

K961155

JUN 18 1996



# Douglas Medical Products

A SoloPak® Company

March 19, 1996

To Whom it may concern:

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act and CFR 807.92:

Trade Name - SoloPak Peripheral Intravenous Catheter Insertion Tray

Common Name - PICC Placement Tray, PICC Procedural Tray

Classification Name - Percutaneous Intravascular Catheter Accessory

The SoloPak Peripheral Intravenous Catheter Insertion Kits are intended to be used for the placement of a peripheral catheter. The SoloPak Peripheral Intravenous Catheter Insertion Kits include a single lumen catheter, introducer, and the necessary accessories to perform the placement.

The components, processes and materials used to manufacture the SoloPak Peripheral Intravenous Catheter Insertion Kits are the same or the equivalent of the predicate devices named in this submission. The named predicate devices in this submission were the Clinicath™ Procedural Tray (K932211) marketed by SIMS Deltec, Inc. and the Per-Q-Cath Tray (K83145) marketed by Gesco Intl., Inc. The SoloPak Peripheral Intravenous Catheter Insertion Kits are sterilized per AAMI guidelines to a 10<sup>-6</sup> sterility assurance level.

Based on the fact that the SoloPak Peripheral Intravenous Catheter Insertion Kits utilize similar and equivalent designs, materials, and components as currently legally marketed products, these products are safe and effective when used as intended.

Sincerely,

Ron Haselhorst  
Director of RAIQA  
Douglas Medical Products