

**NIPRO**

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**SUMMARY OF SAFETY AND EFFECTIVENESS FOR NIPRO® Blood Tubing Set
for Hemodialysis with Transducer Protectors and Priming Set**

§807.92 (a)(1)

Submitter: Nipro Medical Corporation
Contact Person: Luis Candelario
General Manager
Date of Summary Preparation: September 24, 1997

§807.92 (a)(2)

Trade Name: Nipro® Blood Tubing Set for Hemodialysis
with Transducer Protectors and Priming Set
Common Name: Blood tubing set with priming set and transducer/protectors
Classification Name: Blood access device and accessories (21 CFR
876.5540)

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Devices:
Medisystems Corporation ReadySet™ Hemodialysis Blood Tubing Set with Priming Set and
Transducer Protectors

§807.92 (a)(4)

Description of Device:

The Nipro® Blood Tubing Set for Hemodialysis with Transducer Protectors and Priming Set that we intend to market includes the following three components: a Nipro® Arterial and Venous Blood Tubing Set for Hemodialysis; a Nipro® Disposable Solution Infusion Set ; and, a transducer/protector. These devices are packaged together for convenient use during hemodialysis procedures.

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The Arterial and Venous Blood Tubing Sets that we intend to include within the kits include various models of blood tubing sets are available for application with different dialysis machines. A series of 27 arterial line models (A001 - A021, A026, A029 -A032, and A035) and a series of 14 venous line models (V600 - V607, V609 - V613, and V616) have been described. The Disposable Solution Infusion Set that we intend to include in the kit will be one of the 4 types of designs: NNC-3L, NNC-3CL, NNC-3C, and NNC-3CS. A transducer/protector is also included in the kit.

The materials used for the components of the blood tubing sets include polyethylene (PE), polyvinylchloride (PVC), acrylonitrile butadiene styrene (ABS), polyoxymethylene (POM), polypropylene (PP), polyethylene high density (PEHD), and polycarbonate (PC). The materials used for the disposable solution infusion set include polyethylene (PE), polyvinylchloride (PVC), polypropylene (PP), and acrylonitrile butadiene styrene (ABS). The transducer/protector component of this kit is fabricated from either rigid PVC and a 0.2 micron Gore membrane (PTFE and polypropylene) or rigid PVC and PTFE and polyester.

§807.92 (a)(5)

Intended Use: The Blood Tubing Set for Hemodialysis with Transducer Protectors and Priming Set is intended for use during hemodialysis to provide access to a patient's blood. When used in hemodialysis, they are part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions.

§807.92 (a)(6)

Comparison of Technical Characteristics:

The configuration of the subject device kit is similar to legally marketed devices from Medisystems Corporation. Labeling for the competitor's devices is similar to the subject device. According to the device names on the labeling, the intended use for the competitors' products is similar to that of the subject device. They are used for hemodialysis. All of the devices are labeled as sterile and for single use only. The devices are restricted to sale by or on the order of a physician. The blood tubing sets and disposable solution infusion sets are already cleared for market individually and demonstrated to be biocompatible according to necessary testing and prior clinical use. The transducer/protector is fabricated from identical materials to those contained in certain blood tubing set components. Transducer/protectors have also undergone biocompatibility testing and are similar to marketed components.

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§807.92 (b)(1) The following biocompatibility tests were performed on the components of the subject device kit: cytotoxicity, mutagenicity, hemolysis, acute systemic toxicity, intracutaneous reactivity, implantation tests, pyrogenicity, and sensitization. Results indicate that the blood tubing sets conform to the appropriate specifications.

§807.92 (b)(3) The Nipro Disposable Blood Tubing Set for Hemodialysis and Disposable Solution Infusion Set have already been determined to be substantially equivalent to legally marketed devices. The transducer/protector is composed of materials identical to those contained in blood tubing set components and similar to marketed components.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 1997

Mr. Luis Candelario
General Manager
Nipro Medical Corporation
10877 N.W. 33rd Street
Miami, Florida 33172

Re: K972206
Nipro® Blood Tubing Set with Transducer
Protectors and Priming Set for Hemodialysis
Dated: August 27, 1997
Received: September 4, 1997
Regulatory Class: II
21 CFR §876.5820/Product code: 78 KOC

Dear Mr. Candelario:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. 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

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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,

Robert R. Nattang /

for

Lillian Yin, Ph.D.
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): K972206

Device Name: Nipro® Blood Tubing Set for Hemodialysis with Transducer Protectors and Priming Set

Indications for Use: The Nipro® Blood Tubing Set for Hemodialysis with Transducer Protectors and Priming Set is intended for use during hemodialysis to provide access to a patient's blood. When used in hemodialysis, they are part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

Robert R. Sathya /
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972206