K964054

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

1.0 B-D Contact Person

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2.0 Device Name

Becton Dickinson , B-D® Blunt Plastic Cannula

3.0 Predicate Device

Becton Dickinson InterLink® Syringe Cannula

4.0 Product Description / Function

4.1 Product Description

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 to reduce septum insertion forces.

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.

5.0 Comparison of Modified and Predicate Devices

5.1 Comparison to Legally Marketed Devices

The following products are referenced as predicates Devices:

DEVICE	510 K NUMBERS OF DEVICE
Becton Dickinson InterLink® Syringe Cannula	K920422 & K883638
Abbott LifeShield® Blunt Steel 18g x 1" Cannula	K854547
McGaw SafeLine™ Blunt Cannula	K931377

These products are compared to the B-D® Blunt Plastic Cannula in the following manner

5.1.1 Design :
B-D® Blunt Plastic Cannula is a molded plastic blunt tipped cannula for use in pre-slit IV safety systems, (i.e. Baxter InterLink® , Abbott LifeShield®, and McGaw SafeLine™). The B-D® Blunt Plastic Cannula is intended for penetration of pre-slit IV port septums or vials designed for penetration with needleless IV access devices (i.e. Abbott LifeShield® Single Dose Vials). B-D® Blunt Plastic Cannula, InterLink® Syringe Cannula, and McGaw SafeLine™ Blunt Cannula are all plastic devices. LifeShield® Blunt Cannulas is a two (2) piece design which has a plastic hub with a blunt steel cannula attached.

DESIGN COMPARISONS TO PREDICATE DEVICES

	B-D® Blunt Plastic Cannula	InterLink® Syringe Cannula	McGaw SafeLine™ Blunt Cannula	LifeShield® Blunt Cannulas
Design	Single Molded Component	Single Molded Component	Single Molded Component	Molded Hub with Blunt Steel Cannula

5.1.2. Material:
B-D® Blunt Plastic Cannula is molded from copolyester resin. Shield material is the same as the B-D InterLink® Syringe Cannula .

MATERIAL COMPARISONS TO PREDICATE DEVICES

	B-D® Blunt Plastic Cannula	B-D InterLink® Syringe Cannula	McGaw SafeLine™ Blunt Cannula	LifeShield® Blunt Cannulas
Cannula Stem / Hub	copolyester	polypropylene	copolyester	steel / polypropylene
Lubricant			unknown	unknown
Shield	polypropylene	polypropylene	polyethylene	polypropylene

5.1.3. Product Use:

B-D® Blunt Plastic Cannula is a molded, plastic, blunt tipped cannula for use in pre-slit IV safety systems (i.e. Baxter InterLink®, Abbott LifeShield®, and McGaw SafeLine™). The B-D® Blunt Plastic Cannula is comparable in all systems in terms of injection site insertion forces, ability of injection sites to withstand 200 cannula insertions without damage, which would impact, particulate generation, leakage and or microbial ingress. B-D® Blunt Plastic Cannula is designed to access vials which are designed for needleless IV access cannula (i.e. Abbott LifeShield® single dose saline).

PRODUCT USE COMPARISON OF PREDICATE DEVICES

	B-D® Blunt Plastic Cannula	B-D® Blunt Plastic Syringe Cannula	McGaw SafeLine™ Blunt Cannulas	LifeShield® Blunt Cannulas
Applicable claims	For use in IV preslit septums and needleless access vials	For use in InterLink® injection sites	For use with McGaw SafeLine™ System	Use with only prepierced IV reseals
Claims Package Contents	Sterile, Non toxic and Non -pyrogenic	Sterile, Non toxic and Non - pyrogenic	Sterile, Non toxic and Non -pyrogenic	Sterile, Non toxic and Non - pyrogenic

5.2 **Manufacturing Process Changes**

No manufacturing process changes are being made.

5.3 **Manufacturing Site Changes**

No manufacturing site changes are being made.

5.2 **Packaging Component Changes**

No packaging component changes are being made.

6.0 **Equivalence**

6.1 **Testing to Support General Equivalence:**

The following table lists specific tests used to demonstrate general equivalence for the B-D Blunt Plastic Cannula in pre - slit safety systems

SECTION	TITLE REPORTED
6.1.1	Injection Site Peak Penetration Force
6.1.2	Lipid Flow Rate Testing
6.1.3	Lipid compatibility
6.1.4	Microbial Ingress
6.1.5	Leakage
6.1.6	Gravity Flow Rate
6.1.7	Particulate Matter

6.1.1 Injection Site Peak Penetration force

Test Description:
Cannula are inserted axially into injection sites. The injection site penetration test measures the peak axial force required for the cannula to penetrate the slit septum of the needleless injection site.

Conclusions:

B-D® Blunt Plastic cannula performed at an acceptable level in all sites. Differences both lower than the predicate (InterLink® Syringe Cannula , McGaw SafeLine™) and higher forces (Abbott LifeShield®) are a result of the dimensional differences between the stem OD's. Based on the average force levels in all injection sites with predicate devices, forces for the B-D® Blunt Plastic Cannula are within this range.

