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

June 27, 2017

Pdg Product Design Group, Inc
% Georgiann Keyport
Senior Partner
Canopy Medical LLC
1160 Vierling Drive
Shakopee, Minnesota 55379

Re: K163432
Trade/Device Name: Stellar LEAP
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: May 29, 2017
Received: June 2, 2017

Dear Georgiann Keyport:

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 and Part 809); 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 and Part 809), 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" (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 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K163432

Device Name
Stellar LEAP

Indications for Use *(Describe)*
The Stellar LEAP Manual Tilt Wheelchair is intended to provide mobility to persons restricted to a seated position.

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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510(K) SUMMARY – K163432

Date Prepared: June 26th, 2017

510(k) Submitter	Contact
PDG Product Design Group Inc. 103-318 East Kent Ave. South Vancouver, CA-BC CANADA V5X 4N6	Contact: Torr Brown, Chief Engineer Tel: 604-323-9220; Fax: 604-323-9097 Email: tbrown@pdgmobility.com

General Information	
Trade Name	Stellar LEAP
Common Name	Manual Tilt Wheelchair
Classification Information	Mechanical wheelchair (21 CFR 890.3850; Class I) ProCode: IOR; Panel: Physical Medicine
Predicate Device(s)	The Stellar Tilt (K990557)
Reference Device (s)	PDG Elevation Manual Wheelchair (K140023)

1.1 Device Description

The Stellar LEAP manual tilt wheelchair is an indoor / outdoor, manually operated, Tilt-in-Space wheelchair. Its intended function and use is to provide mobility to persons ages 16 and up (adolescents and adults). The Stellar LEAP manual tilt wheelchair consists of metal frame architecture with a backrest, seat, and rear wheels, which allow for occupant or attendant propelling of the device. Smaller caster wheels are also mounted on the front of the frame to facilitate steering and turning. The Stellar LEAP consists of three (3) metal frame sub-assemblies: a lower frame, upper seat frame, and sub-frame assembly. The manual Tilt-in-Space operation is achieved using a gas strut mechanism connected between the upper seat frame and sub-frame. The Stellar LEAP Manual Tilt Wheelchair is available in a standard configuration, which allows 20° Tilt-in-Space (posterior) tilt, with a maximum weight capacity of 250 lbs.

PDG offers optional features / options to be added to the Stellar LEAP wheelchair, including the two below features:

- Stellar LEAP Anterior Tilt Feature (0° - 30°): Functional reach extension & transfer assist
- Stellar LEAP Dynamic Recline Backrest Tilt Feature: 30° range of dynamic recline for the backrest combined with the anterior tilt

Other available options / accessories to complete the Stellar LEAP configuration include: seat width / depth / height, armrests, casters, frog leg suspension forks, rear wheel / tire, hand rim, wheel locks, anti-tippers, back post style, back options, back upholstery, headrest, tilt control, recline control, front rigging, foot plates, footrest / leg rest accessories, position straps, IV pole, O2 holder.

1.2 Intended Use / Indications

The Stellar LEAP wheelchair is intended to provide mobility to persons restricted to a seated position.

The Indications for Use statement for the Stellar LEAP is identical to the predicate device, the Stellar Tilt. Both the subject and predicate devices have the same intended use for providing mobility to persons restricted to a seated position.

1.3 Substantial Equivalence Comparison

The Stellar LEAP and predicate Stellar Tilt wheelchairs have the same basic design, principle of use and intended use / indications. The subject and predicate devices share similar dimensions, weight, and both offer posterior Tilt-in-Space capability. The overall dimensions, seat width, seat depth, and adjustable seat to floor height for both the subject and predicate wheelchairs are very similar. The subject, predicate and reference device differ in their frame design, materials of construction, and tilt features, however the overall function of the wheelchairs are similar. The predicate device does not include the anterior tilt feature, thus the reference device K140023 has been included in the comparison below.

Comparison of Technological characteristics with the Predicate Device and Reference Device.			
	Subject Device Stellar LEAP	**Predicate Device** Stellar Tilt (As cleared under K990557)	**Reference Device** Elevation (As cleared under K140023)
Characteristic	**Dimension/Weight**	**Dimension/Weight**	**Dimension / Weight**
Seat width	14” – 22”	14” – 22”	12” – 19”
Seat depth	16” – 22”	16” – 22”	14” – 20”
Seat to Floor Height (adjustable)	13” – 18”	14” – 20”	18” – 21”
Posterior Tilt	0° to 20°	45°	15°±5° *(depending on set up)*

