

K960661



Douglas Medical Products

A SoloPak® Company

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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 - Maxcess Needlefree Connector
Common Name - Needleless Injection Port or Needlefree Injection Site
Classification Name - Intravascular Administration Set

The Douglas Medical Products Maxcess Needlefree Connector is intended to be used as a needleless injection port that can be attached to a Luer Lock connector. It is intended for single patient use and 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 Connector is a one piece design, Luer interfacing injection port. It is sterile, non-pyrogenic and packaged in a tyvek/polyethylene form, fill, and seal package. The materials used to manufacture the Douglas Medical Products Maxcess Needlefree Connector have been tested per tripartite guidelines and are safe for their intended use. The indicated use of the Maxcess Needlefree Connector is the same or the equivalent of the predicate device named in this submission. The named predicate device in this submission is the Clave™ Connector currently marketed by ICU Medical, Inc. under 510(k) #K915571. The Douglas Medical Products Maxcess Needlefree Connector 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 Connector utilizes similar and equivalent designs, and materials, as currently legally marketed products, it is safe and effective when used as intended.

Sincerely,

Ron Haselhorst
Director of RA/QA
Douglas Medical Products