



March 19, 1997

Summary of Safety and Effectiveness

SoloPak[®] Medical Products

K970800

APR - 3 1997

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 - Maxcess[™] NeedleFree Y-Site
Common Name - Y-Injection Site
Classification Name - Intravascular Administration Set (accessory)

The Douglas Medical Products Maxcess[™] NeedleFree Y-Site is intended for single patient use and intended for placement between the male Luer connection of a primary solution source and the patient's vascular access device. In this position, the y-site body provides unobstructed flow between the fluid source and the patient. The needlefree side port of the y-site can be swabbed and then accessed multiple times within the limits of CDC guidelines and/or institutional guidelines. The closure system has been tested and has been found to maintain line patency throughout the labeled duration of use.

The Douglas Medical Products Maxcess[™] NeedleFree Y-Site is a sterile, non-pyrogenic component packaged in a tyvek/polyethylene form, fill, and seal package. The materials used to manufacture the Douglas Medical Products Maxcess[™] NeedleFree Y-Site have been tested per tripartite guidelines and is safe for its intended use. The indicated use of the Maxcess[™] NeedleFree Y-Site is the same or equivalent to the predicate device named in this submission. The named predicate device in this submission is the Maxcess[™] NeedleFree Connector currently marketed by Douglas Medical Products under 510(k) #K960661. The Douglas Medical Products Maxcess[™] NeedleFree Y-Site 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 Douglas Medical Products Maxcess[™] NeedleFree Y-Site utilizes similar and equivalent designs, and materials, as current legally marketed products, it is safe and effective when used as intended.

Sincerely,

Elizabeth Loya, RN
Regulatory Affairs Associate
Douglas Medical Products