



K961327

MAY 15 1996

510(k) Summary

Headquarters/
Laboratory
705 front street
toledo, ohio 43605
phone: (419) 693-5307
fax: (419) 691-0418

Re: Trade Name: BEC Needleless Injection Site
Common Name: Needleless Injection Site
Classification Name: Set, Administration, Intravascular 80 FPA

Environmental
Laboratory
1732 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 Needleless Injection Site consists of a tubular body with a male luer lock attachment at one end. This attachment is designed to connect to a female luer lock or luer slip connector of a catheter or other intravascular administration device. The other end of the tubular body is provided with an enlarged section adapted to receive a cylindrical retaining ring which surrounds and compresses a pre-slit, natural rubber septum. The septum retaining ring and enlarged section of the tubular body are adapted to receive and latch with the BEC, MED-NET, or IMED shrouded plastic cannula. The pre-slit septum re-seals upon removal of the cannula.

Sales Office
57 west elmwood drive
suite 123
dayton, ohio 45459
phone: (513) 438-1711

The Needleless Injection Site is intended to provide additional protection against inadvertent "needlestick" injuries to health care providers during the administration of fluids and medications. The Needleless Injection Site provides for the entry to an intravascular administration set or catheter without the need of a sharp needle by allowing for the use of a blunt cannula.

Medical Products Division
615 front street
toledo ohio 43605
phone: (419) 693-5309

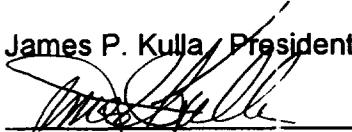
This needleless injection site is identical to Medical Network Associates, Incorporated's Needleless Injection Site reviewed by FDA in 510(k) # K953343 which was identical to and found to be substantially equivalent to IMED Corporations Needleless Injection Site submitted under 510(k) #K944320. These injection sites 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



4/3/96

Date Prepared