



NIPRO MEDICAL CORPORATION  
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SEP 18 1997

**SUMMARY OF SAFETY AND EFFECTIVENESS FOR NIPRO®  
DISPOSABLE SOLUTION INFUSION SET**

§807.92 (a)(1)

Contact Person: Luis Candelario  
General Manager

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10877 NW 33<sup>rd</sup> Street  
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Date of Summary Preparation: July 1, 1997

§807.92 (a)(2)

Trade Name: Nipro® Disposable Solution Infusion Set

Common Name: Disposable Solution Infusion Set or I.V. Administration Set

Classification Name: Intravascular administration set (21 CFR §880.5440)

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Device: I.V. Administration Set, Gainor Medical U.S.A., Inc. (K926448) and Medistystems Dialysis Priming Set

§807.92 (a)(4)

Description of Device: Intravascular administration sets are described in 21 CFR §880.5440. The Disposable Solution Infusion Sets that we intend to market include 4 types of designs. The sets consist of a length of polyvinylchloride tubing with a clamp roller along it and a male luer lock at one end and a non-vented infusion subassembly without filter at the other end. Model number NNC-3L has a male luer-lock connector (without injection site) and NNC-3CL has the male luer-

lock connector and Y-connector with injection site. Model NNC-3CS has the cone luer slip and Y-connector with injection site and NNC-3C has the cone slip connector (without injection site).

The materials used for the components include polyethylene (PE), polyvinylchloride (PVC) (contains DEHP), polypropylene (PP) and acrylonitrile butadiene styrene (ABS). Cyclohexanone and adhesive bond are used and are present in trace amounts.

§807.92 (a)(5)

**Intended Use:**

The Solution Infusion Sets are intended to be used for the administration of intravenous fluid solution into the body. They are also intended for use in administering intravenous fluids to a dialysis set in conjunction with hemodialysis

§807.92 (a)(6)

**Comparison of Technical Characteristics:**

The Nipro and Gainor Medical devices are exactly the same devices, therefore, all technical characteristics are identical.

As these sets have been marketed for several years, safety and effectiveness has been established through years of clinical use. There have not been problems reported during use of the sets.

The Medisystems Dialysis Priming Set includes similar indications for use in hemodialysis.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K972493  
Nipro® Disposable Solution Infusion Set  
Dated: July 2, 1997  
Received: July 3, 1997  
Regulatory class: II  
21 CFR §876.5820/Product code: 78 KOC

SEP 18 1997

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. 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 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 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/dsmamain.html>.

Sincerely yours,

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

K972493

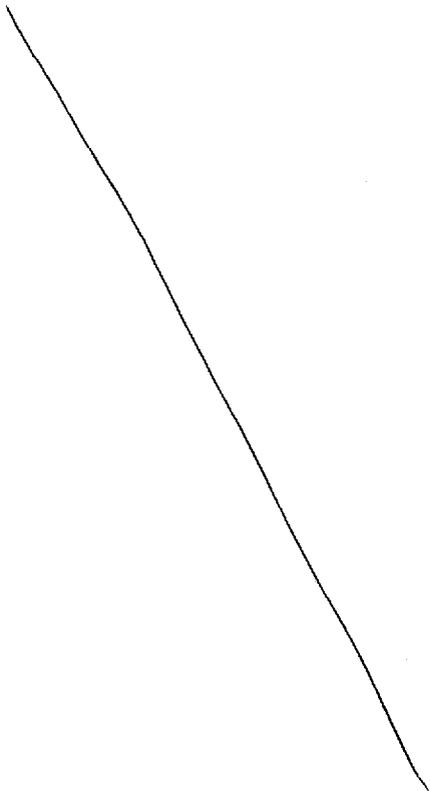
Indications for Use

510(k) Number (if known): Unknown

Device Name: Nipro Disposable Solution Infusion Set

**Indications for Use:**

The Solution Infusion Sets are intended to be used for the administration of intravenous fluid solution into the body. They are also intended for use in administering intravenous fluids to a dialysis set in conjunction with hemodialysis.



(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. Rathling  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K972493