K071613 p. 1 of 12

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DEC 1 4 2007

"510(k) Summary"

Amigo® Insulin Pump

Owner:	Nipro Diabetes Systems, Inc
Address:	3361 Enterprise Way Miramar, FL 33025
Phone:	(954)-435-5665
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Name of contact person:	Harry Russell
Date prepared:	November 5, 2007
Submission type:	Traditional 510(k)
Proprietary name:	Amigo® Insulin Pump
Common name(s):	Insulin pump
Classification name:	Pump, infusion, insulin
Device class:	II
Panel:	80 (General hospital and personal use devices)
Product code:	80LZG
Regulation:	21 CFR § 880.5725
Establishment registration:	Nipro Diabetes Systems, Inc. #1066380
Predicate device(s)	Animas IR1250 Insulin Infusion Pump K042873 Nipro Amigo® Insulin Pump K050312 Smiths Medical Deltec Cozmo® Insulin Pump K062323

DEVICE DESCRIPTION

The proposed Amigo® Insulin Pump is a small, lightweight, battery-operated programmable insulin infusion pump. The pump houses a replaceable single-use insulin syringe containing up to 300 units (3mL) of U-100 insulin.

Programming is accomplished via a keypad and LCD display. A microcomputer controls the rotation of a stepper-motor which is connected to a gear reduction assembly. The output of the reduction assembly turns a lead-screw which moves a linear piston. The piston mechanically engages the plunger of the insulin syringe, and the programmed amount of insulin is dispensed through an external seal and luer lock connector to an infusion set.

Various hardware and software systems monitor the pump's operation and provide a method of control and monitor function to keep the pump within safe parameters. A hierarchy of alarms based on IEC 60601-1-8 criteria and priorities notifies the user to possible error conditions. Notifications are via visual, audible, and vibration means through the use of the LCD backlight, the audio speaker, and a vibrator motor, respectively. If the alarm priority warrants, the system is put into a safe state with infusion stopped.

Power is provided by a user-replaceable primary battery (CR2), allowing for a minimum of 22 days of typical usage. An internal, rechargeable backup battery is used for primary battery end-of-life alarms and for operating redundancy.

Provision is made for an infrared communications port, which is accessible only to Nipro for manufacturing use.

INTENDED USE

The Amigo® Insulin Pump is intended for the subcutaneous infusion of insulin.

COMPARISON WITH THE PREDICATE DEVICE

The following table compares the Amigo® Insulin Pump with its predicate devices, the Animas IR1250 Insulin Infusion Pump, the Nipro Amigo® Insulin Pump, and the Smiths Medical Deltec Cozmo® Insulin Pump.

Areas of minor difference are shaded, with discussion on the difference(s) immediately to the right.

Characteristic	Animas IR1250 Insulin Infusion Pump (Predicate Device)	Amigo® Insulin Pump (Predicate Device)	Smiths Medical Deltec Cozmo Pump (Predicate Device)	New Amigo® Insulin Pump (This Submission)	Discussion
510(k) Number	K042873	K050312	K062323	N/A	
General					
Intended Use	Intended to provide subcutaneous delivery of insulin at programmable basal and bolus rates for the daily management of diabetes mellitus in insulin dependent patients	Intended for the subcutaneous infusion of insulin.	Designed for Continuous Subcutaneous Insulin Infusion (CSII) for the control of diabetes.	Intended for the subcutaneous infusion of insulin.	
Pump Type	Linear Piston	Linear Piston	Pushrod	Linear Piston	
Power transmission	Plastic gears	Stainless steel gears	Not available	Stainless steel gears	
Dimensions	2.9 x 2.0 x 0.76 inches	Less than 3.54 x 2.36 x 1.18 inches	3.2 x 1.8 x 0.95 inches	3.28 x 2.18 x 0.93 inches	
Weight	3.13 ounces	Less than 3.2 ounces	Approx. 3.2 ounces	3.1 ounces	

