



Douglas Medical Products
A SoloPak® Company

K962663

June 10, 1996

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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 - SoloPak® Sidekick Infusion Pump and Administration Set
Common Name - Ambulatory Infusor/Infusion Pump and Infusion Set
Classification Name - Infusion Pump with Administration Set

The SoloPak® Sidekick Infusion Pump and Administration Set is intended to be used for the general use infusion of small volumes (50 - 100 ml) . The infusion pump is reusable, however the administration set is intended for single use. The infusion sets have been tested and have been found to accurately deliver medication within $\pm 15\%$.

The SoloPak® Sidekick Infusion Pump is individually packaged and can be cleaned and reused for multiple infusions. The Administration Set is sterile, non-pyrogenic, and packaged in a tyvek/polyethylene pouch. It is a single use set. The materials used to manufacture the SoloPak Sidekick Infusion Pump and Administration Set are the same as those used in currently legally marketed products with the same intended uses. The indicated use of the SoloPak® Sidekick Infusion Pump and Administration Set are the same as the predicate device named in this submission. The named predicate device in this submission is the I-Flow VIVUS 50 and VIVUS 100 marketed under 510(k) #K915646. The SoloPak® Sidekick Administration Set is 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 SoloPak® Sidekick Infusion Pump and Administration Set utilize the same design, materials, and manufacturing processes as the named predicate device, they are safe and effective when used as intended.

Sincerely,

Ron Haselhorst
Director of RA/QA
Douglas Medical Products Corporation
A SoloPak® Company