August 25, 2021

Medos International SARL
Samuel K. Shimp
Senior Regulatory Affairs Program Lead
6303 Blue Lagoon Drive, Suite 315
Miami, Florida 33126

Re: K210838
Trade/Device Name: PROWLER SELECT PLUS Microcatheter; PROWLER EX Microcatheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA, DQY, QJP
Dated: July 23, 2021
Received: July 26, 2021

Dear Dr. Samuel Shimp:

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,

Xiaolin Zheng, Ph.D.
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)*
K210838

Device Name
PROWLER SELECT PLUS Microcatheter;
PROWLER EX Microcatheter

Indications for Use *(Describe)*
The PROWLER SELECT PLUS Microcatheter is intended for the introduction of interventional devices, delivery of therapeutic devices, and infusion of diagnostic agents into the peripheral and neuro vasculature.

The PROWLER EX Microcatheter is intended for the introduction of interventional devices, delivery of therapeutic 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K210838: 510(K) SUMMARY

I. Submitter

Medos International SÀRL
Chemin-Blanc 38
2400 Le Locle, Switzerland

Tel: +1 (757) 790-9275

Contact Person: Samuel Shimp
Email of Contact Person: sshimp@its.jnj.com
Date Prepared: 23 Aug 2021

II. Device

Table 1. Device	
Device Proprietary Name	PROWLER SELECT PLUS Microcatheter; PROWLER EX 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	K162563	5 Jan 2017	YOGA Microcatheter	
	K191237	8 Nov 2019	CERENOVUS Large Bore Catheter	
	K131437	11 Oct 2013	MODIFIED CONCENTRIC MICROCATHETER	Concentric Medical, Inc.

IV. Device Description

The PROWLER SELECT PLUS Microcatheter and PROWLER EX Microcatheter are variable stiffness, single lumen catheters designed to access small, tortuous vasculature. They are available in a variety of outer and inner diameters. Each configuration has a hydrophilic coating to provide lubricity for navigation of vessels. The inner lumen is lined with lubricious PTFE to facilitate movement of guidewires and other devices. The distal sections of the catheter bodies are radiopaque to aid visualization under fluoroscopy, and the distal tips are clearly distinguished by a radiopaque marker.

Continued next page

K210838: 510(k) Summary, *continued*

V. Indications for Use

The PROWLER SELECT PLUS Microcatheter is intended for the introduction of interventional devices, delivery of therapeutic devices, and infusion of diagnostic agents into the peripheral and neuro vasculature.

The PROWLER EX Microcatheter is intended for the introduction of interventional devices, delivery of therapeutic 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		Primary Predicate
	PROWLER SELECT®PLUS	**PROWLER®EX**	**PROWLER SELECT® (K021591)**
Indications	The PROWLER SELECT PLUS Microcatheter is intended for the introduction of interventional devices, delivery of therapeutic devices, and infusion of diagnostic agents into the peripheral and neuro vasculature.	The PROWLER EX Microcatheter is intended for the introduction of interventional devices, delivery of therapeutic 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.

Continued next page

K210838: 510(k) Summary, *continued*

VI. Comparison of Technological Characteristics with Predicate Device, *continued*

Table 3. Predicate Comparison, continued

Description	Subject Devices		Primary Predicate
	PROWLER SELECT®PLUS	**PROWLER®EX**	**PROWLER SELECT® (K021591)**
Useable Length (cm)	110, 135, 150, 160, 170		110, 135, 150, 170
Tip Shapes	Straight, J, 45-, and 90-degree		
Inner Diameter	0.021”		
Outer Diameter	2.8/ 2.3F		
Hub Material	Girlamid		
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)

Continued next page

K210838: 510(k) Summary, *continued*

VII. Non-Clinical Performance Testing

Performance Testing

Testing was conducted according to existing design controls and protocols / test methods previously reviewed by FDA in relevant prior submissions. Table 4 provides a description of each performance test used to support substantial equivalence determination.

Table 4. Performance Testing

Test	Test Method Summary	Results
Simulated Use Testing in a tortuous anatomical model	To provide evidence that the subject devices can safely and effectively deliver interventional devices to the peripheral and neurovasculature. The test method and anatomical model were the same established for reference devices K162563 and K191237.	Test sample microcatheters successfully delivered interventional devices, including vascular stents, stent retrievers, and aneurysm coils. Results demonstrated substantial equivalence for delivery of interventional devices.
Particulate Testing	To evaluate and compare the quantity of particles generated by the subject device during simulated device delivery in a tortuous anatomical model versus particles generated by an applicable reference device (K131437). The test method and anatomical model were the same established for reference devices K162563 and K191237.	Particle generation from baseline and aged subject devices were comparable with the reference device (K131437).
Static Burst Pressure Testing	This test verified that the subject devices meet the established static burst pressure specification, after simulating the delivery of an interventional device. Static burst pressure specifications were the same as those established for predicate K021591. The test method was the same established for reference devices K162563 and K191237.	All tested baseline and aged samples met the minimum static burst pressure acceptance criteria with a demonstrated 95% confidence and 99% reliability and substantial equivalence for delivery of interventional devices.

Continued next page

K210838: 510(k) Summary, *continued*

VII. Non-Clinical Performance Testing, *continued*

Shelf-Life

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

Biocompatibility

N/A - Changes did not impact biocompatibility.

Packaging

N/A - Changes did not impact packaging design.

Sterilization Validation

N/A - Changes did not impact sterilization.

VIII. Clinical Performance Data

No clinical studies were required as appropriate verification and validation of the catheter modifications were achieved based on the similarities of the proposed device to the primary predicate device, and from results of bench testing.

IX. Conclusion

The selective non-clinical tests performed support the substantial equivalence of the subject devices for the proposed indications for use, with a shelf-life of 27 months. 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