August 29, 2022

Vygon USA
Jay Wigley
Regulatory Affairs Manager
2750 Morris Rd Suite A200
Lansdale, Pennsylvania 19446

Re: K212370
Trade/Device Name: Leaderflex Mini and Leaderflex Nano
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: May 26, 2022
Received: May 31, 2022

Dear Jay Wigley :

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Wolloscheck, Ph.D.
For Payal Patel
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212370

Device Name
Leaderflex Mini and Leaderflex Nano

Indications for Use *(Describe)*
Leaderflex mini and Leaderflex nano are indicated for:
•Peripheral venous catheterization (midline) in any patient population with consideration given to the adequacy of vascular anatomy and appropriateness of procedure, or
•Arterial catheterization

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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K212370 510(k) Summary

5.1. Applicant:

Vygon USA
2750 Morris Road
Suite A200
Lansdale, PA US 19446

5.2. Sponsor Contact Person:

Jay Wigley
Contractor, acting as Regulatory Manager
Vygon USA
2750 Morris Road Suite A200
Lansdale, PA US 19446
(865) 824-6355
Email: jayw@maegroups.com

5.3. Regulatory Correspondent/ 510(k) Submission Contact:

Same as above

5.4. Date Prepared: August 26, 2022

5.5. Device Information:

Trade Name	Leaderflex Mini and Leaderflex Nano
Product Code	FOZ
Common Name	Short-Term Less Than 30 Days Therapeutic Intravascular Catheter
Classification	Class II
Regulation	21 CFR 880.5200 – Intravascular catheter

5.6. Predicate Device:

Leaderflex (K141026)

5.7. Submission Purpose:

The purpose of this 510(k) submission is to implement design changes to the predicate Leaderflex (K141026) to create a product line extension: Leaderflex Mini and Leaderflex Nano

with additional working diameters and lengths to encompass different configurations of Leaderflex models along with associated accessories- guidewire and needle. These modifications to the Leaderflex do not change the indications for use of the device, nor do they change the fundamental scientific technology of the device.

5.8. Device Description:

Leaderflex Mini and Leaderflex Nano are a radiopaque biostable polyurethane catheters suitable for peripheral venous catheterization (midline) in any patient population with consideration given to the adequacy of vascular anatomy and appropriateness of procedure. Leaderflex Mini and Leaderflex Nano catheters are inserted via Seldinger technique, same as the predicate device. The Leaderflex mini and Leaderflex nano catheters are intended to be used by clinicians such as nurses at in- and out-patient locations. The primary requirement for environment of use is to ensure the environment is appropriate for supporting aseptic technique. These catheters are typically inserted into a peripheral vein on the forearm or leg, with the catheter tip located below the axilla of the arm or below the groin of the leg; however, the catheter is not limited to these anatomical placement locations. This is the same environment of use and anatomical location as the predicate device.

The subject Leaderflex Mini and Leaderflex Nano devices are accompanied by compatible accessories necessary to perform the Seldinger technique; these include: an introducer needle, guidewire, and guidewire insertion aid. The predicate Leaderflex device (K141026) is currently available in 22G configurations with usable lengths of 4cm, 6cm, 8cm and 20cm. The subject device will extend the device configurations to include 24G (Leaderflex Mini) and 26G catheters (Leaderflex Nano) with usable lengths of 2cm, 3cm, and 4cm and will add introducer needle and guidewires.

The subject device also introduces a new guidewire insertion aid for all gauge sizes. The overall device description of the subject and predicate Leaderflex models is the same.

The proposed device models are detailed below:

Product Code	Model	Catheter Usable Length (cm)	Gauge	Diameter OD, ID (mm)	Flow Rate (ml/min)	Guidewire Length (cm)
VYLFM1002	Mini	2	24G	0.73, 0.53	17ml/min	23
VYLFM1003	Mini	3	24G	0.73, 0.53	16ml/min	23
VYLFM1004	Mini	4	24G	0.73, 0.53	15ml/min	23
VYLFN1002	Nano	2	26G	0.51, 0.33	5ml/min	25
VYLFN1003	Nano	3	26G	0.51, 0.33	4ml/min	25

Product Code	Model	Catheter Usable Length (cm)	Gauge	Diameter OD, ID (mm)	Flow Rate (ml/min)	Guidewire Length (cm)
VYLFN1004	Nano	4	26G	0.51, 0.33	3ml/min	25

The Leaderflex Mini and Leaderflex Nano are single use and provided sterile, via ethylene oxide sterilization according to ISO 11135.

