K092246

NIPRO MEDICAL CORPORATION
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510(k) Summary
NIPRO Needleless Transfer Device

NOV 12 2009

807.92(a) (1)

Contact Person: Jessica Oswald, Regulatory Affairs Specialist
Date of summary preparation: July 22, 2009

807.92(a) (2)

Trade Name: NIPRO Needleless Transfer Device
Common Name: TRANSFER NEEDLE
Classification Name: Set, IV, Fluid transfer
Regulation Number: 21 CFR part 880.5440
Regulatory Class: II
Panel: 80
Product Code: LHI

807.92(a) (3)

Legally marketed substantial equivalent device:
K972117: MSI Transflow

807.92(a) (4)

Description of device:

The Nipro Needleless Transfer Device with or without 20mm vial closure adapters is a sterile, single-use needleless liquid transfer device with the intent of transferring sterile water from its vial into an evacuated vial containing lyophilized product requiring reconstitution.

This device consists of a single piece injection molded main body with 2 capped spikes on both ends. The device is provided with and without 2 adapters used for setting at the mouth of the solution bottle in order to stabilize the container at the time of mixture.

The device is sterile, single-use only, latex-free, non-toxic and non-pyrogenic.

807.92(a) (5)

Indications for Use:

The NIPRO Needleless Transfer Device is a sterile device for the aseptic transfer of solutions from container to container or reconstituting medications.

807.92(a) (6)

Comparison of technological characteristics:

The NIPRO Needleless Transfer Device is substantially equivalent to the predicate device in the following technological characteristics –

- Design
- Physical characteristics
- Basic Scientific Technology
- Intended Use

807.92(b) (1)

Non-clinical tests performed and included in this submission include:

- Dimensional
- Mechanical
- Operational
- Chemical
- Biocompatibility

807.92(b) (3)

Conclusions drawn from non-clinical and clinical tests:

The results of the non-clinical tests and the comparison of technological characteristics with the predicate device demonstrate that the NIPRO Needleless Transfer Device performs equivalent to the predicate device and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Jessica Oswald
Regulatory Affairs Specialist
Nipro Medical Corporation
3150 NW 107th Avenue
Miami, Florida 33172

NOV 12 2009

Re: K092246
Trade/Device Name: NIPRO Needleless Transfer Device
Regulation Number: 21CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: October 6, 2009
Received: October 9, 2009

Dear Ms Oswald:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting 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):

Device Name: NIPRO Needleless Transfer Device

Indications For Use:

The NIPRO Needleless Transfer Device is a sterile device for the aseptic transfer of solutions from container to container or reconstituting medications.

Prescription Use ___√___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices