K013309

JUN 24 2002

NIPRO DIABETES SYSTEM
3150 N.W. 107 Avenue
Miami, Florida 33172
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SUMMARY OF SAFETY AND EFFECTIVENESS
Glucopro™ Infusion Pump

§807.92 (a)(1)

Contact Person: Kirk Ramey
Senior Vice President

Date of Summary Preparation: June 19, 2002

§807.92 (a)(2)

Trade Name: Glucopro™ Infusion Pump

Classification Name: Electrical piston infusion pump (21 CFR §880.5725), Class II

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Devices: Disetronic H-Tron Plus V100 infusion pump (K973044) and Minimed Model 507 (K960001)

§807.92 (a)(4)

Description of Device: The GlucoPro Infusion Pump is intended for use with the disposable compatible infusion sets and the GlucoPro syringe for subcutaneous delivery of insulin. The catheter or needle of the compatible infusion set is inserted into the subcutaneous tissue of the user and is connected to the syringe that is the drug reservoir. The syringe is installed in the infusion pump and attached by means of screw threads. The medicine solution is delivered and infused into the user continuously. The user sets continuous basal infusion rate and selects bolus delivery. The infusion pump contains many safety features including alarms to indicate infusion error or system malfunction.

The pump is 91 mm wide, 52 mm in height, and 21 mm in depth. It weighs 80 grams. The power is supplied by a Duracell CR-2 (3V) battery (or equivalent) that should last 30 – 60 days.

§807.92 (a)(5)

Intended Use: The GlucoPro Infusion Pump is intended for the subcutaneous infusion of insulin.

§807.92 (a)(6)

Comparison of Technical Characteristics:

The GlucoPro Infusion Pump is similar to legally marketed devices with the same intended use and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2002

C/O Ms. Kaelyn B. Hadley
Consultant
Nipro Diabetes Systems, Incorporated
1384 Copperfield Court
Lexington, Kentucky 40514

Re: K013309
Trade/Device Name: GlucoPro Infusion Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: March 21, 2002
Received: March 28, 2002

Dear Ms. Hadley:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

Enclosure

K013309

Indications for Use Statement

510(k) number (if known): K013309

Device name: GlucoPro Infusion Pump

Common Name: Syringe pump

Classification Name: Electrical piston infusion pump

Product code: LZG

Classification: 880.5725, Class II

Indications for use: The GlucoPro Infusion Pump is intended for the subcutaneous infusion of insulin.

(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___
(Per 21 CFR 801.109) (optional Format 1-2-9)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
[illegible] Number K013309