5.9. Indication for Use:

Leaderflex mini and Leaderflex nano are indicated for:

- Peripheral venous catheterization (midline) in any patient population with consideration given to the adequacy of vascular anatomy and appropriateness of procedure, or
- Arterial catheterization

5.10. Comparison of Technological Characteristics:

The table below includes a comparison of technological characteristics between the new devices and those of the predicate device:

Comparative Characteristics	**Proposed Device:** Leaderflex Mini and Leaderflex Nano	**Predicate Device:** Leaderflex	**Comments:**
510(k) Number	K212370	K141026	
Indication for Use	Leaderflex Mini and Leaderflex Nano are indicated for: • **Peripheral venous catheterization (midline) in any patient population with consideration given to the adequacy of vascular anatomy and appropriateness of procedure, or** • **Arterial catheterization**	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.**	See Comment #1 below
Prescription required?	Yes, Rx Only	Yes, Rx Only	Same
User Group	Clinicians qualified to place intravascular catheters such as nurses or doctors	Clinicians qualified to place intravascular catheters such as nurses or doctors	Same
Use Environment	Clinical setting appropriate for aseptic technique	Clinical setting appropriate for aseptic technique	Same

Comparative Characteristics	**Proposed Device:** Leaderflex Mini and Leaderflex Nano	**Predicate Device:** Leaderflex	**Comments:**
Anatomical placement locations	Peripheral veins in any patient population with consideration given to the adequacy of vascular anatomy (Peripheral veins are available in numerous anatomical locations such as scalp, hand, arm, foot, or leg)	Peripheral veins in any patient population with consideration given to the adequacy of vascular anatomy (Peripheral veins are available in numerous anatomical locations such as scalp, hand, arm, foot, or leg)	Same
Single Use	Yes	Yes	Same
Principle Device Components (Sterile, Disposable, Single Use)	Catheter Hub, Clamp, Fixation Wing, Tube	Catheter Hub, Clamp, Fixation Wing, Tube	Same
Other devices for interfacing/ Accessories	Guidewire, Introducer Needle, Guidewire Insertion Aid	Guidewire, Introducer Needle	See Comment #2 below
Sterilization	Supplied Sterile, EtO Sterilization (ISO 11135)	Supplied Sterile, EtO Sterilization (ISO 11135)	Same
Product Codes	**FOZ**	**FOZ**	Same
Materials			
Catheter tube	TECOFLEX EG60D B40	TECOFLEX EG60D B40	Same
Wing	PELLETHANE 90A 25B	PELLETHANE 90A 25B	Same
Extension line	PELLETH.80 AE BLAU	PELLETH.80 AE BLAU	Same
Luer hub	VITAMIDE 6 BK10 NATURAL	VITAMIDE 6 BK10 NATURAL	Same
Clamp	Polycarbonat PC HP3REU-8H9D273	Polycarbonat PC HP3REU-8H9D273	Same
Guidewire	Stainless Steel	Stainless Steel	Same
Introducer Needle	ABS, stainless steel	ABS, stainless steel	Same
Biocompatibility of Materials	Meets ISO 10993-1 requirements	Meets ISO 10993-1 requirements	Same
Technical Features/Design			
Catheter Gauge Sizes	24G- Leaderflex Mini 26G- Leaderflex Nano	22G- Leaderflex	See Comment #3 below
Catheter Usable Length	2cm, 3cm, 4cm	4cm, 6cm, 8cm, 20cm	See Comment #3 below
Guidewire Length Dimension	23cm and 25cm	23cm, 26cm and 50 cm	See Comment #3 below
Introducer Needle Dimension	24G Leaderflex Mini: 21G x 2.0cm 26G Leaderflex Nano: 24G x 2.5cm	22G Leaderflex: 21G x 4.2 cm	See Comment #3 below
Flow Rate (ml/min)	3 to 17 ml/min	4.4 to 17 ml/min	See

