K960001

MINIMED TECHNOLOGIES

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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 Technologies, 12744 San Fernando Road, Sylmar, California 91342. Contact: Terrance H. Gregg (818) 362-5958, ext. 2569. FAX: (818) 362-6928.

B. Name of Device: MiniMed MMT-507 (Insulin Infusion Pump).

C. Predicate Device: MiniMed MMT-506 (cleared: 510(k) K901588).

D. Description of the Device: The MMT-507 external insulin pump is a rate-programmable syringe infusion pump, designed for continuous delivery of insulin, at set and variable rates, as prescribed by the user's physician. The MMT-507 is restricted to sale by or on the order of a physician. It is not intended or indicated for the delivery of blood or blood products.

The MMT-507 consists of an external case, a microprocessor, a Liquid Crystal Display (LCD), a syringe compartment with a lead screw connecting to a motor. None of these components contact the fluid pathway.

E. Intended Use of the New Device: The MMT-507 is intended for continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

F. Comparison of the Technological Features of the New Device and Predicate Device: The principal differences between the new device and the predicate device include a back-light for the LCD display, software changes to allow link to a personal computer for in-house evaluations, a user self-test, the addition of audible tones, an increase in memory capacity relative to bolus programming and bolus recalls, the display of the 24 hour basal rate profile following programming, an increase in the temporary basal rate duration, and a time-delay feature for bolus delivery. These modifications do not negatively affect the safety or effectiveness of the device.

Signed,

Terrance H. Gregg
Vice President
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12/29/95
Date

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