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

JUN 1 1 2012

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

Re: K082776
NuCLEUS and NuCLEUS-X BAV Catheters
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 870.1255
Regulation Name: Balloon Aortic Valvuloplasty Catheter
Regulatory Classification: Class II
Product Code: OZT
Dated: December 23, 2008
Received: December 24, 2008

Dear Ms. LaFlesh:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Evaluation of Automatic Class III Designation Petition (de novo) for classification of the NuMED NuCLEUS and NuCLEUS-X BAV Catheters, prescription devices under 21 CFR Part 801.109 that are indicated for balloon aortic valvuloplasty. FDA concludes that these devices, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the NuCLEUS and NuCLEUS-X BAV Catheters, and substantially equivalent devices of this generic type, into class II under the generic name, balloon aortic valvuloplasty catheter.

FDA identifies this generic type of device as: A balloon aortic valvuloplasty catheter is a catheter with a balloon at the distal end of the shaft which is intended to treat stenosis in the aortic valve when the balloon is expanded.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the FD&C Act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval,

unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act (21 U.S.C. 360c (i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on December 3, 2008 automatically classifying the NuCLEUS-X PTV Catheter in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On January 14, 2009, FDA filed your petition requesting classification of the NuCLEUS and NuCLEUS-X BAV Catheters into class II. The petition was submitted under section 513(f)(2) of the FD&C Act. In order to classify the NuCLEUS and NuCLEUS-X BAV Catheters into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the petition, FDA has determined that the NuCLEUS and NuCLEUS-X BAV Catheters indicated for balloon aortic valvuloplasty can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type.

Table - Potential Risks and Mitigations

Identified Potential Risk	**Recommended Mitigation Measure**
Adverse Tissue Reaction	Biocompatibility Testing Labeling
Infection	Sterility Shelf Life Testing
User Error	Labeling
Valve Leaflet Perforation	Non-clinical Performance Evaluation In Vivo Evaluation Labeling

Perforation of Vascular or Cardiac Tissue	Non-clinical Performance Evaluation In Vivo Evaluation Labeling
Procedural Complications, including Bleeding, Cardiac Tamponade, Calcium Embolic Events, Valvular Regurgitation and Death	Non-clinical Performance Evaluation In Vivo Evaluation Labeling
Balloon Burst	Non-clinical Performance Evaluation In Vivo Evaluation Labeling
Inability for Balloon Deflation	Non-clinical Performance Evaluation In Vivo Evaluation
Increased Balloon Inflation and Deflation Times	Non-clinical Performance Evaluation In Vivo Evaluation Labeling
Inability to Steer Toward Valve of Interest	Non-clinical Performance Evaluation In Vivo Evaluation

In addition to the general controls of the FD&C Act, the Balloon Aortic Valvuloplasty Catheter is subject to the following special controls: (1) The device should be demonstrated to be biocompatible; (2) Sterility and shelf life testing should demonstrate the sterility of patient-contacting components and the shelf-life of these components; (3) Non-clinical performance evaluation of the device should demonstrate substantial equivalence in terms of safety and effectiveness for device delivery, inflation, deflation, and removal; (4) In vivo evaluation of the device should demonstrate device performance, including the ability of the device to treat aortic stenosis; and (5) Labeling must include a detailed summary of the device-related and procedure-related complications pertinent to use of the device.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the balloon aortic valvuloplasty catheter they intend to market prior to marketing the device and receive clearance to market from FDA.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the de novo, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Albert E. Moyal at (301) 796-6333.

Sincerely yours,

Jonette Foy, Ph.D.
Deputy Director
for Science and Regulatory Policy
Office of Device Evaluation
Center for Devices and
Radiological Health