SUMMARY OF SAFETY AND EFFECTIVENESS DATA

May 14, 2004

Submitted By: NuMED, Inc., 2880 Main St., Hopkinton, NY 12965 (Ph) 315-328-4491

Contact Person: Nichelle LaFlesh

Device Name: NuMED PTS X Catheter

Predicate Devices: NuMED PTS Catheter

Device Description: The NuMED, Inc. **PTS X™** Sizing Balloon catheter is a coaxial catheter for use in those patients with cardiovascular defects wherein accurate measurement of the defect is important to select the appropriately sized occluder device. The outer body is made of polymeric tubing, and the inner tubing is comprised of a multi layer extrusion of polyamide (Vestamid PA12) that surrounds a braid of 304 LV Stainless Steel. The catheter features a proximal end bifurcate with two distinct luminal passages. The inflation lumen terminates into a distally mounted balloon. This balloon is of the non-compliant variety and will have a typical single wall thickness of **0.0004"**. This balloon is designed to insert through the smallest possible introduction sleeve. The through lumen terminates at the tip of the catheter and will accept the passage of the appropriate guidewire. This lumen has radiopaque platinum marker bands under the balloon shoulders for placement using fluoroscopy. Additionally, there are two radiopaque platinum marker bands spaced at 10mm (as measured from leading edge to leading edge). These bands are located at the balloon center and are used as a distance reference. The catheter is white in color and the balloon material is clear. The catheter balloon diameter is stamped onto the Y sleeve and the balloon extension is labeled with balloon diameter x balloon length x introducer size x shaft size x usable length x guidewire size and the catheter lot number. The catheter is packaged in a polyethylene loop and is double packed in two heat sealed Tyvek pouches.

Biocompatibility Testing: The materials used in the NuMED PTS X Catheter are the same as those used in our other PTA Catheters (510(k) #K931009) and PTV Catheters (510(k) #K991977) which were tested for biocompatibility in compliance with the Tripartite Biocompatibility Guidance for Medical Devices. There have been no changes in material from the original PTS approval (K003320) except for the change to the inner tubing. The inner tubing has already been use in our other catheters and has been approved through 510(k) #022722. Test results indicate that all materials demonstrate the biocompatibility of the NuMED catheter and are on file at NuMED, Inc.

Laboratory (Bench) Testing: All bench testing was performed in accordance with GMP's and the results are kept on file at NuMED, Inc.

Intended Use: For use in those patients with cardiovascular defects wherein accurate measurement of the defect is important to select the appropriately sized occluder device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 0 2004

NuMED Inc.
c/o Ms. Nichelle LaFlesh
Regulatory Affairs Manager
2880 Main Street
Hopkinton, NY 12965

Re: K041306
NuMED PTS X Sizing Balloon Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Catheter, Intravascular Occluding, Temporary
Regulatory Class: Class II (two)
Product Code: MJN
Dated: May 14, 2004
Received: May 17, 2004

Dear Ms. LaFlesh:

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) 594-4648. 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041306

Device Name: **PTS X Catheter**

Indications For Use:

- For use in those patients with cardiovascular defects wherein accurate measurement of the defect is important to select the appropriately sized occluder device.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna P Lachmer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041306