JUL 15 1998

K972728

510(k) SUMMARY

Date of preparation: July 18, 1997

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR 807.92.

A. REASON FOR 510(k): Introduction of a new product.

B. NAME OF DEVICE:

Classification Name:	Piston syringe
Common Name:	Sterile Water for Injection Prefilled Syringe (SWFIPS)
Proprietary Name:	not established

C. CLASSIFICATION:

Name/Class:	21 CFR 880.5860 Piston syringe / Class II
Panel:	General Hospital, Panel 80

D. ESTABLISHMENT REGISTRATION NUMBER: 8023072

E. SUBMITTER'S NAME AND ADDRESS:

Becton Dickinson and Company
Pharmaceutical Systems Division
1 Becton Drive
Franklin Lakes, New Jersey 07417-1886

Contact person:

Michael Gross, Ph.D.
Tel : 201-847-5930
Fax : 201-847-4854

F. MANUFACTURING AND STERILIZATION FACILITIES:

Vetter Pharma-Fertigung GmbH & Co KG
Schützenstrasse 99-101
88212 Ravensburg, Germany

G. PERFORMANCE STANDARD(S):

No performance standard applicable to this device have been promulgated under Section 514 of the Food, Drug and cosmetic Act.

H. DEVICE DESCRIPTION AND INTENDED USE :

SWFIPS is a glass piston syringe filled with USP Sterile Water for Injection.

SWFIPS is composed of an assembled glass piston syringe filled with a diluent, Sterile Water for Injection, USP.

SWFIPS is used for the reconstitution of non-liquid injectable drugs, in containers, and subsequent injection, according to their labeling. In the reconstitution of non-liquid drugs packaged in vials or ampules, a health care provider uses a syringe-needle assembly to remove a specified volume of diluent (e.g., Sterile Water for Injection) from a separate container and transfer it by injection into another vial or ampule containing the drug. A specific volume of drug is then removed and injected into the patient. By providing the Sterile Water for Injection prefilled in a Syringe, SWFIPS eliminates a number of reconstitution manipulations, reduces medical waste and reduces the possibility of microbial and/or particulate contamination. When SWFIPS is used to reconstitute, a needle is affixed to the syringe tip and is used to enter a vial or ampule containing a drug. The syringe contents (i.e., Sterile Water for Injection) are then expressed into the container dissolving the drug. All or part of drug solution is then withdrawn according to labeling. The needle-syringe assembly is then ready for injection through the skin or, depending on medical preference, the needle may be replaced with a fresh needle before injection into the patient occurs.

The Sterile Water for Injection contained in the syringe conforms to USP monograph specifications at release and throughout the shelf life. The glass and the elastomeric closures meet USP requirements. The SWFIPS has been tested according to a stability protocol designed to support the shelf life claim.

I. SUBSTANTIAL EQUIVALENCE

SWFIPS is substantially equivalent to the BD® GLASPAK® syringe, a legally marketed device.

The term « substantial equivalence » as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as supplied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. 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 statement 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 court.

SWFIPS is substantially equivalent to the predicate device in that:

a) both can be used for the reconstitution of a non liquid drug and for the injection of a drug solution.

b) both container materials are biocompatible and chemically compatible with the Sterile Water for Injection.

c) both syringe tips are compatible with a female Luer fitting

d) both employ the same tehnological characteristics with the exception that SWFIPS is filled.

SWFIPS is different from the predicate device, without adverse effect to safety or efficacy, in that:

a) it is filled with 1 mL Sterile Water for Injection whereas the predicate device is empty.

b) it is terminally sterilized by steam whereas the predicate device is sterilized by ethylene oxide.

[END OF SUMMARY]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 1998

Michael Gross, Ph.D.
Director, Corporate Regulatory Affairs
Pharmaceutical Systems Division
Becton Dickinson & Company
1 Becton Drive
Franklin Lakes, New Jersey 07417-1886

Re: K972728
Trade Name: Sterile Water for Injection Prefilled Syringe
Regulatory Class: II
Product Code: FMF
Dated: April 20, 1998
Received: April 22, 1998

Dear Dr. Gross:

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.

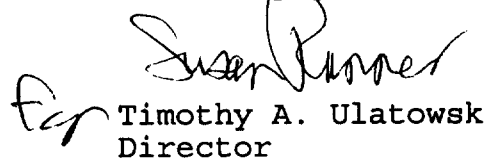
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,



for 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):

Device Name: Sterile Water for Injection Prefilled Syringe, USP (SWFIPS)

Indications for Use:

SWFIPS is a combination product intended to be used by patients, pharmacists or physicians for the reconstitution and administration of approved prescription drug products.

SWFIPS is not labeled or intended for stand alone use. The indications for use of the reconstituted drug or biologic are contained in the package insert for each product.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CRF 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972728