K974006

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

JAN 22 1998

1.0 B-D Contact Person

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2.0 Device Name

Becton Dickinson TWINPAK™

3.0 Predicate Device

Becton Dickinson Blunt Plastic Cannula and Tubing Adapter

4.0 Product Description/Function

4.1 Product Description

The B-D® TWINPAK™ is an assembly consisting of currently marketed and previously approved devices incorporated into a protective shield – TWINPAK comprises the following legally marketed devices.

1. B-D Blunt Plastic Cannula [cleared for marketing 510(k) #K964654]

2. Syringe Filling Device (SFD) – This is a 20G x ½" steel cannula, which is exactly the same as legally marketed device by Becton Dickinson, B-D® Tubing Adapter, Reorder #8210.

Devices (1) and (2) without their respective original shields are assembled into a plastic shield, as shown in figure. A plastic cap is also placed over the syringe filling device. The TWINPAK™ can be sold by itself or with a syringe.

4.2 Product Function

The syringe filling device replaces standard, sharp hypodermic needles and all other syringe filling devices and accessories for syringe filling from vials and ampoules. Once the syringe is filled, the filling device is detached from the syringe. The syringe is then reattached to the blunt plastic cannula which provides access to fluid path for injection/aspiration of fluids. The B-D® TWINPAK™ offers the convenience of delivering a syringe filling device and a blunt plastic cannula for access into split septum IV sites for injection/aspiration of fluids.

5.0 **Comparison of Modified and Predicate Devices** – Predicate, legally marked device: The following products are referenced as predicate devices:

Device	510(k) #
Becton Dickinson 20G hypodermic needle	Pre-amendment device
Becton Dickinson Interlink® Vial Access Cannula	K920422 and K883638
Becton Dickinson Tubing Adapter	Pre-amendment device

These products are compared to the syringe filling device of B-D® TWINPAK™.

5.1 **Design**

The syringe filling device is a standard 20G x ½" steel cannula. The cannula has a ground blunt point geometry with 45° bevel. This is exactly the same design as B-D Tubing Adapter.

5.2 **Material**

Material Comparison to Predicate Devices

	Syringe Filling Device	B-D Tubing Adapter	B-D Hypodermic Needle
Cannula	Stainless Steel	Stainless Steel	Stainless Steel
Lubricant	Silicone	Silicone	Silicone
AK Shield	Polypropylene	N/A	N/A
Cap	Polypropylene	N/A	N/A
Cannula hub	Polypropylene	Polypropylene	Polypropylene
Adhesive	Epoxy	Epoxy	Epoxy

5.3 **Manufacturing Process**

The manufacturing process used for the syringe filling device is exactly the same as that of B-D Precision Glide Needle and B-D Tubing Adapter. The process includes cannulating the steel cannula to molded plastic hub using epoxy adhesive. The TWINPAK™ shield and cap are manufactured by injection molding.

5.4 **Product Use**

The syringe filling device component of B-D® TWINPAK™ is for use in drawing up fluids/medications from vials and ampoules without requiring other accessories. Standard B-D hypodermic needle is also used for the same use. B-D Interlink® Vial Access Cannula is for use in drawing up medications from single dose vials only. The syringe filling device is comparable to predicate devices in dose drawing, vial penetration forces, vial stopper leakage and particulate matter generation.

5.5 Safety and Effectiveness

5.5.1 The syringe filling device was tested to demonstrate a general equivalency in safety and effectiveness measures with predicate devices. Following tests were conducted as measures of safety and effectiveness for the intended use/application:

a. Dose drawing
b. Vial Stopper Particulate Matter
c. Vial Stopper Access
d. Ampoule Access

6.0 Equivalence

6.1 Testing to Support General Equivalence

The following table lists specific tests used to demonstrate general equivalence for the Syringe Filling Device (SFD) to predicate devices when aspirating fluids.

a. Dose Drawing
b. Vial Stopper Particulate Matter
c. Vial Stopper Access
d. Ampoule Access

6.1.1 Dose Drawing – Test Description

Cannula are attached to a syringe. Air is aspirated into the syringe, the amount of air corresponds to the dose to be drawn. The dose was defined as the full volume for the single dose vials and ten 1ml doses per vial for the multiple dose vial. Cannula are penetrated through the vial stoppers and the vials are inverted. The air is injected into the vials and the appropriate dose is withdrawn. The fluid is measured using the scale of the syringe. The measurement tolerance for the single dose vials was +/- 0.2cc and for the multiple dose vial was +/- 0.1cc. This test is designed to determine if the cannula geometry allows for the full dose to be withdrawn from the vial and to determine equivalence with predicate devices. Thirty vials per cannula type were tested.

