MiniMed™

APR - 8 1997

K963948

Part I. 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, CA 91342
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B. Name of Device: MiniMed Insulin Pump, model 505.

C. Predicate Device: MiniMed Insulin Pump, model 506 (cleared: 510(k) K901588).

D. Description of Device: The 505 insulin pump is a rate-programmable syringe infusion pump, designed for continuous delivery of insulin, as prescribed by the user's physician. The 505 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 505 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 505 insulin pump is intended for continuous delivery of insulin for the management of diabetes mellitus in persons requiring exogenous insulin. It is not intended or indicated for the delivery of blood or blood products

F. Comparison of the Technological Features of the New Device and Predicate Device: The 505 insulin pump is identical to the 506 insulin pump in nearly every way, except that the software has been simplified, i.e., the new device has a single rate profile, instead of the six rates programmable with the predicate device, and the memory retains fewer values. Both devices use the same case and drive mechanism, same microprocessor, same reservoir and infusion sets, and are programmed the same way by the user. The indications, contraindications, warnings, precautions, and adverse reaction statements in the User's Guide are not substantially different if at all. The intended use of the devices is nearly the same.

The modification described does not negatively affect the safety or effectiveness of the device.

Signed,

23 Sep 96

Terrance H. Gregg
Executive Vice President, Operations
MiniMed, Inc.

Date