K962956

Oct. 7, 1996

H. 510(k) Summary

1. Summary of Basis for Substantial Equivalence

a. Submitter

Name:	Medi-Ject Corporation
Address	1840 Berkshire Lane Minneapolis, MN 55441
Telephone Number:	(612) 553-1102
Contact Person:	Peter L. Sadowski, Ph. D.
Date of Summary Preparation:	29 July 1996

b. Device Name

Trade or Proprietary Name:	Medi-Ject Corporation Medi-Jector Choice Needle-Free Insulin Delivery System
Common or Usual Name:	Fluid Injector
Classification Name:	Non-electrically powered fluid injector

c. Identification of Legally Marketed Devices to Which Equivalence is Claimed

1) Medi-Ject Corporation Medi-Jector IV, the subject of 510(k) K864561
2) Medi-Jector V, the subject of 510(k) K883847
3) Medi-Ject Corporation Medi-Jector Needle-Free Bio-Tropin™ Drug Delivery System, the subject of 510(k) K960285

d. Device Description

The Medi-Jector Choice Needle-Free Insulin Delivery System consists of a spring powered windable power pack injector assembly, a detachable sterile reusable needle-free syringe and a sterile adapter for connecting the needle-free syringe to a drug the vial. Spring energy is provided by winding the power pack to compress the spring. The power pack also contains a dial mechanism that defines the dosage to be injected. The needle-free syringe consists of a chamber or barrel and a plunger. Both the chamber and the plunger connect to the power pack. One end of the syringe barrel or chamber reduces to a micro-orifice and comes in contact with the injection site; the other end of the syringe connects to the power pack. The adapter consists of a plastic body and seal and connects the needle-free syringe on the power pack to the drug vial. An elastomeric seal in the adapter is compressed against the syringe tip aligning at the micro-orifice to make connection; the connection with the drug vial is by means of plastic spike capable of puncturing the vial septum. Additionally, the adapter end connection with the drug vial has locking tabs to stabilize the vial and to promote the discarding of the adapter with the vial (which is the intended usage).

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Using the dosage dialing mechanism in the power pack results in the movement of the plunger away from the tip of the syringe which results in the aspiration of a measured amount of drug into the syringe barrel. The connection of the plunger with power pack is through an adjustable lost motion connection. The adjustment of this gap results in a power adjustment so that patients can adjust the depth of penetration.

Upon filling the needle-free syringe with the appropriate amount of medication, the safety switch is deactivated and by pressing the injection release button, the force of the compressed spring is exerted on the plunger. Initially the ram which is connected to the plunger is driven forward very rapidly over the gap created by the lost motion connection. This acceleration causes a very high pressure in the syringe chamber which is far greater than what would be expected from the force of the compressed spring. The initial pressure spike quickly disipates to pressures consistent with the spring force. The initial pressure is adjustable by the user by reducing the size of the gap in the lost motion connection. The pressures created in the chamber results in the ejection of fluid through the micro-orifice at velocities sufficient to give an injection. The larger micro-orifice chosen for use in the Medi-Jector Choice Needle-Free Insulin Delivery System allows deeper penetration since the mico-column of liquid ejected from the syringe has a greater mass; the smaller micro-orifice is suitable for subjects with less subcutaneous tissue, typically younger subjects.

The Medi-Jector Choice Needle-Free Insulin Delivery System power pack is cylindrical in shape and contains a spring with a spring force of 105 lbs at maximum compression within the device. A triggering button is found at one end of the power pack, and the needle-free syringe attaches to the other. The needle-free syringe is provided sterile and is intended to be used for fourteen injections and then discarded. The adapter is provided sterile and is intended for use with one vial of insulin; to promote the discarding of the vial with the used insulin vial, locking tabs on the adapter engage the vial cap to stabilize the connection and to make removal difficult. Adapters can only be obtained with needle-free syringes, and this is being done to promote compliance with the 14 injection reuse directions for the syringe. Syringes with 0.0055 and 0.0065 inch orifices are available to provide different penetration depths. In general, the 0.0055" syringes are for younger patients and are labeled "pediatric"; the needle-free syringes with 0.0065" orifices are labeled "adult".

