SECTION SIX: 510(K) Summary

A. Trade Name: NuMED, Inc. Tyshak™ PTV Catheter
Z-MED™ PTV Catheter

B. Common Name: PTV Catheter

C. Device Class: II, 74MAD; 21 CFR 870.1250

D. Predicate Devices: This catheter is the same as the approved NuMED Tyshak™, and Z-MED™ PTA Catheters, 510(K) 931009.

E. Description - The Tyshak™, and Z-MED™ PTV Catheters are coaxial over-the-wire catheters with a balloon near the distal tip. One lumen permits guidewire insertion to facilitate advancement of the catheter into the pulmonary valve while the other lumen is for balloon inflation and deflation.

The balloon of the Tyshak™, and Z-MED ™ models are all made of a non-compliant polyethylene, however the Z-MED™ balloon is manufactured with an increased wall thickness. The increased wall thickness allows the balloon to achieve a higher pressure before rupture occurs. The balloons are designed to inflate to a specific diameter at a given pressure. The change in diameter is minimal over the range of inflation pressures.

The catheter body ends proximally in a molded 'Y' connector with a guidewire port and a balloon extension. The balloon extension is marked with the product lot number and the balloon size.

The outer body and inner body tubing is made of pebax. The area under the balloon is enhanced with either one or two radiopaque platinum image bands depending on the model. If marked with one image band, it is centered under the midpoint of the balloon. If it is marked with two image bands, they are located under the shoulders of the balloon.

F. Indication - This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) for pulmonary applications.

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

G. Technological Characteristics – The technological characteristics for the PTV catheter are the same as the approved PTA catheter, because it is the same catheter with a different intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2000

Ms. Nichelle LaFlesh
Regulatory Affairs Manager
NuMed, Inc.
P.O. Box 129
Nicholville, NY 12965

Re: K991977
Trade Name: Tyshak™ PTV Catheter and Z-Med™ PTV Catheter
Regulatory Class: II (two)
Product Code: LIT
Dated: June 28, 2000
Received: June 29, 2000

Dear Ms. LaFlesh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K991977

Device Name: **NuMED, Inc. PTV Catheter**

Indications For Use:

This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) for pulmonary applications.

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

(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 Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K991977

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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