FEB 14 2000

K992699

NIPRO

NIPRO MEDICAL CORPORATION
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Miami, Florida 33172
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SUMMARY OF SAFETY AND EFFECTIVENESS FOR NIPRO® BLOOD COLLECTION NEEDLE

§807.92 (a)(1)

Contact Person: Luis Candelario
General Manager

Date of Summary Preparation: August 2, 1999

§807.92 (a)(2)

Trade Name: Nipro® Blood Collection Needle

Common Name: Blood Collection Needle

Classification Name: Hypodermic Single Lumen Needle (21 CFR 880.5570)
Establishment Registration Number: 9611446
Class: II
Panel: 80
Procodes: FMI

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Device: Exel International Blood collection needle (K861152A)

§807.92 (a)(4)

Description of Device: The Nipro Blood collection needles that we intend to market include gauges 18, 20, 21, and 22. Each gauge is available in various lengths from 20 to 40 mm.

Blood Collection Needles are described in hypodermic single lumen needle (21 CFR 880.5570).

The materials used for the components include stainless steel SUS 304 (SS), synthetic rubber, and polypropylene

(PP). Epoxy resin as an adhesive and silicone oil as a lubricant are also used.

§807.92 (a)(5)

Intended Use: The blood collection needles are intended to be used to collect blood for various blood tests.

§807.92 (a)(6)

Comparison of Technical Characteristics:

The Nipro and Exel 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

FEB 14 2000

Nipro Medical Corporation
c/o Ms. Kaelyn B. Hadley
Nipro Medical Corporation
Consultant
C.L. McIntosh & Associates, Incorporated
1384 Copperfield Court
Lexington, Kentucky 40514-1268

Re: K992699
Trade Name: Nipro® Blood Collection Needle
Regulatory Class: II
Product Code: FMI
Dated: November 24, 1999
Received: November 26, 1999

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 (Premarket 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 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) 594-4692. 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

Enclosure

Indications for Use

510(k) Number (if known) _____
Device Name: Nipro Blood Collection Needle

Indications for Use: The Nipro Blood Collection Needle are intended to be used to collect blood for various blood tests.

(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)

Patricia Cusmato

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993699