PREMARKET NOTIFICATION
510(k) SUMMARY
(As Required By 21 CFR §807.92)

JUL 3 0 2014

510k number: K141026

Applicant:
Vygon Corporation
2750 Morris Road, Suite A200
Lansdale, PA 19446

Contact Name:
Jillian Mikovich
Regulatory Affairs Manager
Phone: 800-473-5414
Fax: 215-672-6740

Trade Name: Leaderflex
Common Name: Intravascular Catheter
Regulation Number: 21 CFR 880.5200
Product Code: FOZ
Classification Name: Catheter, Intravascular, Therapeutic, Short-term Less than 30 days
Regulatory Class: Class II
Predicate Devices: Vygon Leaderflex, K052564
Bard Powerglide Midline Catheter, K121073
Bard Poly Per-Q-Cath Midline, K001901
Date Prepared: April 21, 2014

Device Description: Leaderflex is a radiopaque biostable polyurethane catheter suitable for a variety of venous and arterial applications. Leaderflex is inserted via Seldinger technique.

Intended Use: Leaderflex catheters are indicated for:

- Arterial catheterization in adults
- Central venous catheterization (jugular, subclavian) in children
- Peripheral venous catheterization (Midline) in any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure

Technology Characteristics: Leaderflex is identical to the legally marketed Vygon predicate device. The subject device shares the midline indication with both the Bard Powerglide and Poly Per-Q-Cath Midline catherters.

Non-Clinical Summary: The subject device is completely identical to the Vygon predicate and shares a common indication with both Bard predicates. A risk analysis has been completed to show that the safety and effectiveness of the device has not been altered with the addition of the midline indication.

Given the above, the subject device, using Vygon Leader-Flex, Bard Powerglide Midline and Bard Poly Per-Q-Cath Midline as the predicate devices, meets regulatory requirements for demonstration of substantial equivalence (see Premarket Notification Review Program 6/30/86 (K86-3) FDA blue book memorandum, "Guidance on the CDRH Premarket Notification Review Program").

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

July 30, 2014

Vygon Corporation
Jillian Mikovich
Regulatory Affairs Manager
2750 Morris Road, Suite A200
Lansdale, PA 19446

Re: K141026
Trade/Device Name: Leaderflex
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular catheter
Regulatory Class: II
Product Code: FOZ
Dated: July 17, 2014
Received: July 18, 2014

Dear Ms. Mikovich:

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" (21CFR 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,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141026

Device Name
Leaderflex

Indications for Use *(Describe)*
Leaderflex catheters are indicated for:

- Arterial catheterization in adults
- Central venous catheterization (jugular, subclavian) in children
- Peripheral venous catheterization (Midline) in any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman -S
Date: 2014.07.29 12:37:10 -04'00'

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

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