SUMMARY OF SAFETY AND EFFECTIVENESS DATA

SEP 13 2002

August 14, 2002

Submitted By: NuMED, Inc. , 2880 Main St., Hopkinton, NY 12965 (Ph) 315-328-4491
(F) 315-328-4941

Contact Person: Nichelle LaFlesh

Device Name: Tyshak-X, Tyshak II-X, Z-MED-X, Z-MED II-X, Mullins-X

Predicate Devices: Tyshak, Tyshak II, Z-MED, Z-MED II, Mullins

Biocompatibility Testing: The only material that has changed is the material in the inner tubing. It has gone from being Pebax to Vestamid with stainless steel braiding. The testing that was done on this new material in enclosed in the biocompatibility section of this submission as well as the data for the other materials that have not changed.

Laboratory (Bench) Testing:

Bench Testing Performed	Acceptance Criteria
2. Balloon Deflatability	Deflation achieved in less than 20 seconds.
3. Inflation/ Deflation Times Test	Inflation and deflation achieved in less than 20 seconds.
5. Maximum Luminal Injection Pressure Test	Must withstand 400 psi.
6. Bond Integrity	Minimum of 2 lbs. at all test points.
7. Diameter/ Profile Test and Introducer Test	Must fit through rated introducer size.
9. Guidewire Compatibility	Minimal resistance while pushing catheter over guidewire. Force may not be great enough to bend guidewire.

Comparison Information:

Change Description:

The only change from the current catheter configuration to the new X line is the inner tubing configuration. The current inner tubing on all catheter models is composed of Pebax

polyamide material. The tubing is sized to accept a 0.035" guidewire and provide adequate guidewire movement and catheter trackability. This tubing is also fitted with radiopaque image bands of platinum/iridium. This tubing is common to all catheters in NuMED's product lines.

The proposed tubing is comprised of a multi layer extrusion of polyamide (Vestamid PA12) that surrounds a braid of 304 LV Stainless Steel. This tubing is loaded with 20% $BaSO_4$ and is Colored blue with Pantone 295C. All materials have been certified as biocompatible. This tubing is designed to enhance guidewire movement and also to avoid any stretching of the catheter body during a tougher than normal catheter removal.

Important Considerations:

The proposed inner tubing is a nylon (polyamide) tubing that is very similar to the current material. There will be no significant material changes in the tubing or the image bands. The only change will be the construction of the inner tubing in changing from a polyamide tubing to a braided polyamide tubing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2002

Numed, Inc.
c/o Ms. Nichelle R. LaFlesh
Regulatory Affairs Manager
P.O. Box 129
Nicholville, NY 12965

Re: K022722
Trade Name: PTA and PTV
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: August 15, 2002
Received: August 16, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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,

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

Enclosure

K022722

Indications For Use

510(k) Number (if known):

Device Names: Z-MED-X Catheter, Tyshak-X Catheter, Tyshak II-X Catheter, Z-MED II-X Catheter, and Mullins-X PTA Catheter

Indications For Use:

Z-MED-X Catheter - This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve.

- A patient with isolated pulmonary stenosis
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention. And;

This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. **These catheters are not designed to be used in the coronary arteries.**

Tyshak-X Catheter - This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve.

- A patient with isolated pulmonary stenosis
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention. And;

This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. **These catheters are not designed to be used in the coronary arteries.**

Tyshak II-X Catheter - This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve.

- A patient with isolated pulmonary stenosis
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention. And;

Z-MED II-X Catheter - This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve.

- A patient with isolated pulmonary stenosis
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention. And;

Mullins-X PTA - This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. **These catheters are not designed to be used in the coronary arteries.**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter-Use_____ (Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022722