K041093

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SUMMARY OF SAFETY AND EFFECTIVENESS DATA

April 23, 2004

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

Contact Person: Nichelle LaFlesh

Device Name: NuMED Mullins X PTA Catheter; 21 CFR 870.1250 – Percutaneous Catheter

Predicate Devices: NuMED Mullins X PTA Catheter

Device Description: The Mullins X™ catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac and renal arteries. The catheter is a coaxial over the wire catheter with a balloon near the distal tip. One lumen permits guidewire insertion to facilitate advancement of the catheter, while the other lumen is for balloon inflation and deflation.

The balloons of the MULLINS X™ PTA Catheter are made of a non-compliant polymeric material. The two laminate balloon system is designed to inflate to a specific diameter at a given pressure. The change in diameter is minimal over the range of inflation pressures. The balloons are heat bonded to the shaft.

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 area under the balloon is enhanced with five radiopaque platinum image bands. Two that are 5mm on each side of the balloon center and two more under the balloon shoulders. An additional image band is imbedded into the tip of the catheter as an additional safety measure.

The catheter is white in color and the balloon material is clear. The catheter balloon diameter and name 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 sheath and is double packed in two heat sealed Tyvek pouches.

Biocompatibility Testing:

The materials used in the NuMED Mullins PTA Catheter is 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 Mullins X approval (K022722).

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: 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.**

Comparison Information:

MODEL:	NUMED MULLINS X	NUMED MULLINS X – WITH THE ADDITIONAL SIZES
Indications:	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.**	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.**
Introducer:	9 Fr – 13 Fr	9 Fr – 16 Fr
Shaft Size:	7 Fr – 8 Fr	7 Fr – 9 Fr
Guidewire Size:	0.035"	0.035"
Usable Length:	100 cm	100 cm
Balloon Diameter:	12 mm – 20 mm	12 mm – 25 mm
Balloon Length:	3 cm – 4 cm	3 cm – 4 cm
Materials:	Shaft: Pebax Balloon: PES2 Image Band: Platinum	Shaft: Pebax Balloon: PES2 Image Band: Platinum
Construction:	Coaxial construction with distally mounted non-compliant balloons.	Coaxial construction with distally mounted non-compliant balloon.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2004

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

Re: K041093
NuMED Mullins X PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: Class II (two)
Product Code: DQY
Dated: April 23, 2004
Received: April 27, 2004

Dear Ms. LaFlesh:

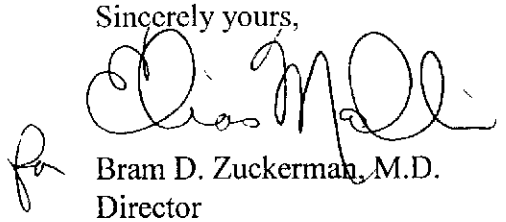
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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): K041093

Device Name: **Mullins X PTA Catheter**

Indications For Use:

- 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.**

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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041093