K05-1574

NIPRO MEDICAL CORPORATION
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Miami, Florida 33172
Tel.: (305) 599-7174
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AUG 26 2005

SUMMARY OF SAFETY AND EFFECTIVENESS
DISPOSABLE HYPODERMIC SYRINGES

807.92 (a)(1)

Contact Person: Cary Goldsmith
Marketing Manager

Date of Summary Preparation: June 6, 2005

807.92 (a)(2)

Trade Name: Disposable Hypodermic Syringes with or without Needle
Common Name: Sterile Disposable Syringe with/without needle
Classification Name: Syringe, Piston (880.5860)
Hypodermic Single Lumen Needle (880.5570)

807.92 (a)(3)

Legally Marketed Substantially Equivalent Device:
Nipro Branded Disposable Syringes (K944355 and K030683)

807.92 (a)(4)

Description of Device:
The subject devices can be classified as piston syringes as described in 21 CFR 880.5860. Among the syringe types described are: luer lock, slip-tip, eccentric, and catheter tip. Syringes will be packaged with and without needles. Various sizes are described including: 1, 3, 5, 10, 20, 30, and 60 milliliters.

807.92 (a)(5)

Intended Use: The Disposable Hypodermic Syringes with or without Needle are intended for use to inject fluids into or withdraw fluids from the body.

807.92 (a)(6)

Comparison of Technical Characteristics:

The subject and Nipro predicate devices are similar in materials, design and technological characteristics. Performance tests demonstrated that the devices are substantially equivalent and meet voluntary standards for syringes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2005

Nipro Medical Corporation
C/O Kaelyn B. Hadley, Ph.D.
Regulatory Affairs Consultant
1384 Copperfield Court
Lexington, Kentucky 40514-1268

Re: K051574
Trade/Device Name: NIPRO Disposable Syringe with or without needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: FMF, FMI
Dated: June 6, 2005
Received: June 14, 2005

Dear Dr. Hadley:

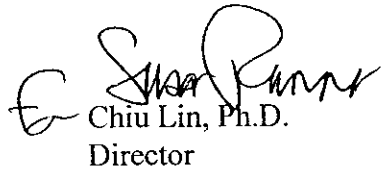
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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), 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): ~~05????~~ K05 1574

Device Name: Disposable Hypodermic Syringes with or without Needles

Indications For Use: The Disposable Hypodermic Syringes and Needles are intended for use to inject fluids into or withdraw fluids from the body.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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,
Infection Control, Dental Devices

510(k) Number: K051574