



Food and Drug Administration  
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June 20, 2016

NuMED, Inc.  
Nichelle LaFlesh  
Regulatory Affairs Manager/ Compliance Officer  
2880 Main Street  
Hopkinton, New York 12965

Re: K160598  
Trade/Device Name: REBOA Catheter  
Regulation Number: 21 CFR 870.4450  
Regulation Name: Vascular Clamp  
Regulatory Class: Class II  
Product Code: MJN  
Dated: May 17, 2016  
Received: May 19, 2016

Dear Nichelle 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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 -S**

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)

K160598

Device Name

REBOA Catheter

Indications for Use (Describe)

Recommended for temporary occlusion of the aorta.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**K160598****510(k) Summary****Contact Information**

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NuMED, Inc.  
2880 Main Street  
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Telephone – (315) 328-4491  
Contact Person: Nichelle LaFlesh, RAC  
Date summary was prepared – 29 April 2016

**General Provisions**

**Trade Name:** REBOA Catheter

**Common Name:** Catheter, Intravascular Occluding, Temporary

**Classification Name:** Catheter, Intravascular Occluding, Temporary

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**Name of Predicate Devices**

PTS-X PTV Catheter – K041306, K110903, and K131869  
Class II, 21 CFR 870.4450 – Product Code MJN

Fogarty Occlusion Catheter – K152762 and K093911  
Class II, 21 CFR 870.4450 – Product Code MJN

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**Classification**

Class II, 21 CFR 870.4450 – Product Code MJN

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**Performance Standards**

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

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**Intended Use**

Recommended for temporary occlusion of the aorta.

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## 510(k) Summary, Continued

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**Device Description**

The REBOA Balloon Occlusion Catheter is a coaxial catheter recommended for temporary occlusion of the aorta. 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 catheter features a proximal end bifurcate with two distinct luminal passages. The inflation lumen terminates into a distally mounted balloon. This balloon is of the non-compliant variety and is designed to insert through the smallest possible introduction sleeve. The through lumen terminates at the tip of the catheter, and will accept the passage of the appropriate guidewire. All catheter sizes will have radiopaque platinum marker band(s), centered or under the balloon shoulders, for placement using fluoroscopy. There are also markings on the catheter shaft to aid in placement. The catheter is packaged in a polyethylene loop and is double packed in two heat sealed Tyvek pouches.

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**Biocompatibility**

All materials used to manufacture the REBOA Catheter are available on other commercially available NuMED, Inc. devices (K041360, K022722, K081680, and K014124) and have passed all relevant biocompatibility tests. No additional biocompatibility testing was conducted for the REBOA Catheter.

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**In-Vitro Testing**

A complete list of tests performed and the results are provided in the table below.

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<b>Test Performed</b>	<b>Acceptance Criteria</b>	<b>REBOA Results</b>	<b>Predicate Device – PTS-X Results</b>
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 / volume 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 / rated volume 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 rated volume. 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.

<b>Test Performed</b>	<b>Acceptance Criteria</b>	<b>REBOA Results</b>	<b>Predicate Device – PTS-X Results</b>
Balloon Minimum Burst Strength / Volume	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 / volume.	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 59 seconds	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.
Tip Pull and Torque Test	Must withstand at least 8 turns without breaking	No breaks	No breaks
Bond Strength Test	All bonds must withstand at least 8.9 Newtons / 2 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 700 psi.	All samples met the established acceptance criteria.	All samples met the established acceptance criteria.

**Comparison of Technological Characteristics with the predicate Device**

The technological characteristics of the REBOA balloon are identical to those in the predicate (PTS-X) in terms of the following:

- Mode of Operation;
- Materials;
- Design;
- Performance testing;
- Method of delivery;
- Sterilization Method;
- Packaging Method.

The technological characteristics of the REBOA balloon is substantially equivalent in intended use, indications for use, sterilization, and size range to those in the predicate device (Fogarty).

Both devices are for temporary vessel occlusion. The REBOA is specific to the aorta, whereas, the larger Fogarty balloon catheters are for the aorta. The Fogarty balloon catheter has a broader indications for use than the REBOA.

Both devices are provided sterilized via EtO sterilization and are for single use only.

Both devices are catheters with distal end balloons that are inserted percutaneously.

Both devices are similar in the size ranges being offered. The REBOA catheter is available in balloon diameters of 15mm – 40mm, and the Fogarty larger balloon catheters are available in sizes of 11mm – 45mm.

**Conclusions**

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

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