



Douglas Medical Products

A SoloPak® Company

K954428

September 16, 1995

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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 - SoloPICC and SoloMidline Peripheral Intravenous Catheter

Common Name - PICC, Peripherally Inserted Central Catheter, Flexible Intravenous Catheter

Classification Name - Percutaneous Intravascular Catheter

The SoloPICC and SoloMidline Peripheral Intravenous catheters are intended to be used for the administration of medications, fluids and nutritional therapy of thirty days or less duration.

The SoloPICC and SoloMidline catheters are sterile, non-pyrogenic, single lumen radiopaque catheters with a PVC female Luer lock adapter. A stiffening stylet is inserted into the female adapter and runs the length of the catheter. The catheter is shrouded in a polyethylene protector and packaged in a printed tyvek\mylar peel pouch. A TFX T-Peel™ peelable introducer catheter is included in the tyvek\mylar package for catheter insertion purposes.

The processes and materials used to manufacture the SoloPICC and SoloMidline catheters are the same or the equivalent of the predicate devices named in this submission. The named predicate devices in this submission were the Luther Medical Products, Inc. L-Cath® Intravenous Placement Unit (K801575) and the Medical Profiles, Inc. Peripheral Intravenous Catheter (K914378). The SoloPICC and SoloMidline catheters are sterilized per AAMI guidelines to a 10⁻⁶ sterility assurance level. Each production lot is LAL tested per USP guidelines.

Based on the fact that the SoloPICC and SoloMidline catheters 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