K060034

NIPRO MEDICAL CORPORATION
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FEB 2 8 2006

SUMMARY OF SAFETY AND EFFECTIVENESS
NIPRO HYDROPHILIC GUIDEWIRE

807.92 (a)(1)

Contact Person: Luis Candelario
President

Date of Summary Preparation: February 16, 2006

807.92 (a)(2)

Trade Name: Nipro Hydrophilic Guidewire
Common Name: Guidewire for Urological and Laparoscopic Use
Classification Name: Endoscope and Accessories (21 CFR 876.1500)
Urological Catheter and Accessories (21 CFR 876.5130)
Panel: 79

807.92 (a)(3)

Legally Marketed Substantially Equivalent Device:

Nipro Hydrophilic Guidewire (K001251)
Terumo Medical Corporation RadiFocus Guidewire (K926214, K923607)

807.92 (a)(4)

Description of Device:

The subject devices is contructed from a superelastic Nitinal core wire. A plastic cladding is applied over the core with a hydrophilic coating applied over that to provide a virtually frictionless surface when wet. The polymer cladding is impregnated with a radiopacive agent for enhanced contrast under fluoroscopy.

807.92 (a)(5)

Intended Use: The Nipro Hydrophilic Guidewires are designed for use in urological, laparoscopic, and radiological procedures where a smooth guidewire is desired to introduce/position catheters, direct and maintain access and be used to guide and exchange endoscopic accessories.

807.92 (a)(6)

Comparison of Technical Characteristics:

The Nipro subject device is either identical (K001251) or very similar to the predicate devices materials, design and technological characteristics, and indications for use. Performance, voluntary standards, and biocompatibility tests demonstrate that the devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2006

Nipro Medical Corporation
% Kaelyn B. Hadley, Ph.D.
Consultant
1384 Copperfield Court
LEXINGTON KY 40514

Re: K060034
Trade/Device Name: Nipro Hydrophilic Guidewire for Urological and Laparoscopic Use
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: KOG
Dated: January 5, 2006
Received: January 5, 2006

Dear Dr. 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 (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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/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 (if known): K060034

Device Name: Nipro Hydrophilic Guidewire for Urological and Laparoscopic Use

Indications For Use: The Nipro Hydrophilic Guidewires are designed for use in urological, laparoscopic, and radiological procedures where a smooth guidewire is desired to introduce/position catheters, direct and maintain access, and be used to guide and exchange endoscopic accessories.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (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 Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060034