Comparative Characteristics	**Proposed Device:** Leaderflex Mini and Leaderflex Nano	**Predicate Device:** Leaderflex	**Comments:**
			Comment #4 below
Markings	Yes: Leaderflex catheters and guidewires	No	See Comment #5 below
Shelf-life	5 years	5 years	Same
Performance Standards Compliance	ISO 10555-1	ISO 10555-1 ISO 10555-3	Different Comment #6
Packaging Description	Peel Pouch	Peel Pouch	Same
Discussion of differences in technological characteristics:	<u>Comment #1</u>: The indications for use statements are nearly identical for the subject and predicate devices except that the proposed device is a subset of the predicate device and removes the central venous catheterization indication. The indications remain identical for peripheral venous catheterization and for arterial catheterization. This difference does not affect safety or effectiveness of the subject device. <u>Comment #2</u>: The subject devices include an optional guidewire insertion aid which assists clinicians with seeing the wire when threading the catheter on the wire. The predicate/kit does not have this optional accessory. This difference does not affect the safety or effectiveness of the subject device. <u>Comment #3</u>: The Leaderflex Mini and Nano catheters, guidewire and introducer needles have minor dimensional differences compared to the predicate device. The subject device is available in 24g/26g size with lengths of 2, 3, 4 cm. The predicate is available in a 22 g size with lengths of 4, 6, 8 & 20cm length. The smaller length and gauge is to make the subject device more suitable for smaller veins compared to the predicate device. Performance testing was done per ISO 10555-1:2013 to demonstrate that the minor dimensional differences in the catheter, guidewire and introducer needles do not affect the clinical safety or effectiveness of the device. The Leaderflex Mini and Nano device and associated needle and guidewire meet the adequate performance tests specification as the predicate device in terms of being tested to internationally recognized standards and critical functional requirements tested to internal bench test procedures. These dimensional difference do not affect the safety or effectiveness. <u>Comment #4</u>: The flow rate of the subject device is 3-17 mL/minute whereas, the predicate is 4.4-17mL/min The predicate device has a slightly larger gauge thus the flow rate is slightly faster. <u>Comment #5</u>:		

Comparative Characteristics	Proposed Device: Leaderflex Mini and Leaderflex Nano	Predicate Device: Leaderflex	Comments:
	The subject device has the addition of black locational markings on the catheter as well as on the guidewire which the predicate device does not. The purpose of the location markings is to provide the user a better indication of how much of the subject device has been placed into the body. The black ink has been used on other cleared devices and does not affect safety or effectiveness of the proposed device. The predicate device is being reviewed now to add the same black locational markings under the Quality Management System change control process. Comment #6: Both subject device and the predicate device conform to ISO 10555-1, testing to ISO 10555-3 is not applicable as the subject device does not have a central venous indication. Although there are slight differences in the design features of the subject device and the predicate device, these differences were found to be minor and do not affect the safety or effectiveness, as discussed in the Comments above for each difference identified. The principle of operation remains the same for both devices. The Leaderflex Mini and Nano device is considered substantially equivalent to the predicate device in indication for use and technological characteristics (design and materials) based on the above evaluation.		

5.11. Summary of Non-Clinical Testing

The catheters described in this summary were either tested or comply with the following FDA recognized standards:

Performance Testing-Bench

- ISO 10555-1:2013 "Intravascular catheters-Sterile and single-use catheters-Part 1: General requirements"
- ISO 14971:2019 "Medical Devices – Application of risk management to medical devices" ISO 594-1 & 2 "Conical Fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment Part 1 and Part 2" (Complies with)

Biocompatibility:

The Leaderflex Mini and Leaderflex Nano are classified as: Externally Communicating, Circulating Blood, Prolonged Contact (<30 days). The devices comply with the following recognized standard:

- ISO 10993-1:2018 "Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process (Complies with)

Sterility and Shelf-life:

- ISO 11135:2014 Sterilization of healthcare products-Ethylene Oxide-Requirements (Complies with)
- AAMI TIR 28 (Complies with)

- AAMI ST 72 (Complies with)
- ASTM F1980-16 “Standard Guide for Accelerated Aging of Sterile Barrier System of Medical Devices” (Complies with)
- ISO 11607-1:2019 “Packaging for terminally sterilized medical device-Part 1: Requirements for materials, sterile barrier systems and packaging systems” (Complies with)
- ISO 10993-7:2008 “Biological evaluation of medical devices=Part 7: Ethylene Oxide sterilization residuals

5.12. Clinical Testing:

Not applicable

5.13. Conclusion:

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Leaderflex Nano and the Leaderflex Mini are substantially equivalent to the Leaderflex device with respect to indications for use, target population, treatment method, and technological characteristics.