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510(k) Summary

Re: Trade Name: Safe Mate I.V. Extension Sets
Common Name: I.V. Extension 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. Extension Sets consist of a PVC tubing set which has a male luer (slip, fixed luer-lock, or rotating luer-lock) connector at one end intended to connect to an I.V. catheter or needle. At the distal end (or ends in the case of the bifurcated extension set or T-Connector extension set) is a female luer and/or split septum Needleless Injection Site for connection to an I.V. administration set. Extension set lengths may vary from 4" up to 36" or longer. The PVC tubing may be of standard bore (approximately 0.115" I.D.) or Minibore (approximately 0.040" I.D.) design and may be configured into a J-loop to facilitate tape fixation. Extension 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. Extension 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. Extension Sets provide for the entry to an intravascular administration set 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. Extension Sets utilize materials and components identical to Medical Network Associates, Incorporated's I.V. Extension 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