K042873

DEC 1 0 2004

Section 6 510(k) Summary

Submitter: Animas Corporation, 200 Lawrence Drive, West Chester, PA 19380

Contact: Thomas L. Parker, Manager, Regulatory Affairs, Telephone: (484)-568-1257, Fax: (484)-568-1329, Email: thomasp@animascorp.com

Name of Device: Animas Model IR1250 Insulin Infusion Pump

Predicate Device: Animas Model IR1200 Insulin Infusion Pump

Description of the Modified Device: The Animas Model IR1250 Insulin Infusion Pump is an external syringe pump and delivery system that provides subcutaneous delivery of insulin for patients with diabetes mellitus who would benefit from a continuous insulin infusion process. The Model IR1250 is used with any insulin infusion set which incorporates a luer style connection.

The pump incorporates serial communications via an infrared (IR) interface with accessories which include the Animas IR to RS-232 serial interface adaptor (the "dongle"), the Animas IR1200 cradle to hold the pump and the Animas ezManager Plus software for the user's personal computer. As with the IR1200, this connection allows the user and/or the physician to transfer (download) data stored in the pump to the personal computer where it may be displayed, printed and saved. With the IR1250 this same connection will allow the user to program the pump, via the PC with ezManager Plus software, with selected user pump settings (basal program, bolus limits, etc.) and non-operational, personalized information including user selection of names for basal settings and musical tunes for initial alert/reminder warnings prior to the present pump alert/warning sounds. Also available to the user is the option to use a PC with ezManager Plus software, to upload and/or modify selected food items and related carbohydrate information, for storage in, and reference/use directly from, pump memory.

The pump is intended for multiple years of use. To hold the insulin for subcutaneous delivery, Animas provides sterile, single use, disposable insulin cartridges for use specifically with the IR1200 series pumps.

As with the IR1200, the IR1250 will deliver a prescribed dosage of insulin as a single programmable bolus or at multiple programmable basal rates. The system will also provide set up information, dosage history, alarms, error and warning messages, device status, and self test capabilities.

Intended Use of the Modified Device: The intended use of the Animas Model IR1250 Insulin Infusion Pump is the same as that of the Series IR1200 Insulin Infusion Pump, namely to provide subcutaneous delivery of insulin at programmable basal and bolus rates for the management of diabetes mellitus in insulin dependent patients.

Accessories to the Model IR1250 are the same as the IR1200 and include the Animas IR serial interface adaptor (the "dongle") and the Animas IR1200 Cradle to hold and align the pump while using with Animas ezManager Plus software on a personal computer. As with the IR1200, this connection allows the user and/or the physician to transfer (download) data stored in the pump to the personal computer where it may be displayed, printed, and saved. With the IR1250, this same connection will allow the user the option to program the pump, via a PC using the ezManager Plus software, with selected user pump settings (basal program, bolus limits, etc.) and non-operational, personalized information. Also available to the user, using the IR connection to the PC with ezManager Plus software, will be the ability to upload and/or modify selected food items and related carbohydrate information, for storage in, and reference/use directly from pump memory.

This device is intended for home use and is a prescription device.

Comparison of the Technological Features of the Modified Device and the Predicate Device: The modified device and the predicate device are identical in terms of design, materials, and construction. The only change made to the IR1200 is increased storage capability, in pump memory, and the minor software modifications which allow the IR1250 pump to receive program instructions from a PC, with ezManager Plus software, and accept into pump storage approximately 500 food items with associated carbohydrate information. This information can be referenced, at any time, on the pump screen, for evaluating insulin needs.

These minor differences between the modified device and the predicate device do not affect the safety or effectiveness of the device's performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2004

Mr. Thomas L. Parker
Manager, Regulatory Affairs
Animas Corporation
200 Lawrence Drive
West Chester, Pennsylvania 19380

Re: K042873
Trade/Device Name: Animas Model IR1250 Insulin Infusion Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: October 15, 2004
Received: October 18, 2004

Dear Mr. Parker:

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/dsma/dsmamain.html

Sincerely yours,

Susan Runner

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): K042873

Device Name: Animas Model IR1250 Insulin Infusion Pump

Indications For Use: The Animas Model IR1250 Insulin Infusion Pump is intended to provide subcutaneous delivery of insulin at programmable basal and bolus rates for the daily management of diabetes mellitus in insulin dependent patients.

Prescription Use ___X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 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

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