K041779

SEP 2 1 2004

SUMMARY OF SAFETY AND EFFECTIVENESS
NIPRO DISPOSABLE STOPCOCKS

807.92 (a)(1)

Contact Person: Cary Goldsmith
Marketing Manager

Date of Summary Preparation: June 30, 2004

807.92 (a)(2)

Trade Name: Nipro Disposable Stopcocks
Common Name: Stopcocks
Classification Name: Stopcocks, I.V.sets (880.5440)

807.92 (a)(3)

Legally Marketed Substantially Equivalent Device:
B. Braun Medical Inc.3-way Stopcocks (K911415)

807.92 (a)(4)

Description of Device:
The subject devices can be classified as stopcocks as described in 21 CFR 880.5440. Among the types described here are: click – stop; 3W-R; 3W-L; and, NCN. Both slip tip and luer lock are included.

807.92 (a)(5)

Intended Use: The Nipro Disposable Stopcocks are intended to be used to change the direction of flow of fluids through a tubing set.

807.92 (a)(6)

Comparison of Technical Characteristics:

The Nipro subject devices are similar to the predicate devices in materials, design and technological characteristics. Performance tests demonstrated that the subject devices are safe and suitable for human use. They are substantially equivalent to similar legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2004

Nipro Medical Corporation
C/O Ms. Kaelyn B. Hadley
Consultant
1384 Copperfield Court
Lexington, Kentucky 40514

Re: K041779
Trade/Device Name: Nipro Disposable Stopcocks, Models 3W-RC, NCN-3, 3W-R, 3W-L
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FMG
Dated: June 30, 2004
Received: July 1, 2004

Dear Ms. Hadley:

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.

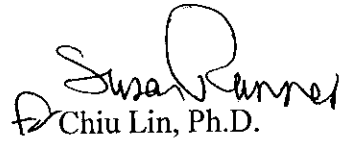
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4618. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
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): K041779

Device Name: Nipro Disposable Stopcocks

Indications For Use:
The Nipro Disposable Stopcocks are intended for use to change the direction of flow of fluids through a tubing set.

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

510(k) Number: K041779