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SEP - 7 2007

# 510(k) Summary of Safety and Effectiveness for NIPRO SafeTouch TULIP™ Safety Fistula Needle

807.92(a)(1)

Contact Person: Jessica Oswald
Regulatory Affairs Specialist

Date of summary preparation: April 10, 2007

807.92(a)(2)

Trade Name: NIPRO SafeTouch TULIP™ Safety Fistula Needle
Common Name: Safety AVF Needle
Classification Name: Blood access device and accessories
Product Code: FIE

807.92(a)(3)

Legally marketed substantial equivalent device:
Medisystems Masterguard™ AVF Needle (K932074)
Nipro AVF Needle (K955182)

807.92(a)(4)

Description of device:
The NIPRO SafeTouch TULIP™ Safety Fistula Needle is a sterile, single use, safety AVF needle. It consists of an arterial and venous adaptor, flexible tube and needle with an active sharps safety feature (non-implanted blood access device) as described in 21 CFR 876.5540.

The NIPRO SafeTouch TULIP™ Safety Fistula Needle 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 integrated sharps injury prevention feature requires physical action by the clinician to activate and is designed to cover the cannula after treatment. Correct uses of this anti-stick feature will eliminate accidental needlesticks.

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

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807.92(a)(5)

Indications for Use:
The NIPRO Safetouch TULIP™ Safety AVF Needle 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:
The NIPRO Safetouch TULIP™ Safety AVF Needle is substantially equivalent to the Medisystems Masterguard™ AVF Needle (K932074) with regard to intended use, operational characteristics, labeling, and overall performance characteristics. It is identical to the NIPRO AVF needle (K955182), with the addition of the TULIP needle protector, in regards to materials of construction.

807.92(b)(1)

Non-clinical tests submitted:
The results of biocompatibility data support the equivalence of the predicate device and include sterility, bacterial endotoxin, systemic injection, intracutaneous reactivity, hemolysis, and implantation testing. Performance testing was also conducted to verify:

1. The tensile, flexural, and elongation strength of the materials.
2. Force to attach and detach connections
3. Rate of fluid flow simulating extremes of pressure
4. Force to activate and deactivate the safety feature
5. Strength of joints, bonds, connections, hinges, valves, locking mechanisms.

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 TULIP™ Safety AVF Needle performs equivalent to the predicate devices and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP - 7 2007

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

Re: K071145
Trade/Device Name: NIPRO SafeTouch TULIP™ Safety Fistula Needle
Regulation Number: 21 CFR §876.5540
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: MPB, KOC and LLB
Dated: August 15, 2007
Received: August 17, 2007

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

K071145

# Indications for Use

510(k) Number: K071145

Device Name: NIPRO SafeTouch TULIP™ Safety Fistula Needle

Indications for Use:

The NIPRO SafeTouch TULIP™ Safety Fistula Needle 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 anti-stick needle protector 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K071145