e. The Medi-Jector Choice Needle-Fee Insulin Delivery System is intended for the subcutaneous injection of U-100 insulin. This is the same intended use as the Medi-Jector IV and the Medi-Jector V.

f. The Medi-Jector Choice Needle-Fee Insulin Delivery System utilizes a needle-free syringe which is reusable to a maximum of fourteen (14) injections. This is a major technological difference from the three predicate devices cited in this notification. The Medi-Jector Choice needle-free syringe is manufactured from polycarbonate, is supplied to the user sterile, and should be discarded after 14 injections. In contrast, the equivalent assembly on the three predicate devices, the head assembly, is manufactured of stainless steel, requires cleaning and

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disinfection upon receipt by the user, and is usable for two weeks after which another cleaning and disinfection is required. One change that discarding the needle-free syringe has caused to the device specifications is that the volume delivery specification has been changed to match the ISO insulin standard for delivered volume. This was necessitated since different syringes would be used over the course of the life of the power pack. This is in contrast to the steel head assemblies which where sold with the device and allowed power pack/head assembly calibration as a single unit.

The Medi-Jector Choice Needle-Fee Insulin Delivery System is technologically similar to all three predicate devices. All have windable, spring powered, power packs which are cylindrical in shape. The dosage mechanisms and lost motion connection are accomplished with similar mechanisms. The power pack energy is controlled by a safety and is released by a rear trigger button. The spring force employed in the Medi-Jector Choice Needle-Fee Insulin Delivery System is identical to that employed in the Medi-Jector IV. The subject device uses one power pack with two different needle-free syringes to provide different penetration options which is the same approach taken in the Medi-Ject Corporation Medi-Jector Needle-Free Bio-Tropin™ Drug Delivery System

2. Performance testing supporting the determination of substantial equivalence

a. Discussion of the nonclinical tests submitted

A variety of testing to confirm substantial equivalence to the cited predicate devices has been performed with a focus on the principle change to the subject device, the plastic needle-free syringe. The two considerations were to show that this changed did not effect penetration and that indicated dosages were delivered within the ISO insulin syringe standards. The mechanical similarities between the power packs, head assemblies (needle-free syringes) and the adapters for all the predicate devices and the Medi-Jector Choice Needle-Fee Insulin Delivery System focused the attention of the testing on the significance of the material change in the needle-free syringe (head assembly).

Dosage delivery testing with saline was done over the course of thirty (30) injections, more than a 100% of the indicated usage. The dosages delivered at both a low (10 units) and high (50 units) volume was well within the ISO standards and was therefore deemed to be safe. Additionally, dosage delivery was tested over the course of 14 days, with two ejections per day, using the three commonly used types of insulin (R, NPH and Ultralente). The dosages delivered at 100% over the indicated usage were found to be safely within the ISO standards for all types of insulin.

Penetration testing was done to show that the stream resulting from a pressurization of a plastic chamber would be similar to that produced in a stainless steel head assembly. Testing was done using the Medi-Jector Needle-Free Bio-Tropin™ Drug Delivery System as the comparison device since it relies on one power pack and two different head assemblies to produce "adult" and "pediatric" subcutaneous injections.

The penetration of saline streams produced by the Medi-Jector Choice Needle-Free Insulin Delivery Systerm into an artificial test matrix (Whatman #3 filter paper) was comparable to that seen with cited predicate device.

b. Conclusions that the subject device is as safe, effective and performs as well as or better than the legally marketed predicate devices.

Based on dosage delivery data and penetration data, plus the similarity in mechanicals and design lead us to conclude that the Medi-Jector Choice Needle-Free Insulin Delivery System is substantially equivalent in safety and efficacy to the cited predicate devices.

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