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K02-2394

Section 5 510(k) Summary

Submitter: Animas Corporation, 590 E. Lancaster Avenue, Frazer, PA 19355

Contact: Michael J. Andrews, Ph.D., Director, Regulatory Affairs, Telephone: (610)-644 8990, extension 257, Fax: (610)-644-8717, Email: michaeland@animascorp.com

Name of Device: Animas ezManager Plus

Predicate Devices: Minimed Solutions Software, Model 7311, and Therasense FreeStyle Tracker Diabetes Management System

Description of the New Device: The Animas ezManager Plus diabetes management software is intended for a Microsoft Windows based personal computer or a Palm handheld organizer. The ezManager Plus allows the user to download, view, print, and save data from a number of commercially available glucose meters and the Animas IR1000 Insulin Infusion Pump. It also calculates an insulin or carbohydrate dosage based physician prescribed settings and data entered by the user. This software was developed using a Borland Delphi integrated development environment using an MS Access database structure and ActiveX Data Objects database connections. The synchronization dynamic library is totally compliant with the Palm Operating System (OS) Conduit requirement and was developed using Microsoft Visual C++ and the Palm OS Software Development Kit.

Intended Use of the New Device: The Animas ezManager Plus is intended to serve as an accessory to the Animas IR1000 insulin pump and a number of commercially available blood glucose meters to download data from these devices to a patient's or a physician's personal computer where it may be displayed, printed, and saved. It is also intended for use in the management of diabetes by calculating an insulin or carbohydrate dose based on physician prescribed settings and user data input.

Comparision of the Technological Features of the Modified Device and the Predicate Device: The Animas ezManager Plus and the predicate devices are very similar in their technological features. Both the ezManager and the Solutions Software facilitate the transmission of pump data to a computer. The ezManager Plus can calculate an insulin or carbohydrate dosage based on the user's input. The FreeStyle Tracker

uses data input by the user to calculate an insulin dosage necessary to correct an out of range blood glucose level.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Michael J. Andrews Ph.D.
Director, Regulatory Affairs
Animas Corporation
590 E. Lancaster Avenue
Frazer, Pennsylvania 19355

Re: K022394
Trade/Device Name: Animas ezManager Plus
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: March 19, 2003
Received: March 20, 2003

Dear Dr. Andrews:

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 (301) 594-4618. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 7 Indications for Use Statement

510(k) Number: _____

Device Name: Animas ezManager Plus

Indications for Use: The Animas ezManager Plus is indicated for use as an accessory to the Animas IR1000 insulin pump and a number of commercially available blood glucose meters to download data from these devices to a patient's or a physician's personal computer where it may be displayed, printed, and saved. The Animas ezManager Plus is also indicated for the management of diabetes by calculating an insulin or carbohydrate dose based on physician prescribed settings and user entered data.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K022394