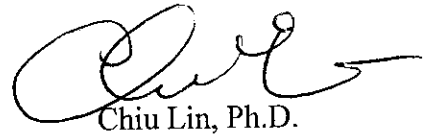
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051899

Device Name: BD Pen Needles

Indications For Use:

Becton Dickinson Pen Needle is intended for use with pen injector device for subcutaneous injection of drugs, including insulin and exenatide.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X___ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman For ACW 9/13/05

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

510(k) Number: K051899