6.1.2 Lipid Flow Rate testing:

Test Description:

Laboratory syringe infusion pump testing was conducted to determine flow rates through a series cannula as a function of time and volume of fluid being infused. Additionally the fluid was filtered to determine if there was any particle generation during course of flow rate testing. The fluid used in evaluations was Intralipid® 20% fat emulsion. Two different volumetric flow rates were evaluated for a duration of 6 hours. Volumetric flow rate accuracy was determined based on weight of the fluid delivered per each test cycle. Fluids were filtered at cannula inlet inlet per manufactures recommendations (syringe output) and outlet of the cannula string. Filters used were a membrane type with a porosity of 1.2µm (filter porosity was minimum recommended by 20% Intralipid® manufacturer's literature). After infusion was complete, the outlet filters were removed and allowed to dry under laminar flow hood and then microscopically examined at 30X magnification. All particles larger than 10µm were counted and presented for characterization or identification using optical microscopic and Fourier transform infra red (FTIR) analysis techniques.

Conclusions:
Flow rates are equivalent for the B-D® Blunt Plastic Cannula to all predicate devices.

6.1.3 Lipid Compatibility:

Test Description:
Lipid infusion thru B-D® Blunt Plastic cannula molded were conducted for a 24 hour period. Each luer slip torque to a specified level (32in/oz) over a luer post in order to prestress the slip and ears.

Conclusion:
No leakage due to physical changes as a result material degradation were observed. Examination of the luer slips via magnification (20X) revealed no damage which would effect the function of the cannula.

6.1.4 Microbial Ingress Testing:

Test Description:
Injection sites were penetrated two hundred (200) times with various cannula. Injection sites were then subjected to a microbial challenge.

Conclusions:
Based on the data it can be concluded that the B-D® Blunt Plastic cannula when used in pre slit needleless septums did not compromise the microbial barrier efficacy. Microbial ingress did not occur for the six (6) combinations of cannula and injection sites challenged in this study. Recommended aseptic technique, such as, swabbing the injection site with an antiseptic agent prior to each insertion and using a new sterile cannula for each insertion were also challenged in this test, in as far as, the septum was wiped and cannula changed after every fourth penetration. Even with this added stress of the microbial challenge, no ingress was found.

6.1.5 Leakage testing

Test Description;
Injection sites were penetrated two hundred (200) times with various cannula. Injection sites were then subjected to a pressure test. A cannula with the luer slip sealed (to prevent leakage through cannula) was inserted into site. Pressure (45 psi) was initiated and held for 30 seconds. Criteria for failure was that no drops of water would form and fall off within this time.

Conclusions:

No mechanical damage to the pre-slit septum resulting in leakage was caused by the B-D® Blunt Plastic Cannula.

6.1.6 Flow Rate Testing

Test Description:

Flow rate testing to determine equivalency by using a typical IV drip gravity set-up (0.9% 100ml saline bag and adapters) connected to a cannula. Height of the bag was held at a constant (39 inches) to simulate arterial pressure Flow was initiated and timed and volume measured to give a flow rate in ml/min.

Conclusions:

B-D® Blunt Plastic Cannula flow rate is greater than the Abbott LifeShield® 18 G Blunt Steel Cannula. The larger ID of the McGaw SafeLine™ and the InterLink® Syringe Cannula allow for greater flow rates. However, the B-D® Blunt Plastic Cannula's reduced ID / OD provides access to all systems, not only McGaw SafeLine™ and Baxter InterLink®.

6.1.7 Particulate matter generation

Test Description;

Injection sites were penetrated two hundred (200) times with cannula. During each penetration solution was flushed through the cannula and septum and collected on a filter. This filter was then examined and visible particles, greater than 100 µm, were counted and identified via Fourier transform infra red (FTIR) technique as septum material.

Conclusions:

B-D® Blunt Plastic Cannula produced equivalent or reduced particulate matter as compared to the predicate devices.

6.2 Supporting data for specific claims

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

6.2.1 Peak Penetration forces in Abbott LifeShield® Single dose vials.

Test Description:
Cannula were attached to a force transducer and penetrated through the vial stopper in an axial direction. Peak penetration forces were recorded.

Conclusions:
Slightly higher penetration forces observed with the B-D® Blunt Plastic Cannula are a result of the larger cannula OD. This increase does not effect stopper integrity based on subsequent tests.

6.2.2 Full dose draw/ Vial integrity.

Test description:
Air (10cc) is aspirated into a syringe with cannula attached. Cannula are penetrated through vial stoppers. Air is injected into the vial and is allowed to pressurize the vial for 10 seconds. Plunger rod of syringe is then released and fluid is aspirated into syringe. After the syringe has stopped filling, fluid is measured using scale on the syringe. If vial integrity is compromised the equalization of pressure in the vial would not displace the same volume of fluid aspirated, as the volume of air injected. This test is designed to determine if the cannula OD or other design features of the B-D® Blunt Plastic Cannula has an effect on the sealing ability of the Abbott LifeShield® Single dose vial stopper for full dose drawing as compared to the predicate device.

Conclusions:
Vial integrity is maintained through pressurization of vial with full injection of air into vial (10cc air = 10 ml fluid (+ /- 10%)). B-D® Blunt Plastic Cannula can be used for vial penetration and aspiration of fluid from vial without leakage.

6.2.3 Vial particulate matter generation testing.

Test Description:
Cannula were attached to a syringes. Syringe was drawn with 10cc of air. Air was injected into a vial and fluid allowed to be drawn from the vial. Vial was then inverted and the cannula distal tip was at a position close the bottom of vial, to allow for maximum draw of fluid. Fluid was then expelled onto a filter. Filters were then examined for visible particulate matter.

Conclusion: No particulates of vial stopper material were observed on filters for either device.