



K961328

510(k) Summary

MAY 30 1996

Headquarters/
Laboratory

705 front street

toledo, ohio 43605

phone: (419) 693-5307

fax: (419) 691-0418

**Re: Trade Name: BEC Shrouded Plastic Cannula
Common Name: Shrouded Plastic Cannula
Classification Name: Needle, Aspiration & Injection, Disposable
79 GAA**

Environmental
Laboratory

1632 enterprise parkway

twinsburg, ohio 44087

phone: (216) 425-8200

fax: (216) 425-1349

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92 and DSMA 1995.

Sales Office

129 dixie way south

south bend, indiana 46637

phone: (219) 272-2200

The BEC Shrouded Plastic Cannula consists of a shrouded blunt tubular cannula at one end and a female luer attachment at the other. This luer attachment is designed to connect to a male luer lock or luer slip connector of a tubing set, syringe, or other intravascular administration device. The cannula end of the body is designed to penetrate a pre-slit, natural rubber septum and latch with the BEC, MED-NET or IMED Needleless Injection Site or Y-site.

Sales Office

77 west elmwood drive

suite 123

dayton, ohio 45459

phone: (513) 438-1711

The Shrouded Plastic Cannula is intended to provide additional protection against inadvertent "needlestick" injuries to health care providers during the administration of fluids and medications. The Shrouded Plastic Cannula provides the ability to penetrate a split septum injection site or Y-site for entry into a intravascular system without the need of a sharp needle.

Medical Products Division

615 front street

toledo, ohio 43605

phone: (419) 693-5307

fax: (419) 691-1227

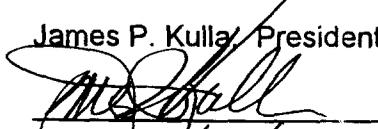
This Shrouded Plastic Cannula is identical to Medical Network Associates, Incorporated's Shrouded Plastic Cannula reviewed by FDA in 510(k) #K952834 which was identical to and found to be substantially equivalent to IMED Corporations Shrouded Plastic Cannula submitted under 510(k) #K945070. These cannulas are made of the same material by the same foreign manufacturer. Technological data and performance data were submitted for the IMED predicate device.

510(k) Summary (Continued)

Packaging of the device is either performed in-house or under contract by a registered device establishment. Sterilization is performed in-house using a validated ethylene oxide process. Both packaging and sterilization procedures are consistent with those generally used by the medical device industry.

Contact Person:

James P. Kulla, President



4/22/96

Date Prepared