

K96098

THIS SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION IS BEING SUBMITTED IN ACCORDANCE WITH THE REQUIREMENTS OF SMDA 1990.

510(k) Summary of Safety & Effectiveness  
Monoject™ Blunt I.V. Access Cannula

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The Monoject™ Blunt I.V. Access Cannula is a Class II device per 21 CFR 880.5860, General Hospital Devices Panel 80, Procode FMF.

The Monoject™ Blunt I.V. Access Cannula is a sterile, lubricated plastic cannula with a female luer hub. It is used to provide access to pre-pierced IV line injection sites and pre-pierced medication vials.

The Monoject™ Blunt I.V. Access Cannula will be available in the following configurations: Individual Blunt Cannula; Blunt I.V. Access Cannula attached to piston syringe of 3 ml, 6ml and 12 ml sizes.

The Monoject™ Blunt I.V. Access Cannula is substantially equivalent in its intended use and function to the following currently marketed devices: B-D Interlink Syringe Cannula, Monoject Lifeshield Blunt Cannula, Monoject Lifeshield Blood Collection Device.

The Monoject™ Blunt I.V. Access Cannula and SE devices have undergone the following comparative testing:  
Insertion Force Test  
Bend Test  
Break Resistance and Resilience Test

In addition, the following testing will be performed to confirm that no issues of biological safety or effectiveness are raised.

Cytotoxicity  
Intracutaneous Irritation  
Acute Systemic Toxicity  
Sensitization  
Hemolysis  
Subchronic Toxicity  
Drug Compatibility Testing.

The results of this testing will indicate that the Monoject™ Pointless Blunt I.V. Access Cannula perform equivalently to or better than the B-D Interlink Cannula product. No new issues relating to safety or efficacy were raised.

The Monoject™ Blunt I.V. Access Cannula will be manufactured per specifications and good manufacturing practices that ensure the device is safe and effective for its intended use.