02-0005

K071613 p.3 of 3

Characteristic	Animas IR1250 Insulin Infusion Pump (Predicate Device)	Amigo® Insulin Pump (Predicate Device)	Smiths Medical Deltec Cozmo Pump (Predicate Device)	New Amigo® Insulin Pump (This Submission)	Discussion
Control Technology	Microprocessor	Microprocessor	Microprocessor	Microprocessor	
Insulin Reservoir)	2 mL (200 Units)	3 mL (300 Units)	(300 Units)	3 mL (300 Units)	
Insulin Type	Rapid-acting U-100 insulin or regular (short-acting) U-100 insulin	U100		Rapid-acting or short-acting U-100 insulin	
Power Source	One 1.5 Volt lithium battery	One 3 Volt lithium primary battery	One AAA alkaline battery	One 3 Volt lithium primary battery (replaceable); one lithium cell backup battery (internal)	The new Amigo pump has a backup battery for redundancy, and mitigation of end-of-primary-battery-life issues.
Programmable Basal Delivery	Yes	Yes	Yes	Yes	
Programmable Bolus Delivery	Yes	Yes	Yes	Yes	
User Notification	Audible, visual, and vibration	Audible, visual, and vibration	Audible and vibration	Audible, visual, and vibration	

Characteristic	Animas IR1250 Insulin Infusion Pump (Predicate Device)	Amigo® Insulin Pump (Predicate Device)	Smiths Medical Deltec Cozmo Pump (Predicate Device)	New Amigo® Insulin Pump (This Submission)	Discussion
Visual Display	LCD	LCD	LCD	LCD	
Insulin Syringe / reservoir	Animas disposable cartridge	GlucoPro syringe, single-use reservoir (K014114)	Deltec Cozmo 3 ml Insulin Cartridge (21-1750)	GlucoPro syringe, single-use reservoir (K014114)	
Infusion Set Connector	Standard luer lock	Standard luer lock	Standard luer lock	Standard luer lock	
Flow Rate Accuracy					
Bolus	+ / - 5%	+ / - 5%	+/- 15% at 0.1 U +/- 1.5% at 25 U	+ / - 5%	
Basal	+ / - 5% (0.1 U/hr or greater)	+ / - 5% (0.1 U/hr or greater)	+ / - 2% (nominal) except at low delivery rates	+ / - 5% (0.5 U/hr or greater)	The Animas maintains +/- 5% accuracy at slightly lower flow rates; (The Deltec unit nominal % does not compare to the absolute % of Animas and Amigo).
Basal					
Basal rate adjustment range	0.025 – 25U/hr in .025 U/hr steps	0.00 – 30.00U/hr in .05U/hr steps Normal, Temporary	0.00 – 35.00 U/hr in 0.05 U/hr steps Normal / Temporary	0.00 – 30.00U/hr in .05U/hr steps Normal, Temporary	
Basal Profiles	4	1 to 4	4	1 to 4	
Basal Rates	Up to 12 basal rates	48 available per profile in 15 minute increments	48 available per profile in 30 minute increments	48 available per profile in 15 minute increments	

Characteristic	Animas IR1250 Insulin Infusion Pump (Predicate Device)	Amigo® Insulin Pump (Predicate Device)	Smiths Medical Deltec Cozmo Pump (Predicate Device)	New Amigo® Insulin Pump (This Submission)	Discussion
Temporary Basal Mode	30 min – 24 hr Adjusted in 30 minute intervals; -90% to 200% in 10% increments	15 min – 24 hr Adjusted in 15 minute intervals; As a Percent (%) of active profile; 10 – 200% in 10% increments	30 min – 72 hr Adjusted in 30 minute intervals; As a Percent (%) of active profile; 0 – 250% in 5% increments	15 min – 24 hr Adjusted in 15 minute intervals; As a Rate in U/h or as a Percent (%) of active profile; 10 – 200% in 10% increments	Ranges are substantially equivalent. The new Amigo Insulin Pump also allows programming as a rate in U/hr
Basal Insulin Delivery Frequency	3 minutes	3 or 15 minutes	3 minutes (0.1 U/h or higher); significantly longer for rates less than 0.1 U/h)	3 or 15 minutes	
Bolus					
Bolus Adjustment Range	0.05U – 35 U in 0.05U steps	0.05 to 30.00U in 0.05U steps Normal, Extended and Layered	0.00 – 75.00 U in 0.05 to 5.00 U steps (steps are settable) Meal, Extended, and Combination	0.05 to 30.00U in 0.05U steps Normal, Extended and Layered	
Direct Bolus Increment	0.1 – 2.0U in 0.1 U steps 0.5 – 10.0U in 0.5 U steps 1.0 – 20.0U in 1.0 U steps 5.0 – 35.0U in 5.0 U steps	0.1 to 5.0U in 0.1 U steps	0.05, 0.10, 0.50, 1.00, 2.00, or 5.00 U.	0.1 to 5.0U in 0.1 U steps	
Bolus Estimator	Yes	Yes	Yes	Yes	

