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Part I. 510(k) Summary

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Name of Device: MiniMed Sof-serter™ infusion set insertion system.

Predicate Device: AutoJect® 2 injection device (K945660).

Description of the New Device: The MiniMed Sof-serter infusion set insertion system is a manually operated, spring-loaded injection device. It is similar to most syringe needle introducer devices currently marketed; however, this device is used to insert two specific subcutaneous infusion administration sets, the Sof-set® and Sof-set QR® infusion sets manufactured by MiniMed Inc. The device is contraindicated for use with other infusion sets.

Intended Use of the New Device: The MiniMed Sof-serter infusion set insertion system is intended to help make insertion of a Sof-set or Sof-set QR infusion set simpler and with minimal discomfort. Use of the device may improve the user's consistency of infusion set insertion.

Comparison of the Technological Features of the New Device and Predicate Device: Technologically, both devices are spring-driven devices that require the user to load the infusion set or syringe into a carrier, compress a spring or springs, then activate the device by depressing a release button. Both devices are made of plastic, with metal springs. The differences between the new device and the predicate device involve primarily the type of hypodermic needle introduced by the device. The Sof-serter introduces a subcutaneous infusion set needle and cannula, while the AutoJect 2 introduces a needle attached to an insulin syringe, and simultaneously delivers the insulin. These modifications do not affect the safety or effectiveness of the device.

Signed,

Don Selvey 2-5-97

Don Selvey date
Regulatory Affairs
MiniMed Inc.