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NIPRO

NIPRO MEDICAL CORPORATION
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SUMMARY OF SAFETY AND EFFECTIVENESS FOR NIPRO® ARTERIAL VENOUS FISTULA NEEDLE

§807.92 (a)(1)

Contact Person: Luis Candelario
General Manager

Date of Summary Preparation: April 27, 1999

§807.92 (a)(2)

Trade Name: Nipro® Arterial Venous Fistula Needle
Agulha Para Fistula Arterio-Venosa
Aguja Para Fistula Arterio Venosa

Common Name: Disposable AVF set

Classification Name: Blood Access Device and Accessories (nonimplanted) (21 CFR 876.5540)

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Device: Nipro Arterial Venous Fistula Needle, (K955182)

§807.92 (a)(4)

Description of Device: Arterial Venous Fistula Needles are described in blood access device and accessories (nonimplanted) 21 CFR 876.5540 The Disposable Arterial Venous Fistula Needles that we intend to market include 1 type of design: fixed wing. It is offered with or without a clamp. The device consists of a winged needle (14 - 17 gauge) connected to polyvinylchoride AVF tubing which is connected to a AVF luer connector. Needles with a hole (back eye type) and without a hole are available as well

and are both 1 inch and 1¼ inches in length. Tubing is available in lengths of 300 mm.

The materials used for the components include: polyvinylchloride (PVC), stainless steel (SS), polyoxymethylene (POM), polycarbonate (PC) and polypropylene (PP).

§807.92 (a)(5)

Intended Use:

The AVF sets are intended to be used for intravenous injection and connection with dialysis blood lines to transport blood from the artery of the patient to the dialyzer and transport blood after dialysis to the vein of the patient.

§807.92 (a)(6)

Comparison of Technical Characteristics:

The Nipro subject and predicate AVF needles are similar devices, and most technical characteristics are identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG -9 1999

Nipro Medical Corporation
c/o Ms. Kaelyn Hadley
Consultant
C. L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, MD 20852

Re: K991623
Nipro Arterial Venous Fistula Needle
Dated: April 27, 1999
Received: May 11, 1999
Regulatory Class: II
21 CFR §876.5540/Procode: 78 FIE

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 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). 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 Current Good Manufacturing Practice requirements, 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 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number (if known): K991623
Device name: Nipro Arterial Venous Fistula Needle, Agula Para Fistula
Indications for use: The AVF sets are intended to be used for intravenous injection and connection with dialysis blood lines to transport blood from the artery of the patient to the dialyzer and transport after dialysis to the vein of the patient.

(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) (optional Format 1-2-9)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991623