



NIPRO
NIPRO MEDICAL CORPORATION
10877 N.W. 33rd Street
Miami, Florida 33172
Tel.: (305) 599-7174
Fax: (305) 599-8454

K971582

DEC 22 1997

**SUMMARY OF SAFETY AND EFFECTIVENESS FOR NIPRO®
CORELESS NEEDLE AND CORELESS NEEDLE SET**

§807.92 (a)(1)

Contact Person: Luis Candelario
General Manager

Address: Nipro Medical Corporation
10877 NW 33rd Street
Miami, Florida 33172
(305) 599-7174 (telephone)
(305) 599-8454 (fax)

Date of Summary Preparation: April 30, 1997

§807.92 (a)(2)

Trade Name: Nipro® Coreless Needle and Nipro Coreless Needle Set

Common Name: Hypodermic single lumen needle or I.V. Administration Set

Classification Name: Hypodermic single lumen needle (21 CFR §880.5570) or Intravascular administration set (21 CFR §880.5440)

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Device: Huber Needle and Huber Needle Set, Exel International, Inc. (K895769 and K895770)

§807.92 (a)(4)

Description of Device: Nipro Coreless Needles and Nipro Coreless Needle Sets are described in Hypodermic single lumen needle (21 CFR §880.5570) or Intravascular administration set (21 CFR §880.5440). The Nipro Coreless Needle and Nipro Coreless Needle Set, for which coring is prevented, are intended to be used to inject a drug solution into a reservoir implanted in the body.

The Nipro Coreless Needles and Nipro Coreless Needle Sets that we intend to market include 2 different types: the straight type (7 sizes) and the 90° angle type (7 sizes). The Nipro Coreless Needle consists of a luer hub, a cannula, and a protector over the cannula. The needle base and the needle protector are composed of polypropylene (PP) and the cannula is made of stainless steel (Type 304).

The Nipro Coreless Needle Sets consist of a needle connected to a length (100 mm or 450 mm) of soft polyvinylchloride (PVC) tubing with a clamp roller along it and a luer connector and luer cap at the other end. Models in which there is a Y-shaped tube for mixture injection include a second length of PVC tubing connected at the first luer connector with a clamp roller along it which is then connected to another luer connector and cap.

The materials used for the components include stainless steel (Type 304), polyethylene (PE), polyvinylchloride (PVC), polypropylene (PP), polycarbonate (PC), natural rubber (NR), and polyoxymethylene (POM).

§807.92 (a)(5)

Intended Use:

The Nipro Coreless Needle and Nipro Coreless Needle Set, for which coring is prevented, are intended to be used to inject a drug solution into a reservoir implanted in the body.

§807.92 (a)(6)

Comparison of Technical Characteristics:

The Nipro Medical Corporation and Exel International, Inc. devices are exactly the same devices, therefore, all technical characteristics are identical.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 1997

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

Re: K971582
Trade Name: NIPRO® Huber Needles and Huber Needle Sets
Regulatory Class: II
Product Code: LJT
Dated: October 30, 1997
Received: November 3, 1997

Dear Ms. Hadley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

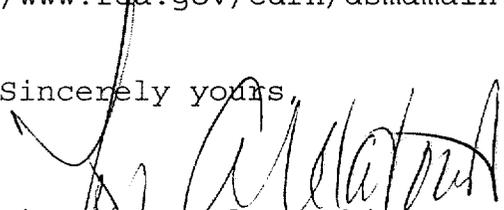
Page 2 - Ms. Hadley

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/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

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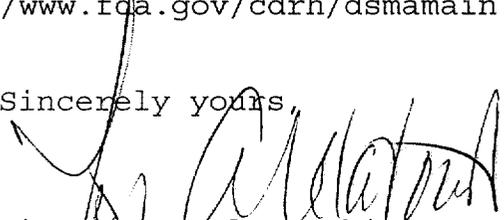
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Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
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Enclosure

Indications for Use

510(k) Number (if known) _____

Device Name: Nipro Coreless Needle and Nipro Coreless Needle Set

Indications for Use: The Nipro Coreless Needle and the Nipro Coreless Needle Set, for which coring is prevented, are intended to be used to inject a drug solution into a reservoir implanted in the body.

(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 Dental, Infection Control,
and General Hospital Devices

510(k) Number Use OR
(Per 21 CFR 801.109)

Over-the-Counter Use _____