

MAR - 8 2000

K982558

13.0 510(k) Summary of Safety and Effectiveness for Preefil® Normal Saline Flush Syringes

13.1	Submitter:	Davis N. Bulman
13.2	Company Name:	Preefil Corporation
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13.4	Contact Person	Kurt Ebenhoe/QA Manager
13.5	Telephone # of Contact Person	414-475-7565
13.6	Fax # of Contact Person	414-475-5117
13.7	Date of Summary Preparation	7/9/98
13.8	Device Name	
	Trade Name	Preefil® Normal Saline Flush Syringe
	Classification Name	Accessory to Intravenous Catheter (880.5200)
	Common Name	Normal Saline Flush Syringe
13.9	Intended Use	Maintain patency of vascular devices
13.10	Description	Sterile Plastic Luer Lock Syringes of various sizes Filled with sterile saline

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510(k) Summary (Continued)

13.11 Substantial Equivalence Matrix (Preefil and Vital Signs Products)

DESCRIPTION	FLUSH SYRINGE	VASCULAR ACCESS FLUSH DEVICE
MANUFACTURER	PREEFIL CORPORATION	VITAL SIGNS
PRODUCT NAME	PREEFIL® SALINE FLUSH SYRINGE	VASCEZE™ HEPARIN LOCK FLUSH SOLUTION AND 0.9% SODIUM CHLORIDE, USP SOLUTION
PRODUCT CODE	FOZ	FOZ
K NUMBER	NOT ASSIGNED	K952645
ADDRESS	MILWAUKEE, WI	TOTOWA, NJ
INDICATED USE	MAINTENANCE OF PATENCY OF VASCULAR DEVICES	MAINTENANCE OF PATENCY OF VASCULAR DEVICES
CONTENTS OF DEVICE	SODIUM CHLORIDE (0.9%) USP	SODIUM CHLORIDE (0.9%) USP
CONTAINMENT DEVICE FOR FLUSH	STERILE PLASTIC LUER LOCK SYRINGE VARIOUS SIZES	POLYMERIC CONTAINER WITH LUER SLIP NOZZLE
STERILITY	FLUID PATH STERILITY PRESERVED BY ASEPTIC PROCESSING	ENTIRE CONTENTS OF PACKAGE STERILIZED BY TERMINAL STERILIZATION
PACKAGING	PERFORATED POLY BAG	POLYMERIC POUCH WITH TYVEK LID
HOW SUPPLIED	SYRINGE SIZES 3-6-12 mL FILL VOLUMES 1-2-3-5- 6-10 MI	5 mL

G. Morgan
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**MAR - 8 2000**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Greg Morgan
BD Medical Quality/Regulatory
BD/Preefil
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K982558

Trade Name: BD Preefil® Normal Saline Flush Syringe
Regulatory Class: II
Product Code: FOZ
Dated: January 3, 2000
Received: January 7, 2000

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 (Pre-market 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 pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of

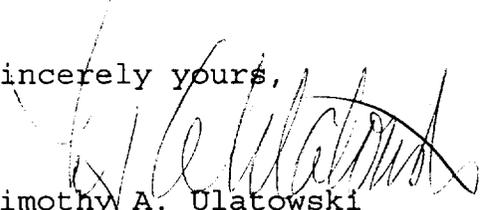
Page 2 -Mr. Morgan

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

12.0 Indications for use statement: BD Prefill Normal Saline flush syringes are intended for the maintenance of the patency of vascular access devices.

Rafaela Cuente

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
Number K982558

E. Morgan
3/6/00