OCT 1 1999

K992734

Summary of Safety & Effectiveness:

1. **BD Contact Person:**

Greg Morgan
Director Regulatory Compliance
BD Medical
BD
1 Becton Drive, Bldg. 2, MC226
Franklin Lakes, NJ
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2. **Device Name:** Becton Dickinson SafetyGlide™ Syringe
3. **Predicate Devices:** Becton Dickinson Syringes & SafetyGlide™ Needle
4. **Product Description/Function:**

4.1 Description: Single-use syringe with needle protection system. Syringes sizes: .3, .5, & 1 ml.

4.2 Function: Syringes are used for aspiration/injection of fluids. The device contains a mechanism that covers the needle point after use. In the activated position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

5. **Comparison of Modified & Predicate Devices:**

5.1 Descriptive Comparison to a Legally Marketed Device
The SafetyGlide™ Syringe can be used in the same fashion as standard insulin / allergy / tuberculin syringes. When the SafetyGlide™ Syringe is in the "ready-to-use" position it provides the same usable needle length as standard insulin / allergy / tuberculin syringes.

Comparison has been made to the standard insulin / allergy / tuberculin syringes. The product is intended to be used for the same general injection and aspiration of fluids. The sharps injury prevention feature of the syringe contains a mechanism that covers the needlepoint after use. In the activated position the spool of the pushrod guards against accidental needle sticks during normal handling and disposal of the used syringe.

5.2 Material Changes: The only significant change in the materials is the use of a more rigid plastic resin in the sharps injury prevention feature of the SafetyGlide™ Syringe.

5.3 Manufacturing Process Changes: The manufacturing processes are being modified for the addition of the sharps injury prevention feature.

5.4 Manufacturing Site Changes: No manufacturing site changes are being made.

5.5 Packaging Component Changes: The package design is being modified to accept the larger size of the sharps injury prevention feature.

6. Equivalence:

The sharps injury prevention feature was compared to the predicate devices using the following criteria: activation forces, security of assembly, safety barrier resistance, impact resistance. The Becton Dickinson SafetyGlide™ Syringe performed in a similar manner to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 1999

Mr. Gregory W. Morgan
Director, Regulatory Compliance
Becton Dickinson and Company
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K992734
Trade Name: SafetyGlide Syringes Models 305930, 305951, & 305950
Regulatory Class: II
Product Code: MEG
Dated: August 12, 1999
Received: August 13, 1999

Dear Mr. Morgan:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 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) 594-4690. 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" (21 CFR 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/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

Indications for Use

510(k) number: K992734

Device Name: BD SafetyGlide™ Syringe (Insulin, Allergy and Tuberculin types)

Indications for Use:
The Becton Dickinson SafetyGlide™ Syringes are used for a variety of injections and aspirations of fluid from vials, ampules and parts of the body below the surface of the skin. The insulin syringe has scale lines in insulin units and is typically used for insulin injections. The allergy syringes come in test and treatment versions. The allergy test syringe has an intra-dermal bevel for intra-dermal injections. The allergy treatment syringe has a regular bevel which is typically used for subcutaneous injections. The tuberculin syringe has a regular bevel which can be used for any of the 3 types of common injections (intra-dermal, intra-muscular or subcutaneous).
The SafetyGlide™ Syringe contains a mechanism that covers the needle point after use. In the activated position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

Prescription Device: The allergy and tuberculin syringes are prescription devices and are labeled appropriately. The insulin syringe is a non-prescription device and does not have the prescription statement.

Steve Nameson for PXC
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992734

Prescription Use ✓
(Per 21 CFR 801.109)