



NIPRO MEDICAL CORPORATION  
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DEC 15 2005

K051828

**SUMMARY OF SAFETY AND EFFECTIVENESS  
NIPRO SUREFUSER AMBULATORY BALLOON INFUSER**

807.92 (a)(1)

Contact Person: Luis Candelario  
President  
Date of Summary Preparation: December 5, 2005

807.92 (a)(2)

Trade Name: Nipro Surefuser Ambulatory Balloon Infuser  
Common Name: Balloon Infusion pump  
Classification Name: Pump, Infusion, Elastomeric (880.5725)

807.92 (a)(3)

Legally Marketed Substantially Equivalent Device: Infusor LV (K011317), Baxter Healthcare Corporation

807.92 (a)(4)

Description of Device:  
The subject device can be classified as a balloon (elastomeric) infusion pump as described in 21 CFR 880.5725. The following models are included: 50, 100, and 250 ml.

807.92 (a)(5)

Intended Use: The Nipro Surefuser Ambulatory Balloon Infuser is intended for continuous and accurate infusion of medications at a predetermined flow rate. Routes of administration include intra-arterial, intravenous, percutaneous, subcutaneous, and epidural. An elastomeric reservoir is used eliminating the need for electrical power. The device is designed for single use in hospital, outpatient, and home care settings.

807.92 (a)(6)

Comparison of Technical Characteristics:  
The Nipro subject devices are similar to the predicate devices in materials, design and technological characteristics. Performance (functional), biocompatibility, and appearance tests demonstrated that the subject devices perform as intended and are safe and suitable for human use. They are substantially equivalent to similar legally marketed devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 15 2005

Nipro Medical Corporation  
C/O Ms. Kaelyn Hadley  
Consultant  
1384 Copperfiled Court  
Lexington, Kentucky 40514

Re: K051828

Trade/Device Name: Nipro Surefuser Ambulatory Balloon Infuser  
Regulation Number: 21 CFR 880.5725  
Regulation Name: Infusion Pump  
Regulatory Class: II  
Product Code: MEB  
Dated: December 5, 2005  
Received: December 7, 2005

Dear Ms. Hadley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K051828

Device Name: Nipro Surefuser Ambulatory Balloon Infuser

Indications For Use: The Nipro Surefuser Ambulatory Balloon Infuser is intended for continuous and accurate infusion of medications at a predetermined flow rate. Routes of administration include intra-arterial, intravenous, percutaneous, subcutaneous, and epidural. An elastomeric reservoir is used eliminating the need for electrical power. The device is designed for single use in hospital, outpatient, and home care settings.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Anton D. Mark*

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Special Agent in Charge  
Division of Anesthesiology, General Hospital,  
Division Control, Dental Devices

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