FEB 1 0 2000

K993184

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The Animas Corporation R1000 Series Insulin Pump is intended to provide subcutaneous delivery of insulin at programmable basal and bolus rates for the daily management of Type 1 and certain instances of Type 2 diabetes mellitus. The pump is indicated for use in diabetics who have good personnal hygiene, who have established control over their blood glucose and who do not have unpredictable or large variations in blood glucose levels.

Description statements were not relied on to show substantial equivalence to legally marketed devices; instead, performance data from device validation is used. The comparison of intended use and technological features of this device to other legally marketed devices taken together with validation results indicate that this device is substantially equivalent to legally marketed predicate devices with regards to safety, effectiveness and intended use.

The intended use of this device is the same as the intended use of other insulin pumps marketed to provide the same clinical benefit. Therefore, all aspect of this device have predicates which are well accepted in the clinical community. This product simply provides an alternative to those currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 0 2000

Ms. Monica Ferrante
Regulatory Affairs
Animas Corporation
590 Lancaster Avenue
Frazer, PA 19355

Re: K993184
Trade Name: R1000 Series Insulin Pump
Regulatory Class: II
Product Code: LZG
Dated: January 21, 2000
Received: January 21, 2000

Dear Ms. Ferrante:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section A – SMDA Requirements

INDICATIONS FOR USE

The Animas Corporation R1000 Series Insulin Pump is intended to provide subcutaneous delivery of insulin at programmable basal and bolus rates for the management of diabetes mellitus in insulin dependent patients.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)

Steven Naumann for PXC

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993184