510(K) SUMMARY

JAN 25 2010

Solo™ MicroPump Insulin Delivery System

510(k) Number K093364

Applicant's Name:

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Contact Person:

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Trade Name:

Solo™ MicroPump Insulin Delivery System

Classification Name:

Insulin infusion pump

Classification:

FDA has classified insulin infusion pumps as class II devices (product code LZG) and they are reviewed by the General Hospital panel.

Predicate Devices:

- Medingo Solo™ Insulin Patch Pump, insulin infusion pump, product code LZG, cleared for marketing under K090245 ("Solo™")
- iXL Diabetes Management System (Insulet Corp.), product code LZG, cleared for marketing under K031373, K042792

Intended Use:

The Solo™ MicroPump Insulin Delivery System is intended for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Device Description:

The Solo™ MicroPump Insulin Delivery System (Solo™) is a miniature, portable programmable insulin pump, which adheres to the patient's skin. The MicroPump is comprised of two connected parts: a disposable reservoir, in which the insulin is stored and a reusable pump, which includes the pumping mechanism and electronic components. The MicroPump is controlled via a remote control unit.

The Solo™ is designed to deliver basal and bolus insulin doses at various rates, volumes and patterns, as prescribed by the user's physician, and includes the features available in the predicate devices.

Technological Characteristics:

The Solo™ MicroPump Insulin Delivery System is identical to the predicate Solo™ approved under K090245 except for some minor modifications, none of which individually, or in aggregate, require the submission of a new 510(k).

Performance Testing:

Two simulated clinical use studies were conducted to support the current 510(k) submission:

1. Operation of the Solo™ MicroPump Insulin Delivery System by Non-Adults– A Summative Usability Study.
2. Simulated Clinical Use of the Solo™ MicroPump Sharps Injury Prevention Features.

These studies, with the non-adult user population, were designed and executed according to FDA guidance and international standards (HE74-2001 and IEC 60601-1-6), as presented in Section 20 of the 510(k) packet. Study results clearly demonstrated that Solo™ is safe for use by non-adults and their caregivers.

Conclusion:

The Solo™ MicroPump Insulin Delivery System presented in this 510(k) submission is the same as the predicate cleared Solo™, except for the deletion of the contraindication for use by persons under the age of 18.

By deleting the age contraindication, the Solo™ MicroPump Insulin Delivery System is substantially equivalent to the predicate iXL Diabetes Management System. Based on the information provided in this submission, Medingo believes that Solo™ is substantially equivalent to its predicate devices without raising any new safety or effectiveness issues.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Arava Hacohen
Vice President Quality and Regulatory Affairs
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Yoqneam 20692
ISRAEL

JAN 25 2010

Re: K093364
Trade/Device Name: Solo™ MicroPump Insulin Delivery System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: October 21, 2009
Received: October 28, 2009

Dear Ms. Hacohen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K093364

Device Name:

Solo™ MicroPump Insulin Delivery System

Indications for Use:

The Solo™ MicroPump Insulin Delivery System is intended for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

The Solo™ Insulin Patch Pump is for prescription use only.

Prescription Use ____X____ OR Over the Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093364