K961474

MAY -6 1996

Part H. Polyfin® 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 and Clinical Research (818) 362-5958, Ext. 3011. FAX: (818) 362-6928; (520) 527-0107 (V/F).

B. Name of the device: Polyfin® infusion set, Models MMT-106, MMT-107, and MMT-133.

C. Predicate device: Pacesetter infusion set, model 124 and 142 (K838445A); Sof-set® Infusion Set, Models MMT-111 and MMT-112 (K861436).

D. Description of new device: This infusion set is intended for the administration of medicine, including insulin, from a portable, external pump to a subcutaneous infusion site, for up to 48 hours. 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 intended use of the new device is subcutaneous infusion of medicine, including insulin, from an external pump, for up to 48 hours.

F. Comparison of the technological features of the new device and predicate device: This device was initially introduced by Pacesetter as a subcutaneous infusion set, models 124 and 142. Several individually non-significant modifications have been made to this device since its initial introduction to the marketplace.

Signed,

Terrance H. Gregg, Executive Vice President
Operations

4/16/96
Date