510(k) Summary

SUBMITTER:

Animas Corporation
200 Lawrence Drive
West Chester, PA 19380

Contact: Amy Smith; Manager, Regulatory & Clinical Affairs

MAR 3 0 2007

DEVICE NAME: Animas ezManager Plus Diabetes Management Software

COMMON OR USUAL NAME: Insulin infusion pump accessory

DEVICE CLASSIFICATION: Class II per CFR 21 §880.5725, Infusion Pump, product code LZG

PREDICATE DEVICE: Animas ezManager Plus, K022394
Deltec, CoZmanager, K062323

DESCRIPTION:

The Animas ezManager Plus diabetes management system is software that is loaded onto a patient's or health care professional's personal computer to allow for downloading information from Animas insulin pumps and specified commercially available blood glucose meters. The system allows for users to view data stored in the pump and meter history such as basal deliveries, bolus deliveries and blood glucose measurements. The data can be displayed in numerous formats and configurations to facilitate trending and better diabetes management.

The Animas ezManager Plus diabetes management system also allows for Animas pump users to upload personal setting information to their pump. Personal setting information includes basal programs and rates, insulin to carbohydrate ratios, insulin sensitivity factors, target blood glucose ranges, and when available pump food database information (food, serving size and carbohydrate information). This feature allows users the convenience of programming and saving all of this information on their personal computers. Once the information is uploaded to the pump, the user is prompted to verify the active basal program before initiating therapy.

For Animas pumps the download and upload is completed using an IR dongle and the IR window on the back of the pump. For the specified meters, the download is accomplished by using the manufacturer specified connection cables.

INTENDED USE:

The Animas ezManager Plus diabetes management software is indicated for use as an accessory to Animas insulin pumps and specified commercially available blood glucose meters. The software supports diabetes management by the patient and/or health care professional by allowing for the review, analysis and evaluation of insulin delivery and blood glucose history information.

The Animas ezManager Plus will also allow download of information from Animas pumps and commercially available blood glucose meters to a hand-held electronic device for display of the information.

The Animas ezManager Plus is also indicated for the management of diabetes by calculating an insulin or carbohydrate dose based on health care professional prescribed settings and user entered data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Amy Smith
Manager, Regulatory & Clinical Affairs
Animas Corporation
200 Lawrence Drive
West Chester, Pennsylvania 19380

MAR 3 0 2007

Re: K063674
Trade/Device Name: ezManager Plus Diabetes Management Software
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: March 8, 2007
Received: March 9, 2007

Dear Ms. Smith:

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.

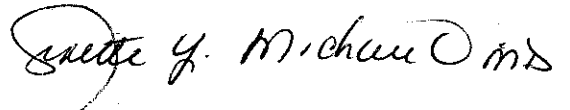
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _K063674_

Device Name: _ezManager Plus Diabetes Management Software

Indications for Use:

The Animas ezManager Plus diabetes management software is indicated for use as an accessory to Animas insulin pumps and specified commercially available blood glucose meters. The software supports diabetes management by the patient and/or health care professional by allowing for the review, analysis and evaluation of insulin delivery and blood glucose history information.

The Animas ezManager Plus will also allow download of information from Animas pumps and commercially available blood glucose meters to a hand-held electronic device for display of the information.

The Animas ezManager Plus is also indicated for the management of diabetes by calculating an insulin or carbohydrate dose based on health care professional prescribed settings and user entered data.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K063674