Conclusion – The SFD is equivalent for dose drawing to the predicate devices and the full dose can be withdrawn.

6.1.2 Vial Stopper Particulate Matter – Test Description

Cannula are attached to a syringe. Air is aspirated into the syringe, the amount of air corresponds to the dose to be drawn. The dose was defined as the full volume for the single dose vials and ten 1ml doses per vial for the multiple dose vial. Cannula are penetrated through the vial stoppers and the vials are inverted. The air is injected into the vials and the appropriate dose is withdrawn. The fluid is measured using the scale of the syringe. The fluid in the syringe is dispensed into a filter. The filters were than examined for visible stopper particulate matter. This test is designed to determine if vial stopper particulate matter is generated with the SFD and predicate devices. Thirty vials per cannula type were tested.

Conclusions - The SFD is equivalent to the predicate devices for generation of vial stopper particulate matter during vial access.

6.1.3 Vial Stopper Access – Test Description

Cannula are attached to a syringe. Air is aspirated into the syringe, the amount of air corresponds to the dose to be drawn. The dose was defined as the full volume for the single dose vials and ten 1ml doses per vial for the multiple dose vial. Cannula are penetrated through the vial stoppers and the vials are inverted. The air is injected into the vials and the appropriate dose is aspirated. During pressurization and aspiration any leakage was noted. Leakage is defined as fluid dripping. This test is designed to determine if equivalent vial stopper leakage occurs while aspirating fluids with the SFD and predicate devices. Thirty single dose vials were penetrated one time each for a total of 30 penetrations per cannula type. Thirty multiple dose vials were penetrated ten times each for a total of 300 penetrations per cannula type.

Conclusions - The SFD is equivalent for vial stopper access to the predicate devices.

6.1.4 Ampoule Access

The ability to access ampoules was assessed by a dimensional comparison between the SFD cannula geometry and ampoule dimensions as defined by ISO 9187-1 (Injection equipment for medical use - Ampoules for injectables) and ISO 9187-2 (Injection equipment for medical use - One-point-cut ampoules). The criteria to determine that the SFD could access an ampoule was if the SFD cannula was longer than the shoulder length of the ampoule. If the cannula length is greater than the shoulder length then fluids would be able to be aspirated using normal protocols The SFD cannula length is greater than the shoulder length for all ampoules identified under nominal dimensions. This evaluation was intended to show equivalence for accessing ampoules with the SFD and predicate devices.

Conclusion – The SFD is equivalent to the predicate device for the ability to access ampoules.

7.0 Testing to Support Specific Claims

The following table lists tests used to support specific claims beyond general equivalence.

CLAIM 1	SFD cannula is 10 times less sharp than an equivalent gauge standard hypodermic needle	Penetration force testing in Dental Dam
CLAIM 2	Vial stopper penetration force is substantially reduced when comparing the SFD to the B-D Vial Access Cannula	Penetration force testing in various vials

7.1 Penetration force testing in Dental Dam – Test Description

Cannula were attached to a force transducer and penetrated through dental dam in an axial direction. Peak penetration forces were recorded. The sample size was 30 cannula per cannula type.

Background

Dental Dam is a thin (.012 inches thick) latex rubber material that has been used to evaluate the penetration force of hypodermic and intravenous catheter needles. Peak penetration force is inversely proportional to the cannula sharpness, i.e. the higher the force, the less sharp the cannula.

Conclusions

The SFD is 10 times less sharp than an equivalent gauge standard hypodermic needle.

7.2 Penetration force testing into various vials – Test Description

Cannula were attached to a force transducer and penetrated through various drug vial stoppers in an axial direction. Peak penetration forces were recorded. The sample size was 30 cannula per cannula type.

Conclusions

Vial stopper penetration force is substantially reduced when comparing the SFD to the B-D Vial Access Cannula.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JAN 22 1998

Re: K974006
Trade Name: Becton Dickinson Twinpak
Regulatory Class: II
Product Code: FMI
Dated: December 8, 1997
Received: December 9, 1997

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 (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 requirement, 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) 594-4618. 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

510(k) Number (if known): K974006

Device Name: Becton Dickinson TWINPAK™

Indications For Use:

The syringe filling device replaces standard, sharp hypodermic needles and all other syringe filling devices and accessories for syringe filling from vials and ampoules. Once the syringe is filled, the filling device is detached from the syringe. The syringe is then reattached to the blunt plastic cannula which provides access to fluid path for injection/aspiration of fluids. The blunt plastic cannula is intended for use with Abbott Life Shield®, McGaw Safeline™ and Baxter Interlink® systems. The B-D TWINPAK offers the convenience of delivering a syringe filling device and a blunt plastic cannula for access into split septum IV sites for injection/aspiration of fluids.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cascante

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974006

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)