Characteristic	Animas IR1250 Insulin Infusion Pump (Predicate Device)	Amigo® Insulin Pump (Predicate Device)	Smiths Medical Deltec Cozmo Pump (Predicate Device)	New Amigo® Insulin Pump (This Submission)	Discussion
Delivery Rates - Bolus	0.2 U/sec to 2.2 U/sec	0.07 U/sec to 0.2 U/sec	0.01 U / sec to 2.5 U/sec	0.2 U/sec	The Amigo pump has a fixed bolus rate that matches an allowed rate within the ranges of all of the predicate devices.
Delivery Rates - Prime	1.8 – 2.9 U/sec	Not available	1.0 U / sec	1.0 U/sec	
Max. Volume infused under single fault conditions	Max 2.0U	Not available	Less than 2 units	Max 1.5 U	
Occlusion Detection Time to Alarm					
Basal	72 hrs – 120 hrs (0.025 U/h basal) Typical – Maximum	Not available	37 hours – 74 hours (0.05 U/h) Minimum – Maximum	58 hours 20 min – 88 hours 40 minutes (0.10 U/h basal) Minimum - Maximum	
Basal	90 min – 3 hours (1.0 U/h basal) Typical - Maximum	Not available	60 min – 3.9 hours (2.0 U/h basal) Minimum – Maximum	85 min – 88 minutes (1.00 U/h basal) Minimum – Maximum	

Characteristic	Animas IR1250 Insulin Infusion Pump (Predicate Device)	Amigo® Insulin Pump (Predicate Device)	Smiths Medical Deltec Cozmo Pump (Predicate Device)	New Amigo® Insulin Pump (This Submission)	Discussion
Occlusion Pressure Threshold	75 kPa – 241kPa	15 psi, 25 psi, 35 psi (104 kPa, 172.5 kPa, 241.5 kPa)	18 psi +/- 5 psi (13 psi to 23 psi)	Low (15 psi nominal), High (35 psi maximum) (104 kPa, 241.5 kPa)	The Cozmo has one setting, Animas and Amigo have two. Maximum (see below) are all below 35 psi.
Maximum Occlusion Pressure	241kPa (35 psi)	35 psi	23 psi	35 psi	
Bolus Volume after Occlusion Release	1.0 U with occlusion sensitivity set to high 3.0 U with occlusion sensitivity set to low (1.0U/hr basal)	Not available	Approx. 4 U	0.65 U with occlusion pressure set to low 0.79 U with occlusion pressure set to high (1.0U/hr basal)	The Amigo Insulin Pump compares favorably with the predicate devices.
Miscellaneous					
Infrared Communication Port	Yes	Yes (for manufacturing use only)	Yes	Yes (for manufacturing use only)	

