SUMMARY OF SAFETY AND EFFECTIVENESS DATA

May 12, 2004

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

Device Name: All NuMED Catheters

Predicate Devices: All NuMED Catheters

Biocompatibility Testing: None of the materials have changed in any of these products, since the most current approval from the FDA.

Comparison Information: The current shelf life validation is for three years. Through the new validation and testing, NuMED would like to extend the shelf life to 5 years.

K003902 – Multi-Track Angiographic Catheter
K003972 – Ghost II PTA Catheter
K003643 – Z-MED Catheter
K003276 – Tyshak Mini Pediatric Catheter
K003114 – Tyshak and Z-MED Catheters
K003052 – Tyshak II and Z-MED II Catheters
K991977 – Tyshak and Z-MED PTV Catheters
K001804 – Z-5 Atrioseptostomy Catheters
K960070 – Z-5 Atrioseptostomy Catheters
K931009 – Tyshak, Z-MED, and Ghost PTA Catheters
K010880 – High Pressure Catheter (Marauder)
K952984 – Multi-Track Angiographic Catheter
K030589 – Tyshak II and Z-MED II Catheters
K032591 – Tyshak Mini Pediatric Catheter
K014124 – COEfficient PTV Catheter
K003320 – PTS Sizing Balloon Catheter
K013601 – Mullins PTA Catheter
K011557 – 'Y' Change Submission
K022722 – X line of Catheters (Tyshak X, Tyshak II X, Z-MED X, Z-MED II X, and Mullins X)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2009

Ms. Nichelle LaFlesh
Regulatory Affairs Manager
NuMED, Inc.
2880 Main St.
Hopkinton, NY 12965

Re: K040830
All NuMED Catheters
Regulation Number: 21 CFR 870.1200, 870.1250, 870.4450, and 870.5175
Regulation Name: Diagnostic Intravascular Catheter, Percutaneous Catheter, Vascular Clamp, Setostomy Catheter
Regulatory Class: Class II
Product Code: DQO, LIT, OMZ, DQY, MJN and DXF
Dated: June 2, 2004
Received: June 3, 2004

Dear Ms. LaFlesh:

This letter corrects our substantially equivalent letter of June 18, 2004.

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 (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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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): K040830

Device Names: Multi-Track Angiographic, Ghost II PTA, Ghost PTA, Z-MED, Z-MED II, Z-MED X, Z-MED II X, Tyshak, Tyshak X, Tyshak II, Tyshak II X, Tyshak Mini Pediatric PTV, Z-5 Atrioseptostomy, Z-5 Braided Atrioseptostomy, High Pressure PTA (Marauder), PTS, Mullins, Mullins X, and COEfficient.

Indications For Use:

Multi-Track Angiographic Catheter (K952984, K003902) - Recommended for use in catheterization for angiography of cardiovascular vessels and/or chambers. It can be used for injection of contrast medium and pressure measurement in any chamber or vessel.

Ghost II PTA (K003972, K011557) - 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.**

Z-MED Catheter (K991977, K003114, K003643, K011557) - 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;

(K931009, K011557) 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 Mini Pediatric PTV Catheter (K003276, K011557, K032591) - This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve in Pediatric applications.

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

Tyshak Catheter (K991977, K003114, K011557) - 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;

(K931009, K011557) 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 Catheter (K003052, K011557, K030589) - 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 Catheter (K003052, K011557, K030589) - 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;

High Pressure PTA (Marauder) (K010880, K011557) - 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.**

Z-5 Atrioseptostomy (K960070, K011557) - Used for the palliation of several congenital heart defects: transposition of the great arteries, total anomalous pulmonary venous drainage without pulmonary obstruction, tricuspid atresia, mitral stenosis, mitral atresia, and pulmonary atresia with intact ventricular septum.

Z-5 Braided Atrioseptostomy (K001804, K011557) - Used for the palliation of several congenital heart defects: transposition of the great arteries, total anomalous pulmonary venous drainage without pulmonary obstruction, tricuspid atresia, mitral stenosis, mitral atresia, and pulmonary atresia with intact ventricular septum.

Tyshak X Catheter (K022722) - 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.

Tyshak II X Catheter (K022722) - 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.

Z-MED X Catheter (K022722) - 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.

Z-MED II X Catheter (K022722) - 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.

COEfficient Catheter (K014124) - 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.

Ghost PTA (K931009, K011557) - 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.**

Mullins PTA (K013601) - 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.**

Mullins X PTA (K022722) - 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.**

PTS (K003320, K011557) - 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 R. Bochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040830

DRL 6/18/04