DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 20, 2016

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

Re: K160889
Trade/Device Name: BiB Stent Placement Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NVM
Dated: March 30, 2016
Received: March 31, 2016

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.

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,

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

Enclosure

Appendix C

Indications for Use

510(k) Number (if known): K160889

Device Name: **BIB Stent Placement Catheter**

Indications For Use:

Indicated for CP Stent / Covered CP Stent placement in vessels over 8mm in diameter.

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)

510(k) Summary

Date Prepared May 17, 2016

Submitter

NuMED, Inc.
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Hopkinton, NY 12965
Telephone – (315) 328-4491
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Contact – Nichelle LaFlesh, RAC
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Device

Trade Name: BIB Stent Placement Catheter
Common Name: Catheter, Percutaneous

Classification Name: Catheter, Percutaneous
Class II, 21 CFR 870.1250 – Product Code NVM

Predicate Device

BIB PTA Catheter, Model 420– K050857

Device Description

The NuMED BIB® Stent Placement Catheter Model 420 is indicated for CP Stent / Covered CP Stent placement in vessels over 8mm in diameter. The catheter is triaxial in construction with two lumens being used to inflate the balloons while one lumen is being used for tracking over a guidewire. The purpose of the double balloon catheter is to apply an incremental inflation for the purpose of dilating a stent. The inner balloon provides initial expansion of the stent and also acts as a tool to hold the stent on the catheter prior to the outer balloon being inflated. The outer balloon is then inflated providing the remainder of the expansion. There are radiopaque platinum marker bands under the balloon shoulders for placement using fluoroscopy. The balloon material is clear. The catheter balloon diameters are stamped onto the inflation extensions and are labeled with balloon diameter x balloon length and the catheter lot number.

Indications for Use

Indicated for CP Stent / Covered CP Stent placement in vessels over 8mm in diameter.

Comparison of Technological Characteristics

The BiB Stent Placement Catheter is identical to the predicate in design, materials and technological characteristics. A new indication for use is being

with the predicate Device	added to allow the use of the BiB Catheter for placement of the CP stent within a vessel.

Performance Data

In Vitro Testing

Bench and biocompatibility testing of the BIB Stent Placement Catheter was leveraged from testing previously completed under K050857 and P150028. Under K050857, *in vitro* testing was completed using the BIB PTA Catheter alone. Under P150028, *in vitro* testing was completed using the BIB PTA Catheter along with the CP stent. Leveraged bench testing included the following:

- Visual inspection
- Balloon Preparation Test
- Diameter and Profile Test
- Balloon Distensibility
- Balloon Minimum Burst Strength / Volume
- Repeated Balloon Inflation (Balloon Fatigue) Test
- Balloon Inflation/Deflation Test
- Balloon Deflatability Test
- Tip Pull and Torque Test
- Bond Strength Test
- Catheter Body Maximum Pressure Test

Leveraged biocompatibility testing included the following:

- Cytotoxicity (L929)
- Sensitization (ISO Guinea Pig Maximization Test)
- Irritation (ISO Rabbit Intracutaneous Reactivity)
- Systemic Toxicity (ISO Mouse Systemic Injection)
- Material-Mediated Pyrogenicity (USP Rabbit Pyrogenicity)
- Hemocompatibility (Hemolysis)

Clinical

The COAST trial was a prospective, multi-center, single arm study to evaluate the NuMed CP stent for the treatment of coarctation of the aorta (approved under P150028). The NuMED BIB® Stent Placement Catheter was used in the COAST trial to place the CP Stent during the implant procedure. The primary safety endpoints were the rate of serious adverse events within 30 days of the procedure and the rate of post-procedure paradoxical hypertension. The primary effectiveness endpoints were the reduction in arm-leg systolic blood pressure gradient from baseline to 12 months and

length of hospital stay. A total of 112 patients were enrolled in the study. The rate of serious adverse events within 30 days of the procedure was 8.9% and the rate of post-procedure paradoxical hypertension was 7.5%. The reduction of arm-leg systolic blood pressure gradient at 12 months was 30 ±22mmHg and the length of hospital stay was 1.1±0.3 days. The results demonstrated that the CP Stent could be successfully mounted and implanted using the BiB Stent Placement Catheter with an acceptable rate of procedure-related adverse events and clinically acceptable systolic blood pressure gradients.

Conclusions

The BIB Stent Placement Catheter has been tested and compared to the predicate device, the BIB PTA Balloon Catheter (K050857). All nonclinical and clinical data gathered demonstrate the BIB Stent Placement Catheter is substantially equivalent to the BIB PTA Catheter.