K022756

OCT 1 8 2002

NIPRO

NIPRO MEDICAL CORPORATION
3150 N.W. 107 Avenue
Miami, Florida 33172
Tel.: (305) 599-7174
Fax: (305) 599-8454

## SUMMARY OF SAFETY AND EFFECTIVENESS
## NIPRO BIO-FLEX CATHETER

§807.92 (a)(1)

Contact Person: Luis Candelario
President

Date of Summary Preparation: August 16, 2002

§807.92 (a)(2)

Trade Name: Nipro Bio-Flex Catheter

Common Name: Intravascular catheter

Classification Name: Intravascular catheter (for short-term use) (§880.5200)

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Device:
Nipro Safelet Cath, Nipro Medical Corporation (K960051)

§807.92 (a)(4)

Description of Device:

The devices that we intend to market are intravascular catheters as described in 21 CFR 880.5200. These devices are similar to those already marketed by Nipro Medical Corporation under K960051.

Two types of catheters will be available: the container case types L (long) and S (short). Type L catheters have needles 1½ to 2½ inches long and Type S have needles ¾ to 1¼ inches long. Six gauges of catheters are described here (14, 16, 18, 20, 22, and 24 gauge). The tip of the cannula is beveled. The proximal end of the catheter has a filter cap.

K022756

§807.92 (a)(5)

Intended Use: The Nipro Safelet Cath is intended for use to be inserted into a patient's vascular system for short-term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously.

§807.92 (a)(6)

Comparison of Technical Characteristics:

The Nipro subject and predicate devices are very similar except for one material change discussed within this application. Performance tests demonstrated that the devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2002

Ms. Kaelyn B. Hadley
Consultant
Nipro Medical Corporation
1384 Copperfield Court
Lexington, Kentucky 40514-1268

Re: K022756
Trade/Device Name: Nipro® Bio-Flex Catheter
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: 80 FOZ
Dated: August 16, 2002
Received: August 20, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022756

## Indications for Use Statement

**510(k) number (if known):** K02----
**Device name:** Nipro® Bio-Flex Catheter
**Indications for use:** The Nipro® Bio-Flex Catheter is intended to be inserted into a patient's vascular system for short-term use to sample blood or administer fluids intravenously.

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

510(k) Number: 022756

(Do not write below this line- continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The- Counter-Use___
(Per 21 CFR 801.109) (optional Format 1-2-9 )