

K964456

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Part II. Polyfin QR® with Wings Infusion Set 510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92:

A. Submitter: MiniMed® Inc. 12744 San Fernando Road, Sylmar, California 91342. Contact: Don Selvey, Regulatory Affairs (818) 362-5958, Ext. 3011. FAX: (818) 362-6928; (520) 527-0107 (V/F).

B. Name of the device: Polyfin QR® with Wings infusion set, Models 365, 366, and 367.

C. Predicate device: Polyfin QR infusion sets, Models 165, 166, and 167 (K961474).

D. Description of new device: This infusion set is intended for the subcutaneous administration of medicine, including insulin, from a portable, external pump to a suitable infusion site. The infusion set is designed to be used in conjunction with a MiniMed infusion pump, but may be used in other pumps capable of supporting a Luer connection to a reservoir; however, care must be exercised by the prescriber and user to ensure delivery accuracy if used with other devices.

Device materials have been successfully tested for biocompatibility. All components having contact with solutions being administered meet the ISO 10993 standard for medical devices of this type.

E. Intended use of the new device: The Polyfin QR with Wings infusion set is intended for use as an infusion administration set for delivery of appropriately labeled fluids or solutions from an external infusion pump or syringe.

F. Comparison of the technological features of the new device and predicate device: The new device introduces no new technological features, compared to the predicate device. The only substantial difference in the devices is the addition of wings to make insertion easier by the user and to add stability to the needle in place. This modifications raises no new issues of safety or effectiveness.

Signed,



Terrance H. Gregg,
President and Chief Operating Officer
MiniMed Inc.

20 Jan 97

Date

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