April 12, 2022

Medos International SÀRL
Ivenette Guzman
Senior Regulatory Affairs Program Lead
6303 Blue Lagoon Drive, Suite 315
Miami, Florida 33126

Re: K214025
Trade/Device Name: PROWLER SELECT LP ES Microcatheter; PROWLER XS Microcatheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA, DQY, QJP
Dated: March 11, 2022
Received: March 14, 2022

Dear Ivenette Guzman:

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,

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K214025

Device Name
PROWLER SELECT LP ES Microcatheter; PROWLER XS Microcatheter

Indications for Use *(Describe)*

The PROWLER SELECT LP ES Microcatheter is intended for the introduction of embolic devices and infusion of diagnostic agents into the peripheral and neuro vasculature.

The PROWLER XS Microcatheter is intended for the introduction of embolic devices and infusion of diagnostic agents into the peripheral and neuro vasculature.

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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K214025: 510(k) SUMMARY

I. Submitter

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Date Prepared: 07 April 2022

II. Device

Table 1. Device	
Device Proprietary Name	PROWLER SELECT LP ES Microcatheter; PROWLER XS Microcatheter
Common or Usual Name	Catheter, Percutaneous
Classification Name	Class II - 21 CFR 870.1210 – Continuous flush catheter Class II - 21 CFR 870.1250 – Catheter, Percutaneous
Regulatory Classification	II
Product Code	KRA, DQY, QJP

III. Predicate and Reference Devices

The predicate and reference devices are listed below in Table 2.

	Table 2. Predicate and Reference Devices			
Type	**510(k) #**	**Date Cleared**	**Name**	**Manufacturer**
Primary Predicate	K021591	22 May 2002	PROWLER SELECT (10, 14, and PLUS) Infusion Catheters with and without pre-shaped tips	Medos International SÀRL
Reference	K210838	25 Aug 2021	PROWLER SELECT PLUS Microcatheter; PROWLER EX Microcatheter	
	K965181	21 Mar 1997	CES Infusion Catheters	

IV. Device Description

The PROWLER SELECT LP ES and PROWLER XS Microcatheters have a 3-zone construction that enables smoother transitions to enhance the stability of the microcatheter. The microcatheters are variable stiffness, single lumen catheters designed to access small, tortuous vasculature. The maximum outer diameter of a guidewire that is allowed inside the subject microcatheter is 0.014 in.

The proximal shaft is reinforced with a stainless-steel braid to aid in pushability. The distal shafts are reinforced with a Platinum/Tungsten coil to provide flexibility. To provide lubricity, the distal 30 cm of the catheter is coated with a hydrophilic coating.

V. Indications for Use

The PROWLER SELECT LP ES Microcatheter is intended for the introduction of embolic devices and infusion of diagnostic agents into the peripheral and neuro vasculature.

The PROWLER XS Microcatheter is intended for the introduction of embolic devices and infusion of diagnostic agents into the peripheral and neuro vasculature.

VI. Comparison of Technological Characteristics with Predicate Device

Table 3 provides comparison of technological characteristics with the predicate device. Based on design verification and validation testing, the minor differences in characteristics do not raise different questions of safety and effectiveness.

Table 3. Predicate Comparison		
Description	**Subject Devices** **PROWLER SELECT LP ES Microcatheter; PROWLER XS Microcatheter (K214025)**	**Primary Predicate** **PROWLER SELECT (10, 14, and PLUS) Infusion Catheters with and without pre-shaped tips (K021591)**
Indications for Use	The PROWLER SELECT LP ES Microcatheter is intended for the introduction of embolic devices and infusion of diagnostic agents into the peripheral and neuro vasculature. The PROWLER XS Microcatheter is intended for the introduction of embolic devices and infusion of diagnostic agents into the peripheral and neuro vasculature.	The PROWLER SELECT (10, 14, and PLUS) Infusion Catheters with and without pre-shaped tips are intended to be used as a mechanism for the infusion of various diagnostic, embolic, and therapeutic agents into the vascular systems (Neuro, Peripheral, Coronary), for Guidewire Exchange/Support, and for superselective angiography of the peripheral and coronary vasculatures.
Useable Length (cm)	150	150
Tip Shapes	Straight, J, 45-, and 90-degree	
Inner Diameter	0.0165”	0.021” (PLUS) 0.0165” (14) 0.015” (10)
Outer Diameter	2.3F /1.9F	2.8F / 2.3F (PLUS) 2.3F / 1.9 F (14) 2.3F / 1.7F (10)
Hub Material	Grilamid	Grilamid
Shaft Material	Nylon and Pellethane	
Inner Lining	PTFE	
Outer Coating	Hydrophilic coating on distal-most 30 cm of the outside surface of the shaft	
Shaft Braid	Stainless-steel	
Distal Tip Radiopaque Marker	1 or 2 Pt-W coils	
Accessories	Shaping mandrel	
Packaging	HDPE Hoop or PETG Tray, Tyvek pouch sealed to PET/PE film, SBS paperboard carton	
Sterilization Method	Ethylene Oxide	
Shelf Life	27 months	36 months (3-years)

VII. Non-Clinical Performance Testing

No new testing was conducted to support the minor changes subject to this submission, because all relevant testing has been previously submitted to and reviewed by the FDA.

Shelf-Life

Referenced comparison testing of baseline and real-time aged samples supports a product shelf- life of 27 months.

Packaging

N/A - Changes did not impact packaging design.

Biocompatibility

N/A - Changes did not impact biocompatibility.

Sterilization Validation

N/A - Changes did not impact sterilization.

VIII. Clinical Performance Data

No clinical studies were required to support the minor changes.

IX. Conclusion

The selective non-clinical tests referenced support the substantial equivalence of the subject devices for the proposed indications for use, with a shelf-life of 27 months. The comparison of the technological characteristics and the intended use of the subject device and the predicate does not raise new questions of safety and effectiveness.

End of 510(k) Summary