

K102473

Appendix D

DEC - 9 2010

510(k) Summary

General Provisions

Trade Name: Mullins-X PTV Catheter

Classification Name: Catheter, Percutaneous (Valvuloplasty)

Name of Predicate Device

Z-MED-X PTV Catheter – K022722

Classification

Class II, 21 CFR 870.1250 – Product Code OMZ

Performance Standards

Performance Standards have not been established by FDA under Section 514 of the Food, Drug and Cosmetic Act.

Intended Use

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.

Original Indication: Recommended for Percutaneous Transluminal 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.**

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510(k) Summary, Continued

Device Description	<p>The Mullins-X catheter is an Ultra High Pressure Dilatation catheter recommended for Percutaneous Transluminal Valvuloplasty of the Pulmonary Valve. The catheter is a coaxial over the wire catheter with a balloon near the distal tip. One lumen is for balloon inflation and deflation.</p> <p>The balloons of the Mullins-X 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.</p> <p>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 four radiopaque platinum image bands. Two are 5mm on each side of the balloon center and two more under the balloon shoulders.</p> <p>The catheter is white in color and the balloon material is clear. The catheter balloon diameter and name is stamped on 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.</p>
Biocompatibility	<p>All materials used to manufacture the Mullins-X Catheter are available on other commercially available NuMED, Inc. devices (K022722, K081680, and K014124) and have passed all relevant biocompatibility tests. No additional biocompatibility testing was conducted for the Mullins-X Balloon Catheter.</p>
In-Vitro Testing	<p>A complete list of tests performed and the results are provided in the table below.</p>

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Test Performed	Acceptance Criteria	Mullins-X Results	Predicate Device – Z-MED-X Results
Visual Inspection	The catheters shall be free from contamination, discoloration, and any form of damage that could impact the proper functioning of the device.	All catheters were visually inspected without any anomalies.	All catheters were visually inspected without any anomalies.
Balloon Preparation Test	Each catheter shall be prepped per the procedure without functional difficulties or anomalies.	All catheters tested were without functional difficulties or anomalies.	All catheters tested were without functional difficulties or anomalies.
Diameter and Profile Test	The balloon diameter at rated burst pressure shall be within +/- 10% of the labeled balloon diameter and the samples should fit through the selected introducer with no problems.	All catheters met the acceptance criteria.	All catheters met the acceptance criteria.
Balloon Distensibility	The results must demonstrate that the balloon diameter are within +/- 10% of the labeled diameter at the RBP and will not be significantly increased at increasingly higher pressures.	All data obtained demonstrates that the balloon diameter is within +/- 10% of the labeled diameter at the RBP. All data obtained demonstrates that the diameter of the balloons will not be significantly increased at increasingly higher pressures.	All data obtained demonstrates that the balloon diameter is within +/- 10% of the labeled diameter at the RBP. All data obtained demonstrates that the diameter of the balloons will not be significantly increased at increasingly higher pressures.
Balloon Minimum Burst Strength	The results must show statistically that with at least 95% confidence, 99.9% of the balloons will not burst at or below the maximum recommended rated burst pressure.	All catheters met the established acceptance criteria.	All catheters met the established acceptance criteria.
Repeated Balloon Inflation (Balloon Fatigue) Test	No breaks allowed	No Breaks.	No breaks.
Balloon Inflation/Deflation Test	Inflation achieved in less than 12 seconds and deflation achieved in less than 20 seconds	All catheters met the established acceptance criteria.	All catheters met the established acceptance criteria.

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Test Performed	Acceptance Criteria	Mullins-X Results	Predicate Device – Z-MED-X Results
Balloon Deflatability Test	There should be no interference with balloon deflation	All catheters met the established acceptance criteria.	All catheters met the established acceptance criteria.
Tip Pull and Torque Test	Must withstand at least 10 turns without breaking	No breaks	No breaks
Bond Strength Test	All bonds must withstand at least 3 lbs. of pull strength.	All bonds met the established acceptance criteria.	All bonds met the established acceptance criteria.
Catheter Body Maximum Pressure Test	All samples must withstand 30 ATM (400psi).	>30 ATM	> 400 psi

Summary of Safety and Effectiveness

The Mullins-X Catheter has been tested and compared to the predicate device listed herein. All data gathered demonstrate the Mullins-X Catheter is substantially equivalent. No new issues of safety or efficacy have been raised.

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Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

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

DEC - 9 2010

Re: K102473
Mullins-X PTV Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: OMZ
Dated: December 6, 2010
Received: December 7, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

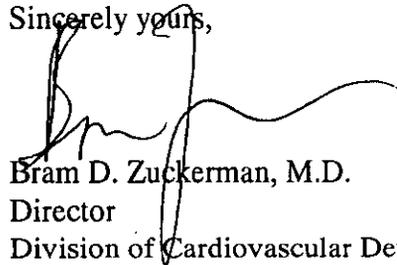
Page 2 - Nichelle LaFlesh, RAC

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Enclosure

Appendix E

Indications for Use

510(k) Number (if known): K102473

DEC - 9 2010

Device Name: **Mullins-X Catheter**

Indications For Use:

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.

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.**

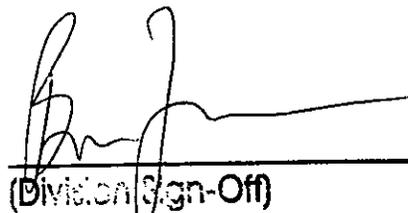
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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

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