October 20, 2017

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

Re: K171206
Trade/Device Name: D'Vill Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: September 15, 2017
Received: September 18, 2017

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 (DICE) 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 (DICE) 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,

Kenneth J. Cavanaugh -S

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171206

Device Name
D'Vill Introducer

Indications for Use *(Describe)*
Recommended for introduction of balloons, catheters and other diagnostic and interventional devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K171206

510(k) Summary

Contact Information	NuMED, Inc. 2880 Main Street Hopkinton, NY 12965 Telephone – (315) 328-4491 Contact Person: Nichelle LaFlesh, RAC Date summary was prepared – 21 April 2017
General Provisions	**Trade Name**: D'Vill Introducer **Common Name:** Catheter, Introducer **Classification Name:** Catheter, Introducer
Name of Predicate Devices	Gore Dryseal Introducer Sheath – K160254, K121234 Class II, 21 CFR 870.1340 – Product Code DYB
Classification	Class II, 21 CFR 870.1340 – Product Code DYB, Cardiovascular Panel
510(K) Type and Reason for Submission	Traditional 510(K) to obtain marketing clearance for the D'Vill Introducer.
Intended Use	Recommended for introduction of balloons, catheters and other diagnostic and interventional devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.

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510(k) Summary, Continued

Device Description

The NuMED D'VILL Introducer is recommended for introduction of balloons, catheters and other diagnostic and interventional devices. The introducer consists of a dilator, and sheath with hemostasis valve and side port on the proximal end of the sheath assembly. There is a single image band embedded in the distal end of the sheath tubing for imaging purposes. The sheath is Pebax braided with stainless steel and a PTFE liner and will accommodate a 0.035" guidewire. The dilator is LDPE. The D'VILL is available in 10, 12 and 14F sizes and 30 and 85cm lengths.

Biocompatibility

All materials used to manufacture the D'Vill Sheath are similar to those used on other commercially available devices. The biocompatibility for the D'Vill Sheath and Dilator was assessed through a combination of testing and a risk assessment.

Performance Testing

A complete list of tests performed are provided below. All tests met their acceptance criteria and specifications.

- Surface Inspection
- Size Designation – Sheath and Dilator
- Freedom from Leakage – Sheath and Hemostasis Valve
- Peak Tensile Force – 3 locations
- Strength of Union Between Hub and Dilator
- Dimensional Requirements – Sheath, Stopcock, and Dilator
- Luer Hub Testing
- Kink/Flexibility Testing – Sheath and Dilator
- Sterilization Testing
- Biocompatibility Evaluation – Short duration contact with circulating blood (< 24 hours)
- Shelf Life Testing

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Comparison of Technological Characteristics with the predicate Device

The technological characteristics of the D'Vill Introducer are similar to those in the predicate in terms of the following:

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

The technological characteristics of the D'Vill Introducer is substantially equivalent in intended use, sterilization, and size range to those in the predicate device.

Both devices are for introduction of devices into the patient. The predicate device is specific to endovascular devices, whereas, the D'Vill Introducers are for interventional devices.

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

Both devices include a sheath as well as a dilator. The predicate device also has a syringe that comes with it, whereas, the D'Vill does not.

Both devices are similar in the size ranges being offered. The D'Vill includes 10Fr – 14Fr sizes, and the predicate device has a much larger size range of 12Fr – 26Fr.

Conclusions

The D'Vill Introducer has been tested and/or compared to the predicate device listed herein. All data gathered demonstrate the D'Vill Introducer is substantially equivalent.