May 14, 2019

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

Re: K190974
Trade/Device Name: D'Vill Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: April 12, 2019
Received: April 15, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Kenneth Cavanaugh
Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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)*
K190974

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K190974

Contact Information	NuMED, Inc. 2880 Main Street Hopkinton, NY 12965 Telephone – (315) 328-4491 Contact Person: Nichelle LaFlesh, RAC Date summary was prepared – 05 April 2019
General Provisions	**Trade Name**: D'Vill Introducer **Common Name:** Catheter, Introducer **Classification Name:** Catheter, Introducer
Name of Predicate Devices	D'VILL Introducer – K171206 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	Special 510(K) to obtain marketing clearance for the additional size of D'Vill Introducer in the 65cm length.
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.

510(k) Summary K190974

Device Description

The NuMED D'VILL Introducer is 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. 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 in both 30 and 85cm lengths, as well as, 12 and 14F in a 65 cm length.

Comparison of Technological Characteristics with the predicate Device

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

- Mode of Operation;
- Materials;
- Design;
- Method of delivery / packaging;
- Sterilization Method;
- Intended Use.

This is the same device design as the predicate. This 510(k) is for a new size that falls in between the previously cleared sizes.

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
- Kink / Flexibility
- Luer Testing (stress cracking, resistance to separation and overriding)

Bio-compatibility

All materials used to manufacture the new size of D'Vill Introducer are identical to the predicate device. There have been no changes to the materials or the processing / manufacturing of the device.

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