

MAY - 9 2005

510(k) Summary

1.0 Date Prepared

January 14, 2005

2.0 Submitter (Contact)

Clarence Odem, III
General Manager
Nipro Diabetes Systems, Inc.
Miramar, FL 32205
(954) 435-5665

3.0 Device Name

Proprietary / Trade Name: Amigo Insulin Pump
Common Name(s): Insulin pump

4.0 Device Classification

Classification Name: Pump, Infusion, Insulin
Prococode: 80LZG Class II 21 CFR § 880.5725

5.0 Device Description

The Amigo Insulin Pump is a small, lightweight, battery-operated programmable Insulin infusion pump. The pump houses a replaceable Nipro GlucoPro™ single-use insulin syringe containing up to 300 units 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.

6.0 Indications for Use

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

510(k) Summary (continued)

7.0 Substantial Equivalence

The Amigo Insulin Pump is substantially equivalent in the intended use, operating principle, overall design, performance, technology, features, functions, and materials to the GlucoPro EVA Pump as described in K013309.

| Characteristic | Amigo Insulin Pump (This Submission) | GlucoPro EVA (K013309) |
|-----------------------------|---|---|
| Intended Use | Intended for the subcutaneous infusion of insulin | Intended for the subcutaneous infusion of insulin |
| Pump Type | Linear Piston | Linear Piston |
| Control Technology | Microprocessor | Microprocessor |
| Insulin Reservoir | 3 mL (300 Units) | 3 mL (300 Units) |
| Insulin Type | U-100 | U-100 |
| Power Source | One 3 Volt lithium battery | One 3 Volt lithium battery |
| Programmable Basal Delivery | Yes | Yes |
| Programmable Bolus Delivery | Yes | Yes |
| User Notification | Audible, visual, and vibration | Audible, visual, and vibration |
| Visual Display | LCD | LCD |
| Insulin Syringe / reservoir | Nipro GlucoPro | Nipro GlucoPro |
| Infusion Set Connector | Standard luer lock | Standard luer lock |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Clarence Odom, III
General Manager
NIPRO Diabetes Systems, Incorporated
3361 Enterprise Way
Miramar, Florida 33025

Re: K050312
Trade/Device Name: Amigo Insulin Pump
Regulation Number: 880.5275
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: January 31, 2005
Received: February 8, 2005

Dear Mr. Odom:

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

510(k) Number (if known):

Device Name: Amigo Insulin Pump

Indications for Use:

The Amigo Infusion Pump is intended for the subcutaneous infusion of insulin

Prescription Use X

AND/OR

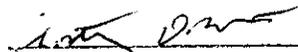
Over-The-Counter Use _____

(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)



(Signature Sign-Off)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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