Comparison of Technological characteristics with the Predicate Device and Reference Device.				
		Subject Device Stellar LEAP	**Predicate Device** Stellar Tilt (As cleared under K990557)	**Reference Device** Elevation (As cleared under K140023)
Back angle (non-dynamic adjustable)		90°, 98°, 106°, 114°, 122°	90°, 98°, 106°, 114°, 122°	N/A
Option / Accessory: Back angle -dynamic or Dynamic Recline Backrest		Range of 30°, @ neutral (90°-120°)	Range of 30°	Range of 30°, @ neutral (90°-120°)
Option / Accessory: Anterior Tilt		30° (max)	N/A	25°±10° *(depending on set up)*
Back height		20” or 25” or 31”	25” or 31”	9.4”-14.6”
Overall width	12” and 16” rear wheels	(seat width +9.5”)	(seat width +9.5”)	N/A
	20”, 22”, 24” rear wheels	(seat width +10.5”)	(seat width +10.5”)	25” rear wheels Min 23.1” Max 27.1”
Overall length (without front rigging)		30” – 37”	30” – 37”	With Legrest (32”-24.5”)
Weight capacity		250 lbs.	250 lbs.	250 lbs.
Chair weight, ISO7176-5 Part 8	8.9	83 lbs. (37.8kg)	75 lbs. (34.2kg)	26.5 lbs. (12.0 kg)
Static stability downhill ISO7176-1 Part 8	8.2	Tipping commences at greater than 10.5°	Tipping commences at greater than 11.0°	Tipping commences at greater than 10°
	8.4	Tipping commences at greater than 10°	Tipping commences at greater than 11.0°	Tipping commences at greater than 10°
Static stability uphill	9.3	Tipping commences at 7.8°	Tipping commences at 7.8°	Tipping commences at

Comparison of Technological characteristics with the Predicate Device and Reference Device.				
		Subject Device Stellar LEAP	**Predicate Device** Stellar Tilt (As cleared under K990557)	**Reference Device** Elevation (As cleared under K140023)
ISO7176-1 Part 9			onto anti-tips	greater than 5.4°
	9.5	Tipping commences at 8.2°	Tipping commences at 8.8° onto anti-tips	Tipping commences at greater than 7.6°
Static stability sideways ISO7176-1 Part 10.2, 10.3	10.2	Tipping commences at greater than 10°	Tipping commences at greater than 12°	Tipping commences at greater than 10°
	10.3	Tipping commences at greater than 10°	Tipping commences at greater than 12°	Tipping commences at greater than 10°
Static stability anti-tip ISO7176-1 Part 11	11.2	Tipping commences at greater than 10°	Tipping commences at greater than 14.0°	Tipping commences at greater than 10°
	11.3	Tipping commences at greater than 17°	Tipping commences at greater than 14.0°	Tipping commences at greater than 10°
	11.4	N/A	Tipping commences at greater than 14.0°	N/A
Minimum turning radius ISO7176-5 Part 8	8.13	830mm	815 mm	515mm

1.4 Performance Data

The Stellar LEAP has been evaluated through ISO 14971-compliant risk analysis and non-clinical testing performed in accordance with the below wheelchair standards:

- ISO 7176 – Part 1 – Determination of static stability
- ISO 7176 – Part 3 – Determination of effectiveness of brakes
- ISO 7176 – Part 5 – Determination of overall dimensions, mass and turning space
- ISO 7176 – Part 7 – Measurement of seating and wheel dimensions.

- ISO 7176 – Part 8 – Requirements and test methods for static impact and fatigue strengths
- ISO 7176 – Part 11 – Test dummies
- ISO 7176 – Part 13 – Determination of coefficient of friction of test surfaces.
- ISO 7176 – Part 15 – Requirements for information disclosure, documentation and, labeling.
- ISO 7176 – Part 16 – Resistance to ignition of postural support devices
- ISO 7176 – Part 19 – Wheeled mobility devices for use as seat in motor vehicles

Results of the above ISO evaluations demonstrated that the Stellar LEAP meets the requirements of ISO 7176- 1, 3, 5, 7, 8, 11, 13, 15, 16, and 19.

Furthermore, a biocompatibility assessment was carried out for the Stellar LEAP by identifying the patient contacting materials and conducting a biomaterial evaluation in accordance with:

- ISO 10993-1 Biological evaluation of medical devices − Part 1: Evaluation and testing within a risk management process (2010)
- FDA Guidance: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (June 16, 2016)

1.5 Conclusions

The Stellar LEAP has substantially equivalent indications and principle of operation to the currently marketed Stellar Tilt. While there are design differences in the frame configuration, materials of construction, joining methods and tilt features, the Stellar LEAP has been evaluated through ISO 14971 - Application of risk management to medical devices and design verification and validation (DV&V) testing was carried out and showed the Stellar LEAP performed compliant to ISO 7176-1, 3, 5, 7, 8, 11, 13, 15, 16 and 19. The subject device has the same intended use, principles of operation, and technological characteristics to the predicate device. Furthermore, similar to the reference device, Elevation, the Stellar LEAP utilizes gas struts to provide anterior tilting function capability. Additionally, the biocompatibility assessment of the Stellar LEAP was carried out in consideration of the safe history of use of these patient contacting materials with other marketed PDG wheelchairs. Thus the Stellar LEAP raises no new questions of safety or effectiveness compared to the predicate device and is, therefore, substantially equivalent.

- End of 510(k) Summary -