JUN 3 1998

K974363

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

1.0 B-D Contact Person

Gregory W. Morgan
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Division Quality Assurance
Becton Dickinson and Company
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2.0 Device Name

Becton Dickinson Blunt Plastic Cannula

3.0 Predicate Device

Becton Dickinson Blunt Plastic Cannula

4.0 Product Description/Function

4.1 **Product Description** – No change from B-D® Blunt Plastic Cannula 510(k) 964654. Sterile, single-use plastic cannula used to penetrate pre-slit septums covering injection sites, as well as, vials designed for penetration with needleless IV access cannula. The cannula is pre-lubricated with medical grade silicone to reduce septum insertion forces.

Product Identification

B-D® Blunt Plastic Cannula	Cat. # 303345
B-D® Blunt Plastic Cannula with 3cc Syringe	Cat. # 303346
B-D® Blunt Plastic Cannula with 5cc Syringe	Cat. # 303347
B-D® Blunt Plastic Cannula with 10cc Syringe	Cat. # 303348

Reference product drawing, Tab 4.

4.2 **Product Function**

The B-D® Blunt Plastic Cannula replaces hypodermic needles currently used to access injection sites, as well as, vials designed for penetration with needleless IV access cannula. The B-D® Blunt Plastic Cannula provides access to the fluid path for injection/aspiration of fluids. Use of this device prevents accidental hypodermic needlesticks in this application. As indicated in section 1.0, these devices can also be used to flush pre-slit injection sites.

5.0 Supporting Date for More Effective Injection Site Flushing Claim

Claim	Predicate Device	Testing
The B-D® Blunt Plastic Cannula flushes compatible pre-slit injection sites more effectively than competitive cannula	• Baxter InterLink® Syringe Cannula • Abbott LifeShield® Blunt Steel Cannula • McGaw SafeLine® Blunt Cannula • Abbott LifeShield® BlunTip™ Cannula	Injection Site Flushing Evaluation, Becton Dickinson Test Protocol

5.1 Injection Site Flushing Evaluation

Test Description:

The B-D® Blunt Plastic Cannula and competitive cannula were used to flush compatible blood filled injection sites per Becton Dickinson protocol (Tab 4). The number of red blood cells remaining in the injection site measured flushing effectiveness. The experiment was designed to examine the following variables: (1)Cannula brand, (2)Quantity of flush(3 or 10cc), (3) Rotation of syringe during flush, and (4) Cannula insertion depth.

The 0.80" outside diameter of the B-D® Blunt Plastic Cannula stem allows access to the Baxter InterLnk®, Abbott LifeShield®, and McGaw SafeLine® pre-slit septums. Unlike the B-D® Blunt Plastic Cannula, competitive cannula are not compatible with all of these injection sites.

The test accounted for the following variables for flushing injection sites:

(1) Cannula Brand

(2) Quantity of Flush - The quantity of flush was limited to 3cc and 10cc of saline. For both quantities, the flow rate was 1cc/sec.

(3) Rotation of Syringe - The effect of rotation was examined by allowing rotation for some trials and no rotation for others. However, rotation was not performed with the Abbott LifeShield® pre-slit septum due to the restrictive internal diameter of the site.

(4) Cannula insertion depth - Cannula insertion depth, the length of the cannula within the site, was tested at full and partial insertion of the cannula into the site. For partial insertion, a spacer was placed over the cannula to reduce the length of the cannula within the site by .080". Because the stem length of each cannula and the septum thickness of each injection site varied, spacers were made so that the cannula insertion depth was identical for each cannula/site combination for full and partial insertion for a given experiment.

Summary/Conclusion:

As noted in Section 7.1 of the 510(k), we developed four(4) experiments to assess the flushing effectiveness of competitive cannula. The experiments compared the performance of the cannula in their respective, compatible pre-slit injection sites. Flushing effectiveness was assessed by counting the remaining red blood cells in the injection site after flushing. The injection sites were flushed under controlled test conditions which reflect hospital protocol or user technique.

Conclusion: The B-D® Blunt Plastic Cannula was observed to provide superior flushing effectiveness as compared to the competitive cannula tested.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Gregory W. Morgan
Manager, Regulatory Affairs
Division Quality Assurance
Becton Dickinson and Company
1 Becton Drive, Building 2
Franklin Lakes, New Jersey 07417-1884

Re: K974363
Trade Name: Becton Dickinson Blunt Plastic Cannula
Regulatory Class: II
Product Code: FMI
Dated: February 18, 1998
Received: March 16, 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) K974363

Device Name: B-D Blunt Plastic Cannula

Indications for Use:

The B-D® Blunt Plastic Cannula replaces hypodermic needles currently used to access injection sites, as well as, vials designed for penetration with needleless IV access cannula. The B-D® Blunt Plastic Cannula provides access to fluid path for injection/aspiration of fluids. Use of this device prevents accidental hypodermic needlesticks in this application. These devices can also be used to flush pre-slit injection sites.

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

Concurrence of CDRH

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974363

Prescription Use ✓
(Per 21 CFR 801.109)