K980987

JUN 11 1998

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

1.0 B-D Contact Person

Gregory W. Morgan
Manager, Regulatory Affairs
Division Quality Assurance
Becton Dickinson & Company
1 Becton Drive, Building 2
Franklin Lakes, NJ 07417-1884
(201) 847-4344 - Phone
(201) 847-4855 - FAX

2.0 Device Name

Becton Dickinson Single Use Hypodermic Syringes

3.0 Predicate Device

Becton Dickinson Single Use Hypodermic Syringes

4.0 Product Description/Function

4.1 Description

Single use sterile and non-sterile disposable hypodermic syringes manufactured by Becton Dickinson.

4.2 Function

The Becton Dickinson hypodermic syringe product line consists of single use disposable syringes intended for dispensing/administering fluids, and collecting/sampling of fluids in medical practice. Their function is mechanical.

5.0 Comparison of Modified and Predicate Devices

5.1 Design Changes

No design changes are being made.

5.2 Material Changes

Becton Dickinson intends to change the medical grade rubber formulation used for its molded syringe plunger tip.

Becton Dickinson manufactures its predicate plunger tip using dry gum natural rubber from the Hevae Braziliensis tree. While this material has proven safe through a long history of use, its composition suggests the possibility of natural rubber allergic reactions in susceptible patients.

The proposed plunger tip contains synthetic rubber. No natural rubber or other naturally occurring protein containing material is used in its formulation.

5.3 Manufacturing Process Changes

No manufacturing process changes are being made.

5.4 Manufacturing Site Changes

No manufacturing site changes are being made.

5.5 Packaging Component Changes

No packaging components are being changed.

6.0 Equivalence

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

6.1 Design Change

No design changes are being made.

6.2 Material Change

The new synthetic "latex/natural rubber free" syringe plunger tip formulation, and syringes made from this material, have been proven equivalent to existing product in functional performance (efficacy). Biological safety has been proven through a series of chemical and biological assays.

6.2.1 **Mechanical Function/Efficacy**

Syringes manufactured using the new synthetic "latex/natural rubber free" stopper material have demonstrated equivalence to syringes manufactured with natural rubber stoppers for:

- Ability to maintain a leak-proof seal.
- Perform after exposure to all expected sterilization conditions syringes will experience. This includes radiation, ethylene oxide, and autoclave methods.
- Exhibit actuation forces equivalent to current natural rubber containing syringes.
- Meet the stringent requirements for use in syringe pump application including low flow rate (0.01 ml/hr) neonatal administration of fast acting drugs.

6.2.2 **Safety**

- **Functional Safety** - Hypodermic syringes can be used in syringe pumps. Post market surveillance has identified the use of syringes in syringe pumps for administration of dopamine to neonates at low flow rates (0.1 ml/hr to 1.0 ml/hr) as the most stringent requirement. At the resultant rates of translation, the consistency of forces of movement are critical. Inconsistency in movement of the plunger and slow start-up/alarm response is undesirable.

  Becton Dickinson's predicate device meets the stringent neonatal pump application functional requirements. The proposed synthetic "latex/natural rubber free" plunger tip also meets this requirement as demonstrated in syringe pump application testing covering the range of use including low flow rate use.

- **Biocompatibility** - Syringes manufactured using the proposed synthetic "latex/natural rubber free" plunger tip have proven to be safe over specified manufacturing process and formulation variables. They pass all biological and chemical evaluations recommended in the ISO biocompatibility guidance.

- **Functional Safety** - Syringes manufactured using the proposed synthetic "latex/natural rubber free" plunger tip have proven to be functionally safe. They demonstrate functional equivalence to the predicate device in all applications, including neonatal syringe pump use.

6.3 **Manufacturing Process Changes**

No manufacturing process changes are being made.

6.4 **Manufacturing Site Changes**

No manufacturing site changes are being made.

6.5 **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 11 1998

Mr. Gregory W. Morgan
Manager, Regulatory Affairs
Division Quality Assurance
Becton Dickinson & Company
1 Becton Drive
Franklin Lakes, New Jersey 07417-1886

Re: K980987
Trade Name: Becton Dickinson Syringe
Regulatory Class: II
Product Code: FMF
Dated: March 13, 1998
Received: March 17, 1998

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 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 at (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 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 Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K980987

Device Name Syringe Plunger Tip Formulation Change Syringes

Indications for Use:

These syringes are intended for use by health care professionals for general purpose fluid aspiration/injection.

3/20/98

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

Concurrence f CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K980987

Prescription Use ✓ OR Over-The Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices (Optional Format 1-2-96)

510(k) Number _____