K113429

NIPRO MEDICAL CORPORATION
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MAR 12 2012

510(k) Summary
SafeTouch PSV winged Infusion Set with/without filter

807.92(a)(1)

Applicant:	Nipro Medical Corporation
Establishment Reg.:	1056186
Contact Person:	Jessica Oswald Regulatory Affairs Specialist
Date of summary preparation:	November 4, 2011

807.92(a)(2)

Trade Name: SafeTouch PSV winged Infusion Set with/without filter
Common Name: Safety Scalp Vein Set
Classification Name: catheter,intravascular,therapeutic,short-term less than 30 days
Regulation Number: 21 CFR 880.5200
Panel: 80
Product Code: FOZ

807.92(a)(3)

Legally marketed substantial equivalent device:
K011297 - NIPRO SafeTouch Scalp Vein Set and Blood Collection Needle

807.92(a)(4)

Description of device:
The SafeTouch PSV winged Infusion Set with/without filter consists of a winged needle (25 gauge x 3/4 inch) with an integrated safety mechanism connected to PVC tubing and a female luer connector with cap. The tubing material is DEHP-free PVC and the filter has been added to prevent the flow of particulate matter.

807.92(a)(5)

Indications for Use:
This device is intended to be used for insertion into a patient's vascular system for single use as an indwelling device to administer fluids intravenously or to sample blood. Secondly it is designed with an active sharp feature that requires physical action by the clinician to prevent accidental needlesticks.

807.92(a)(6)

Comparison of technological characteristics:
The Nipro SafeTouch Scalp Vein Set with/without filter is identical to the predicate device, in terms of:

- basic scientific technology,
- design,
- Intended Use and
- Operational technique.

The differences between the proposed device and the predicate device are:

- Physical characteristics/components – addition of the particulate matter filter
- Material Characteristics – change to DEHP-Free tubing

807.92(b)(1)

Non-clinical tests submitted:

Performance testing was conducted to verify that the device is safe and effective for its intended use. Those tests include appearance, dimensional, package integrity testing and functional testing to include: Penetration force (puncture resistance testing), Pull force of connections, Safety Mechanism Deactivation force, Needle Clogging Test, Leakage of product, Luer Cap Separation, Connector Taper Leakage, Internal/external surface of cannula, Cannula Elasticity, Cannula Bending Strength and Product Air Tightness. The results and conclusions of these tests are included in this submission.

807.92(b)(2)

Clinical tests submitted:

Substantial equivalence was proven through bench testing. No clinical testing was required or performed in support of this 510k submission.

807.92(b)(3)

Conclusions drawn from non-clinical and clinical tests:

The results of the performance testing and the comparison of technological characteristics with the predicate device demonstrate that the SafeTouch PSV 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 –WO66-G609
Silver Spring, MD 20993-0002

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

MAR 12 2012

Re: K113429
Trade/Device Name: SafeTouch PSV winged Infusion Set with/without filter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: March 6, 2012
Received: March 7, 2012

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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,

Anthony D. Watson, B.S., M.S., M.B.A.
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:_____

Device Name: SafeTouch PSV winged Infusion Set with/without filter

Indications for Use:

The SafeTouch PSV Winged Infusion Set with/without filter is intended to be used for insertion into a patient's vascular system for single use as an indwelling device to administer fluids intravenously or to sample blood. Secondly it is designed with an active sharp feature that requires physical action by the clinician to prevent accidental needlesticks.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____✓____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

3/12/2012

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

510(k) Number: K113429