Characteristic	Animas IR1250 Insulin Infusion Pump (Predicate Device)	Amigo® Insulin Pump (Predicate Device)	Smiths Medical Deltec Cozmo Pump (Predicate Device)	New Amigo® Insulin Pump (This Submission)	Discussion
Battery capacity	6 – 8 week life	Not available	Up to 30 days	Minimum of 22 days based on typical use	The Amigo pump has a shorter battery life. This is not clinically significant, as the user has the ability to change batteries and the pump gives multiple warnings.
Infusion Set	23" Comfort	23" Unomedical Comfort infusion set K972135	Unomedical Comfort infusion set	23" Unomedical Comfort infusion set K972135	
Low Insulin Alarm Setting	10 – 50 U in 10 Unit Steps	10 – 50 U in 10 Unit Steps	5 – 50 U in 1 Unit Steps	10 – 50 U in 10 Unit Steps	
Environmental					
IPX8	Yes	Yes	Yes	Yes	
Shipping / Storage Range					
Temperature	-20 to +60 C / -4 to +140 F	-20 to +60 C / -4 to +140 F	-20 to +60 C / -4 to +140 F	0 to +60 C / 32 to +140 F	The new Amigo pump has a higher minimum storage temperature.
Humidity	10 to 100% RH, including condensing	10 to 100% RH, including condensing	Maximum 90% RH, non-condensing	10 to 100% RH, including condensing	
Pressure / Altitude	50 – 106 kPa / 18281 to -1253 feet	50 – 106 kPa / 18281 to -1253 feet	70 – 106 kPa / to 10,000 feet above sea level	50 – 106 kPa / 18281 to -1253 feet	

Characteristic	Animas IR1250 Insulin Infusion Pump (Predicate Device)	Amigo® Insulin Pump (Predicate Device)	Smiths Medical Deltec Cozmo Pump (Predicate Device)	New Amigo® Insulin Pump (This Submission)	Discussion
Operating Range					
Temperature	+5 to +40 C / +40 to +104 F	+5 to +40 C / +40 to +104 F	2 to +40 C / 35.6 to +104 F	+10 to +40 C / +50 to +104 F	The new Amigo pump has a slightly higher minimum operating temperature. This is not a clinical issue, as the pump is typically worn against the body, under clothing, in cold weather.
Humidity	20 to 90% RH, including condensing	20 to 90% RH, including condensing	Maximum 90% RH, non-condensing	20 to 90% RH, including condensing	
Pressure / Altitude	70 – 106 kPa / 9878 feet above to 1253 feet below sea level	70 – 106 kPa / 9878 feet above to 1253 feet below sea level	70 – 106 kPa / to 10,000 feet above sea level	70 – 106 kPa / 9878 feet above to 1253 feet below sea level	

NON-CLINICAL PERFORMANCE DATA

The Amigo® Insulin Pump was tested for electrical safety and infusion pump performance and safety according to:

- IEC 60601-1 (1988): Medical electrical equipment - Part 1: General requirements for safety, including Amendment 1 (1991) and Amendment 2 (1995)
- IEC 60601-2-24:1998 - Medical Electrical Equipment - Part 2-24: Particular Requirements For The Safety Of Infusion Pumps And Controllers

The Amigo® Insulin Pump was tested for electromagnetic compatibility according to:

- IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001).

The Amigo® Insulin Pump also meets:

- IEC 60601-1-4:2000 - Medical Electrical Equipment - Part 1-4: General Requirements For Safety - Collateral Standard: Programmable Electrical Medical Systems.
- ISO 14971:2000 - Medical devices - Application of risk management to medical devices.

The Amigo Insulin Pump has passed the above testing regimens, including specific testing for flow rates, accuracy, occlusion detection, water ingress, and alarms.

SUBSTANTIAL EQUIVALENCE

A review of the above chart shows that the Amigo® Insulin Pump compares similarly with the predicate devices in all features, with minor differences, as noted, not clinically significant.

- The devices have similar intended uses, use the same insulin type and infusion set, and share similar operating and technological principles.
- All devices have similar physical properties and offer similar software features of bolus and basal combinations and rates.
- All devices have nearly identical environmental specifications.

The above-referenced performance testing data supports the claims of substantial equivalence, that the Amigo® Insulin pump is as safe, as effective, and performs as well, or better, than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 4 2007

Mr. Harry Russell
Director of Quality and Regulatory Affairs
Nipro Diabetes Systems, Incorporated
3361 Enterprise Way
Miramar, Florida 33025

Re: K071613
Trade/Device Name: The Amigo® Insulin Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: November 8, 2007
Received: December 3, 2007

Dear Mr. Russell:

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

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,

Anthony D. Watson for
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): K071613
Device Name: Amigo® Insulin Pump
Indications for Use:

The Amigo® Insulin Pump is intended for the subcutaneous infusion of insulin.

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

(Part21 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
nfection Control, Dental Devices

10(k) Number: K071613

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