K992729

JAN 13 2000

NIPRO

NIPRO MEDICAL CORPORATION
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SUMMARY OF SAFETY AND EFFECTIVENESS FOR NIPRO® LUER ADAPTOR

§807.92 (a)(1)

Contact Person: Luis Candelario
General Manager

Date of Summary Preparation: August 2, 1999

§807.92 (a)(2)

Trade Name: Nipro® Luer Adaptor
Common Name: Luer adaptor
Classification Name: Intravascular Administration Set (21 CFR 880.5440)
Establishment Registration Number: 9611446
Class: II
Panel: 80
Procodes: FOZ

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Device: Exel International Luer Adaptor (K861152A)

§807.92 (a)(4)

Description of Device: The Nipro Luer Adaptor that we intend to market is a multi-type with a cannula that has an outer diameter of 0.90 mm and a back end length of 20 mm to 24 mm.

The Luer Adaptor is intended to be used as an attachment for a needle with a luer taper hub for blood collection. The luer adaptor is used as part of the vacuum blood collection equipment for blood collection required for various blood tests. The luer adaptor is used to connect to a blood collection needle that has a female luer taper for use. As such, this product has a hub with a male luer taper. The product is a sterilized single-use product.

Luer Adaptors are described in Intravascular Administration Set (21 CFR 880.5440).

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 luer adaptor is intended to be used as an attachment for a needle with a luer taper hub for blood collection. The luer adaptor is used as part of the vacuum blood collection equipment for blood collection required for various blood tests intended to be used to collect blood for various types of 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

JAN 13 2000

Nipro Medical Corporation
c/o Ms. Kaelyn B. Hadley
Consultant for Nipro Medical Corporation
C.L. McIntosh & Associates, Incorporated
Medical & Regulatory Affairs Services
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

Re: K992729
Trade Name: Nipro® Luer Adaptor
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) K992729

Device Name: **Nipro Luer Adaptor**

Indications for Use: The Nipro Luer Adaptor is intended to be used as an attachment for a needle with a luer taper hub for blood collection. The luer adaptor is used as part of the vacuum blood collection equipment for blood collection required 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)

Katherine Carrite

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992729