K063721
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NIPRO MEDICAL CORPORATION
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JAN 12 2007

510(k) Summary of Safety and Effectiveness for the NIPRO® SafeTouch II Gamma

807.92(a)(1)

Applicant: Nipro Medical Corporation
Establishment Reg.: 1056186

Contact Person: Jessica Oswald
Regulatory Affairs Specialist

Date of summary preparation: December 8, 2006

807.92(a)(2)

Trade Name: NIPRO® Safetouch II Gamma
Common Name: Safety Fistula Needle
Classification Number: 21 CFR 876.5540
Classification Name: Blood access device and accessories
Panel: 78
Product Code: FIE

807.92(a)(3)

Legally marketed substantial equivalent device:
NIPRO® SafeTouch Safety AVF Needle (K032777)

807.92(a)(4)

Description of device:
The NIPRO® SafeTouch II Gamma is a sterile, single use, safety AVF needle. It includes 2 basic types of designs; fixed wing type (stationary) and turnable wing type (rotating). These two designs are offered in 64 configurations with options that include needle gauge, needle length, type of needle (with or without backeye), and tubing length.

The NIPRO® SafeTouch II Gamma includes an arterial and venous fistula adapter consisting of flexible tube and needle with an active sharps safety feature (non-implanted blood access device) as described in 21 CFR 876.5540. The predicate device, NIPRO® SafeTouch Safety Fistula Needle, which is sterilized by Ethylene oxide gas was previously described in detail as part of Premarket Notification cleared by FDA under K032777 on November 14, 2003.

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The safety feature is easily operated through the release of a latch mechanism whereby the user slides a winged cover over the needle, as it is removed from the patient. Once the needle is covered, the safety cover locks into place. The safety feature presented in this document represents a substantially equivalent version of the current brand, which is cleared under K032777. The only difference being the material used for the protector which has changed from a frosted to a transparent component, making it easier to confirm blood flash black.

These devices operate on the principles of a blood access device. They are sterile, single use only, non-toxic and non-pyrogenic.

807.92(a)(5)

Indications for Use:
The NIPRO® Safetouch II Gamma is intended for use as a blood access device for blood purification and for other treatments requiring an extracorporeal circuit of larger volumes of blood. Secondly, it is designed with an active sharp safety feature requiring physical action by the clinician to aid in the prevention of accidental needlesticks. The compatibility of available configurations is the responsibility of the physician in charge.

807.92(a)(6)

Comparison of technological characteristics:
Nipro Medical Corporation considers the modified NIPRO® SafeTouch II Gamma to be substantially equivalent to the current NIPRO® SafeTouch Safety Fistula Needle (K032777) with regard to intended use, materials of construction, labeling, and overall performance characteristics.

807.92(b)(1)

Non-clinical tests submitted:
The results of biocompatibility data support the equivalence of the predicate device and include sterility safety, bacterial endotoxin, systemic injection, intracutaneous reactivity, hemolysis, implantation, cytotoxicity, sensitization and mutagenicity testing. Performance testing was also conducted to verify that the device is safe and effective for its intended use. Those reports along with associated data are included 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 demonstrate that the NIPRO® SafeTouch II Gamma performs equivalent to the predicate device and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Jessica Oswald
Regulatory Affairs Specialist
NIPRO Medical Corporation
3150 N.W. 107 Avenue
MIAMI FL 33172

JAN 12 2007

Re: K063721
Trade/Device Name: NIPRO® SafeTouch II Gamma
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: FIE
Dated: December 13, 2006
Received: December 15, 2006

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 (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 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K063721

Device Name: NIPRO® SafeTouch II Gamma

Indications for Use:

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(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)

David A. Segraves

(Division Sign-Off)
Division of [illegible] Abdominal,
and [illegible]
510(k) Number K063721