K050857
p.1 of 2

JUL 2 8 2005

Appendix D

510(k) Summary

General Provisions	**Trade Name**: BIB PTA Balloon Catheter **Classification Name:** Percutaneous Transluminal Angioplasty Catheter
Name of Predicate Device	Tyshak PTA Balloon Catheter (K931009) Z-Med PTA Balloon Catheter (K931009)
Classification	Class II
Performance Standards	Performance Standards have not been established by FDA under Section 514 of the Food, Drug and Cosmetic Act.
Intended Use	This device 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.

Continued on next page

510(k) 510(k) Summary, Continued

Device Description

The BIB PTA Catheter is This device 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. The BIB PTA Catheter has a tri-axial shaft design which allows for inflation of two balloons, one contained inside the other, and a guidewire lumen for placement inside the vasculature. Both balloons are identical to those currently marketed by NuMed on the Tyshak PTA and Z-Med PTA catheters. The balloons are non-compliant and include radiopaque platinum marker bands on the catheter shaft to facilitate placement of the device under fluoroscopy. The BIB catheter will be available in standard diameters from 8 mm to 24 mm for the outer balloon and 4 mm to 12 mm for the inner balloon. Balloon lengths of 1.5 cm to 5.5 cm will available. The device has an overall shaft length of 110 cm.

Biocompatibility

All materials used to manufacture the BIB PTA Balloon Catheter are available on other commercially available NuMed, Inc. devices (K931009) and have passed all relevant biocompatibility tests. No additional biocompatibility testing was conducted for the BIB PTA Balloon Catheter.

Summary of Safety and Effectiveness

The BIB PTA Balloon Catheter have been tested and compared to the predicate devices listed herein. All data gathered demonstrate the BIB PTA Catheter is substantially equivalent. No new issues of safety or efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2005

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

Re: K050857
BIB PTA Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: NVM
Dated: July 1, 2005
Received: July 5, 2005

Dear Ms. LaFlesh:

This letter corrects our substantially equivalent letter of July 28, 2005.

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear prominently as a boxed warning in the device's labeling immediately following the statement of the Indications for Use:

> The safety and effectiveness of this device for use as a stent delivery system in the placement of intravascular stents has not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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); 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 information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K050857

Device Name: BIB PTA Balloon Catheter

Indications For Use: This device is labeled for Percutaneous Transluminal Angioplasty (PTA) if the femoral, iliac and renal arteries. These catheters are not designed to be used in the coronary arteries.

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. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050857