K122012

OCT 4 2012

Appendix D

510K Summary of Safety & Effectiveness

General Provisions	**Trade Name**: Z-MED and Z-MED II Catheters **Classification Name:** Balloon Aortic Valvuloplasty Catheters
Name of Predicate Device	NuCLEUS-X Catheter (K082776) NuCLEUS Catheter (K082776)
Classification	Class II, 21 CFR 870.1255
Performance Standards	Performance Standards have not been established by FDA under Section 514 of the Food, Drug and Cosmetic Act.
Intended Use	Balloon Aortic Valvuloplasty

Continued on next page

Summary of Safety & Effectiveness, Continued

Device Description

The NuMED Z-MED™ catheter is a coaxial catheter recommended for Balloon Aortic Valvuloplasty. The catheter's inner and outer shafts are constructed of polyamide tubing. The catheter features a molded proximal end bifurcate with two distinct luminal passages. The inflation lumen terminates into a distally mounted balloon made of polyamide. This balloon is of the non-compliant variety. Both the shaft size and the guidewire size vary according to balloon diameter. The distal lumen terminates at the tip of the catheter and will accept the passage of the appropriate guidewire. The lumen has radiopaque platinum marker band(s), centered or under the balloon shoulders, for placement using fluoroscopy. 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 the catheter specifications and lot number. The catheter is packaged in a polyethylene sheath and is double packed in two heat sealed Tyvek pouches.

The NuMED Z-MED II™ catheter is a coaxial catheter recommended for Balloon Aortic Valvuloplasty. The catheter's inner and outer shafts are constructed of polyamide tubing. The catheter features a molded proximal end bifurcate with two distinct luminal passages. The inflation lumen terminates into a distally mounted balloon made of polyamide. This balloon is of the non-compliant variety. Both the shaft size and the guidewire size vary according to balloon diameter. The distal lumen terminates at the tip of the catheter and will accept the passage of the appropriate guidewire. The lumen has radiopaque platinum marker band(s), centered or under the balloon shoulders, for placement using fluoroscopy. 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 the catheter specifications and lot number. The catheter is packaged in a polyethylene sheath and is double packed in two heat sealed Tyvek pouches.

Biocompatibility

All materials used to manufacture the Z-MED and Z-MED II Catheters 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 Z-MED and Z-MED II Catheters.

In-Vitro Testing

In-Vitro testing was completed on the Z-MED and Z-MED II catheters for their original 510(k) submissions (K991977 and K003052). No additional testing was completed for the expanded indication because both indications are for valvuloplasty. A complete list of tests performed and the results are provided in the table below.

Test Performed	Acceptance Criteria	Z-MED Results	Z-MED II Results	NuCLEUS-X Results	NuCLEUS 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.	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.	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.	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.	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	2 x 1 – 10 ATM 2 x 15 – 10 ATM 3mm – 10 ATM 4mm – 10 ATM 5mm – 10 ATM 6mm – 10 ATM 7mm – 10 ATM 8mm – 10 ATM 9mm – 10 ATM 10mm – 9 ATM 11mm – 7 ATM 12mm – 7 ATM	4 x 2 – 15 ATM 4 x 6 – 15 ATM 4 x 10 – 15 ATM 5 x 2 – 15 ATM 6 x 2 – 15 ATM 7 x 2 – 15 ATM 8 x 2 – 15 ATM 9 x 2 – 14 ATM 10 x 2 – 13 ATM 11 x 2 – 10 ATM	18 x 4 – 4 ATM 18 x 6 – 4 ATM 20 x 4 – 4 ATM 22 x 4 – 3 ATM 25 x 4 – 3 ATM 28 x 4 – 2 ATM 30 x 4 – 2 ATM 30 x 6 – 2 ATM	10 x 3 – 9 ATM 10 x 6 – 9 ATM 12 x 4 – 7 ATM 14 x 4 – 6 ATM 16 x 4 – 5 ATM 18 x 4 – 4 ATM 20 x 4 – 4 ATM 22 x 4 – 3 ATM 25 x 4 – 3 ATM 28 x 4 – 2 ATM

Test Performed	Acceptance Criteria	Z-MED Results	Z-MED II Results	NuCLEUS-X Results	NuCLEUS Results
	rated burst pressure.	13mm – 6 ATM 14mm – 6 ATM 15mm – 5 ATM 16mm – 5 ATM 17mm – 4 ATM 18mm – 4 ATM 19mm – 4 ATM 20mm – 4 ATM 22mm – 3 ATM 23mm – 3 ATM 24mm – 3 ATM 25mm – 3 ATM 26mm – 3 ATM 28mm – 2 ATM 30 x 2 – 2 ATM 30 x 6 – 2 ATM 33mm – 1.5 ATM 35mm – 1..5 ATM 40 x 4 – 1 ATM 40 x 6 – 1 ATM	12 x 3 – 10 ATM 13 x 4 – 10 ATM 14 x 3 – 10 ATM 15 x 3 – 8 ATM 16 x 3 – 8 ATM 17 x 4 – 7 ATM 18 x 3 – 7 ATM 20 x 3 – 5 ATM 22 x 3 – 4 ATM 23 x 3 – 4 ATM 25 x 3 – 4 ATM 25 x 6 – 4 ATM 26 x 2 – 4 ATM 28 x 2 – 3.5 ATM 30 x 2 – 3 ATM 30 x 6 – 3 ATM 30 x 10 – 3 ATM		30 x 4 – 2 ATM 30 x 6 – 2 ATM
Repeated Balloon Inflation (Balloon Fatigue) Test	No breaks allowed	No Breaks.	No Breaks.	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.	All catheters met the established acceptance criteria.	All catheters met the established acceptance criteria.
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.	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	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.	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	>30 ATM	>30 ATM	>30 ATM

In Vivo Evaluation

A Clinical Evaluation Report was prepared for the Z-MED and Z-MED II Catheters for this new indication of balloon aortic valvuloplasty (BAV). This Clinical Evaluation Report was compiled to meet the requirements of the Medical Device Directive MOD 93/42/EEC, as amended, and establish the safety and performance of the device, as well as a review of Clinical Literature. The report also includes the history of the device, previous sales and complaints reported.

The information included in the 2012 clinical evaluation report also describes the clinical use of the Z-MED and Z-MED II catheters in those countries where they are used in balloon aortic valvuloplasty (BAV) and balloon mitral valvuloplasty (BMV), as well as for balloon pulmonary valvuloplasty (BPV) here in the United States. Numerous clinical studies reported in literature for Transcutaneous Aortic Valve Implant (TAVI) replacement surgery reference the use of the Z-MED and Z-MED II catheters for BAV prior to TAVI (over 200 patients) without incidents or adverse events.

The totality of this information provides further validation for the use of the Z-MED and Z-MED II catheters for balloon aortic valvuloplasty.

Summary of Safety and Effectiveness

The NuCLEUS-X Catheter has been tested and compared to the predicate devices listed herein. All data gathered demonstrate the NuCLEUS-X 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 4 2012

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

Re: K122012
Z-MED and Z-MED II Catheters
Regulation Number: 21 CFR 870.1255
Regulation Name: Balloon Aortic Valvuloplasty Catheters
Regulatory Class: Class II
Product Code: OZT
Dated: July 9, 2012
Received: July 10, 2012

Dear Mr. 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.

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,

for 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): K122012

Device Name: **Z-MED and Z-MED II Catheters**

Indications For Use:

Balloon Aortic Valvuloplasty

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 K122012