

DEC 16 1998

**510(k) Summary**

B. Braun Medical, Inc  
824 Twelfth Avenue  
Bethlehem, PA 18018  
(610)691-5400

August 31, 1998

**CONTACT:** Mark S. Alsberge, Regulatory Affairs Director**PRODUCT NAME:** Braun Prefilled Syringes**TRADE NAME:** Prefilled Intravascular Catheter  
Flush Syringes**CLASSIFICATION NAME:**

Class: II  
Panel: 80 General Hospital Devices  
Procode: FMF Piston Syringe

These devices have also been reviewed by the FDA as Accessory items  
to:

Class: II  
Panel: 80 General Hospital Devices  
Procode: FOZ Intravascular Catheters

**DEVICE DESCRIPTION:**

B. Braun Medical, Inc. intends to introduce into interstate commerce the Braun Prefilled Syringes. The syringes are aseptically filled with sterile 0.9% saline solutions intended solely for use in flushing intravascular catheters and maintain the patency of indwelling intravascular catheters. The syringes and solutions are not intended for use as anticoagulant therapy. The aseptic filling of these syringes with these solutions does not alter the intended use of the syringes or the solutions. The syringes have been cleared for marketing under K760392. The solutions meet the specifications of the applicable USP monograph for sodium chloride.

**MATERIALS:**

The materials use to manufacture the syringes, as well as, the solutions used to fill the syringes have previously been reviewed by the FDA and determined to be suitable for the intended use of this product. The processes used to aseptically fill these syringes do not alter the properties or intended use of these materials.

**SUBSTANTIAL EQUIVALENCE<sup>1</sup> TO:**

<b>510(k) number</b>	<b>Name</b>	<b>Applicant</b>
K760392	Syringes	B. Braun Instruments, Inc.
K952645	Vital Signs Saline Vascular Access Flush Device	Vital Signs, Inc.
Unknown	Solopak™ 0.9% Sodium Chloride	Solopak Medical Products, Inc.

**SUBSTANTIAL EQUIVALENCE:**

B. Braun has marketed the syringes used in this device since their clearance by the FDA in 1976 (K760392). The solutions used in this device have also been cleared for their intended use by FDA review. The solutions meet the specifications of the applicable USP monograph for 0.9% sodium chloride USP. The processes used to aseptically fill these syringes do not alter the properties or intended use of these materials. The intended use, design, and labeling (warnings and claims) are substantially equivalent to the above listed devices. There are no new issues regarding safety and effectiveness raised by B. Braun Medical, Inc.'s intent to introduce into interstate commerce the Braun Prefilled Syringes.

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<sup>1</sup> The term "substantially equivalent" as use herein is intended to be a determination of substantial equivalence from a FDA -regulatory point of view under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to and does not diminish any patent claims related to this product or the technology used to manufacture the product.

## **SAFETY AND EFFECTIVENESS:**

The aseptic filling of these syringes with the solution does not alter the intended use of the syringe or the solution. The manufacturing processes and controls adhere to currently accepted guidelines and standards of practice.

Currently marketed prefilled syringes incorporate similar features and are available from a number of manufacturers for the same intended use. A review of the current literature and MDRs indicate that there are no additional risks or concerns associated with the use of prefilled syringes solely for use in flushing intravascular catheters or in preventing blood clots in these catheters.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 16 1998

Mr. Mark S. Alsberge  
Regulatory Affairs Director  
B. Braun Medical, Incorporated  
824 12<sup>th</sup> Avenue  
Bethlehem, Pennsylvania 18018-0027

Re: K970736  
Trade Name: Braun Prefilled Syringes  
Regulatory Class: II  
Product Code: FOZ  
Dated: September 11, 1998  
Received: September 21, 1998

Dear Mr. Alsberge:

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

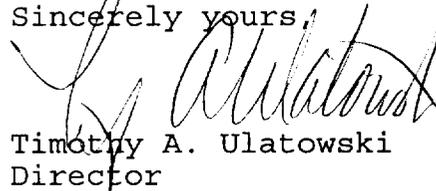
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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" (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

S10(k) Number (if known): K970736

Device Name: Normal Saline Prefilled Syringes

**Indications For Use:**

The Normal Saline prefilled syringes are indicated solely for use in flushing intravascular catheters and maintaining the patency of indwelling intravascular catheters.

The following table lists the available fill volumes and syringe sizes.

**CAPS FLUSH SYRINGE PRODUCT LISTING TABLE**

DESCRIPTION	Fill Vol ml	Syr Size ml	CAPS Product#	WSP#
0.9% Sodium Chloride PF	1ml	3ml	000-NS-0103	8193-9101-11
	2ml	3ml	000-NS-0203	8193-9101-12
	3ml	6ml	000-NS-0306	8193-9101-23
	3ml	12ml	000-NS-0312	8193-9101-33
	5ml	6ml	000-NS-0506	8193-9101-24
	5ml	12ml	000-NS-0512	8193-9101-34
	10ml	12ml	000-NS-1012	8193-9101-35

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Patricia Ciccerola*  
 (Division Sign-Off)  
 Division of Dental, Infection Control,  
 and General Hospital Devices  
 S10(k) Number K970736

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_