

SEP 25 1998

K971924

II 510(k) Summary

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

May 20, 1997

CONTACT: Mark S. Alsberge, Regulatory Affairs Manager

PRODUCT NAME: Blunt Syringe Cannula

TRADE NAME: Blunt Syringe Cannula

CLASSIFICATION NAME:

General Hospital  
Class II, FMF, Piston Syringe  
21 CFR. 880.5860

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

510(k) number	Name	Applicant
K920422	InterLink Syringe Cannula	Becton Dickinson, Inc.
K913177	SafeLine System	McGaw, Inc.

DEVICE DESCRIPTION:

B. Braun Medical Inc. intends to introduce into interstate commerce the Blunt Syringe Cannula. These have the same design and performance characteristics as the InterLink Syringe Cannula currently marketed by Becton Dickinson and covered under K920422. It is also similar to McGaw's SafeLine System covered under K913177. The intended use is to be used with a syringe to pierce a pre-split rubber injection site.

<sup>1</sup> The term "substantially equivalent" as use herein is intended to be a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without

premarket approval or reclassification. Such a determination is not intended to be applicable to patent infringement suits or any other patent matter related to this product or the technology used to manufacture the product.

**MATERIAL:**

B. Braun Medical certifies that the biocompatibility tests recommended in the Tripartite Guidance for this category of contact duration will be completed for all the materials used in the manufacture of the device.

**SUBSTANTIAL EQUIVALENCE:**

The Blunt Syringe Cannula is equivalent in materials, form, and intended use to the InterLink Syringe Cannula currently marketed by Becton Dickinson, covered under K920422. There are no new issues of safety or effectiveness raised by the Blunt Syringe Cannula.

**SAFETY AND EFFECTIVENESS:**

All finished products are tested and must meet all required release specifications before distribution. The array of testing required for release include, but are not limited to; sterility, pyrogenicity (endotoxin/ LAL Method), physical testing, visual examination (in process and finished product).

The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures and parameters which conform to the product design specifications.

The testing instruction records for each of the individually required procedures are approved, released, distributed and revised in accordance with document control GMP"s.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 25 1998

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

Re: K971924  
Trade Name: Blunt Syringe Cannula  
Regulatory Class: II  
Product Code: FMI  
Dated: August 26, 1998  
Received: August 31, 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 (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

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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,



*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): K 971924

Device Name: Blunt Syringe Cannula

Indications For Use:

To be used with a syringe to pierce SafeLine pre-slit rubber injection sites.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Paloma Crescenti*

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

510(k) Number K 971924

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use