Animas®
CORPORATION
a Johnson & Johnson company

MAY 15 2008

510(k) Summary

Submitted by:	Animas Corporation 200 Lawrence Drive West Chester, PA 19380
Contact Person:	Jennifer Bosley, Regulatory Affairs Manager Ph: (610) 644-8990 Fax: (484) 885-2381
Date Prepared:	May 9, 2008
510(k) Number:	**K080587**
Device Trade Name:	Animas ezManager® MAX Diabetes Management Software
Common/Usual Name:	Insulin Infusion Pump Accessory
Proposed Classification:	Infusion Pump 21 CFR § 880.5725 Class II, 80 MRZ—General Hospital

Device Description:
The Animas ezManager MAX Diabetes Management Software, installed onto a patient's or healthcare professional's personal computer, allows downloading and uploading of information to and from Animas insulin pumps and specified commercially available blood glucose meters. The software displays downloaded historical data stored in the pump and blood glucose meter such as basal/bolus deliveries and blood glucose measurements. The data can be displayed in reports and logs to facilitate trending and diabetes management.

Indications for Use:
The Animas ezManager MAX 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 healthcare professional by allowing for the review, analysis and evaluation of insulin delivery and blood glucose history information.

Predicate Device:
K063674 – Animas ezManager® Plus Diabetes Management Software (Animas Corporation)

Substantial Equivalence:
The Animas ezManager MAX is substantially equivalent to the legally marketed predicate, Animas ezManager Plus. Both devices have the same intended use and fundamental scientific technology.

Non-Clinical Testing:
The Animas ezManager MAX met software verification and validation test parameters, and label comprehension study requirements to assure the device performs as intended. Results of all testing provide reasonable assurance of safety and effectiveness for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2008

Ms. Jennifer J. Bosley
Manager, Regulatory Affairs
Animas Corporation
200 Lawrence Drive
West Chester, Pensylvania 19380

Re: K080587
Trade/Device Name: ezManager® MAX Diabetes Management Software
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ
Dated: February 29, 2008
Received: March 3, 2008

Dear Ms. Bosley:

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 (301) 443-6597 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 Statement

510(k) Number (if known): _____

Device Name: ezManager® MAX Diabetes Management Software

Indications For Use:

The Animas ezManager® MAX 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 healthcare professional by allowing for the review, analysis and evaluation of insulin delivery and blood glucose history information.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K080587