K014114

JUN 2 6 2002

NIPRO DIABETES SYSTEMS
3150 N.W. 107 Avenue
Miami, Florida 33172
Tel.: (305) 599-7174
Fax: (305) 599-8454

SUMMARY OF SAFETY AND EFFECTIVENESS
Glucopro™ Syringe

§807.92 (a)(1)

Contact Person: Kirk Ramey
Senior Vice President

Date of Summary Preparation: December 7, 2001

§807.92 (a)(2)

Trade Name: Glucopro™ Syringe

Common Name: Syringe

Classification Name: Piston Syringe (21 CFR §880.5860), Class II

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Device: Disetronic Medical Systems AG, 3.15mL cartridge

§807.92 (a)(4)

Description of Device: The Glucopro Syringe is a medication reservoir placed within an infusion pump and attached to an infusion set for infusion of medicine solutions, such as insulin. The materials used for the components include: stainless steel; polypropylene; and, silicone. All of these materials are typically used in medical devices.

§807.92 (a)(5)

Intended Use: The Glucopro Syringe is intended for subcutaneous infusion of medicine solutions, such as insulin.

§807.92 (a)(6)

Comparison of Technical Characteristics:

The Glucopro Syringe 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 2 6 2002

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

Re: K014114
Trade/Device Name: Glucopro™ Syringe
Regulation Number: 880.5860
Regulation Name: Syringe
Regulatory Class: II
Product Code: FMF
Dated: April 2, 2002
Received: April 11, 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

Indications for Use Statement

510(k) number (if known): K014114

Device name: Glucopro Syringe

Common Name: Syringe

Classification Name: Piston Syringe

Product code: FMF

Classification: 880.5860, Class II

Indications for use: The Glucopro syringe is intended for use in the subcutaneous infusion of insulin. The catheter of the GlucoPro (K011120) or compatible infusion set is inserted into the subcutaneous tissue of the user and it is connected to the Glucopro Syringe. The insulin is infused from an external infusion pump.

(Please do not write below this line- continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The- Counter-Use ___ (optional Format 1-2-9)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K014114