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510(k) Summary

Re: Trade Name: Safe Mate I.V. Fluid Delivery Sets
Common Name: I.V. Fluid Delivery Sets
Classification Name: Set, I.V. Fluid Transfer 80 LHI

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.

The B.E.C. Safe Mate I.V. Fluid Delivery Sets consist of a PVC tubing set which has a male luer (slip, fixed luer-lock, or rotating luer-lock) connector or an attached schrouded plastic cannula at one end intended to connect to an I.V. catheter, needle or a split septum injection site extension set affixed to an I.V. catheter. Fluid delivery set lengths may vary from 60" up to 120" or longer. Fluid Delivery Sets may also have one or more split septum Y-sites for the infusion of other liquid medications. Clamps (slide, clip, or roller) may also be included.

The risk to health care providers of "needlestick" injuries has become a major public health and worker safety concern. These I.V. Fluid Delivery Sets are intended to provide additional protection against inadvertent "needlestick" injuries to health care providers during the intravascular administration of fluids and medications. The I.V. Fluid Delivery Sets provide for the entry into an intravascular administration system without the need of a sharp needle by allowing for the penetration of a split septum injection sites or split septum Y-sites using an 11 gauge blunt plastic cannula.

These I.V. Fluid Delivery Sets utilize materials and components identical to Medical Network Associates, Incorporated's I.V. Fluid Delivery Sets reviewed by FDA in 510(k) #K955821. These sets use needleless split septum components identical to and found to be substantially equivalent to IMED Corporations Needleless Devices submitted under 510(k) #'s K945070, K944320, and K931173. The needleless components are made of the same material by the same foreign manufacturer.

Technological data and performance data were submitted for the IMED predicate devices. Tubing and standard set components are of medical grade and meet USP Class VI and/or Tripartite guideline biocompatability requirements.

Packaging of these 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

7/17/96

Date Prepared