K140136

NIPRO MEDICAL CORPORATION
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FEB 14 2014

510(k) Summary: Nipro SafeTouch PSV Scalp Vein Set with Safety Device

807.92(a)(1)

Applicant:	Nipro Medical Corporation 3150 NW 107th Ave. Miami FL 33172 Tel: 305-599-7174
Establishment Reg.:	1056186
Contact Person:	Jessica Oswald-McLeod Director, Quality Assurance & Regulatory Affairs
Date of summary preparation:	January 14, 2014

807.92(a)(2)

Trade Name: Nipro SafeTouch PSV Scalp Vein Set with Safety Device
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:
Nipro SafeTouch Scalp Vein Set – K011297

807.92(a)(4)

Description of device:
The SafeTouch PSV Scalp Vein Set with Safety Device is a safety intravascular administration set. It incorporates a safety mechanism that requires physical action by the clinician, to help protect against exposure to blood borne pathogens caused by accidental needlestick injuries after use.

The basic structure of the device consists of a 25G X ¾ inch needle, needle hub with incorporated safety mechanism, wing unit, micro bore tubing, a clamp and female luer connector with cap. It is supplied sterile for single use only, non-pyrogenic, non-toxic, is not made with DEHP and does not contain natural rubber latex.

807.92(a)(5)

Indications for Use:
The Nipro SafeTouch PSV Scalp Vein Set with Safety 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 needlestick incidents.

807.92(a)(6)

Comparison of technological characteristics:
The syringe is substantially equivalent to the predicate device in the following technological characteristics:

- Physical characteristics
- Operational mode
- Basic Scientific Technology
- Intended Use

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. These tests include: Gauging test, Liquid leakage test, Mechanical strength of unions, Flow rate, Closure device (EL luer cap) for leakage test, Penetration force of needle, Pull force at connection, Priming volume, Safety mechanism-Return force after locked, Safety mechanism-Move force after activated, Safety mechanism-Pull force after locked and Individual Package integrity. Other test items include: Transportation, biocompatibility, and shelf-life testing.

These tests along with their associated results and conclusions are included in this submission.

807.92(b)(2)

Clinical tests:
This submission does not warrant any clinical testing, therefore no clinical testing performed for or provided in this 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 Nipro SafeTouch PSV Scalp Vein Set with Safety 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 Center – WO66-G609
Silver Spring, MD 20993-0002

February 14, 2014

Nipro Medical Corporation
C/O Jessica Oswald-McLeod
Director, Quality Assurance & Regulatory Affairs
3150 NW 107th ST
Miami, FL 33172

Re: K140136
Trade/Device Name: Nipro SafeTouch PSV Scalp Vein Set with Safety Device
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter, therapeutic, short-term less than 30 days
Regulatory Class: II
Product Code: FOZ
Dated: January 14, 2014
Received: January 17, 2014

Dear Ms. Oswald-McLeod:

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,

Kwame O. Ulmer for
-S FDA

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K140136

Device Name
Nipro SafeTouch PSV Scalp Vein Set with Safety Device

Indications for Use *(Describe)*
The Nipro SafeTouch PSV Scalp Vein Set with Safety 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 needlestick incidents.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA
Digitally signed by
Richard C. Chapman
Date: 2014.02.12
17:02:33 -05'00'

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