K980580

JUN 25 1998

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

1.0 B-D Contact Person

Peter Zurlo
Becton Dickinson & Company
Manager, Regulatory Affairs
1 Becton Drive, Building 2
Franklin Lakes, NJ 07417-1884
(201) 847-6447 – Phone
(201) 848-0457 – FAX

2.0 Device Name

Becton Dickinson Single Use Hypodermic and Insulin Syringes

3.0 Predicate Device

Becton Dickinson Single Use Hypodermic and Insulin Syringes

4.0 Product Description/Function

4.1 **Types** – This change in syringe plunger tip formulation is for the Becton Dickinson syringe. Products include:

1.1.1 General purpose and insulin syringes.
1.1.2 Sterile and non-sterile syringes.
1.1.3 Syringes with and without needles attached.

No design changes are being made.

4.2 **Intended Use** – These syringes are intended for general purpose fluid aspiration/injection and insulin injection.

5.0 Comparison of Modified and Predicate Devices

5.1 **Design Changes** – No design changes are being made.

5.2 **Changes**

5.2.1 **Labeling** – The syringe labeling will be revised to include :

"This product does not contain natural rubber latex."

Or (optionally) :

- **"Latex Free".**

5.2.2 Material Change: Becton Dickinson added an alternate latex free rubber formulation used for its molded syringe plunger tip in 1988.

6.0 Equivalence

The following data demonstrates functional equivalence to the Becton Dickinson predicate plunger tip and fitness for use.

Syringe barrels molded with the alternate plunger tip formulation have demonstrated equivalence to barrels molded with the current plunger tip formulation.

6.1 **Leak Test** – Syringes with the alternate plunger tip formulation passed ISO 7886 and ISO 8537 syringe leakage tests (as did control samples with current plunger tip formulation).

6.2 **Autoclavibility (for syringes that require autoclavibility resistance)** – Syringes assembled with the alternate plunger tip satisfactorily passed autoclavibility testing. (Syringes were autoclaved at 270°F, 15 minutes then tested for ISO leakage resistance testing. All samples tested passed ISO leak testing.)

6.3 **Syringe Infusion Pump Performance (for syringes used in infusion pumps)** – Syringes assembled with the alternate plunger tip demonstrated equivalent performance to natural rubber plunger tip samples in syringe pump application testing.

6.4 **Chemical Testing** – Testing has been performed per ISO and USP requirements. Results were acceptable.

6.5 **Biocompatibility** – Biocompatibility testing was satisfactorily completed on the alternate plunger tip.

6.6 **Plunger Actuation Forces** – Forces for the alternate plunger tip are equivalent or superior to the current plunger tip.

6.7 **Manufacturing Process Changes** – No manufacturing process changes are being made.

6.8 **Manufacturing Site Changes** – No manufacturing site changes are being made.

6.9 **Packaging Component Changes** – No packaging components are being changed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 1998

Mr. Peter Zurlo
Manager, Regulatory Affairs
Becton Dickinson Consumer Products
1 Becton Drive
Franklin Lakes, New Jersey 07417-1883

Re: K980580
Trade Name: Becton Dickinson Syringes
Regulatory Class: II
Product Code: FMF
Dated: June 9, 1998
Received: June 10, 1998

Dear Mr. Zurlo:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance a (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at it 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 Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K980580

Device Name: Becton Dickinson Syringes

Indications For Use:

The general use syringes are intended for the aspiration and injection of fluids. Insulin syringes are intended for the injection of insulin.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rebecca Cricenti

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K980580

Prescription Use X OR Over-The-Counter Use Insulin Syringes
(Per 21 CFR 801.109)

(Optional Format 1-2-96)