



February 13, 2018

Eurogreen International Inc.
David Hsieh
General Manager
No. 48, Lane 220, Sec 1, Fu-Zun Rd., Yuan-Lin Township
Chang-Hua County, Taiwan 51055 R.O.C.

Re: K173315

Trade/Device Name: "SupaChair" Powered Wheelchair: Safari, Safari Sport, Mini
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: December 18, 2017
Received: January 22, 2018

Dear David Hsieh:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Vivek J. Pinto -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

Indications for Use

510(k) Number (if known)

K173315

Device Name

"SupaChair" Powered Wheelchair: Safari, Safari Sport, Mini

Indications for Use (Describe)

The device is a power wheelchair intended to provide mobility to persons restricted to a sitting 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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Date: Dec 21, 2017

5.1 Applicant Information

Type of Submission	Original Application- Traditional 510(k)
Applicant Name	EUROGREEN INTERNATIONAL INC.
Address	No.48, Ln. 220, Sec. 1, Fuzun Rd., Yuanlin Township, Changhua County, Taiwan
Phone	+886-4-8319633
Fax	+886-4-8332226
Contact Person	David Hsieh
Contact Title	General Manager
Contact E-mail	sales@lawia.com

5.2 Device Description

Intended Use : The device is a powered wheelchair intended to provide mobility to persons restricted to a sitting position.

Item	Description
Common Name	Powered Wheelchair
Trade Name	"SupaChair" Powered Wheelchair
Classification Name	Powered Wheelchair
Regulation Number	890.3860
Product Code	ITI
Device Class	Class 2
Model	SAFARI/ SAFARI SPORT/ MINI

Drive wheel size	200mm (8"), 260mm (10")
Caster wheel size	100mm (4"), 178mm (7"), 200mm (8")
Overall Length	850~910mm (33.5~35.8")
Overall Width	550~610mm (21.7~24")
Overall Height	800~865mm (31.5~34")
Standard Seat Width	400~410mm (15.8~16.2")
Standard Seat Depth	380~400mm (15~15.8")
Backrest height	320~370mm (12.6~14.6")
Weight capacity	150kg (330 lbs)
Total weight with batteries (SLA)	37.7~40kg (83~88 lbs)
Weight of motor mount complete	17.9~20.5kg (39.4~45 lbs)
Heaviest Piece	17.9~20.5kg (39.4~45 lbs)
Breaks down into	2 pieces
Weight of seat (included armrest)	9.4~10.6kg (20.7~23.4 lbs)
Maximum speed SLA battery	5.2~9kph (3.2~5.6mph)
Turning Radius	590~730mm (23.2~28.7")
Ground clearance	42~105mm (1.6~4.1")
Battery (SLA/Lithium)	24V 15ah
Weight of battery (SLA/Lithium)	9.2/4 kg (20/9 lbs)
Slope grade ability	4~9 degrees
Travel Distance SLA/Lithium	Up to 10/16.5km (Up to 6.2/10.2 mile)

Battery charger SLA	2A Off board
Battery charger Lithium	4 A Off board
Armrest height	200mm (7.9")
Brake	Dynamic braking and electromagnetic brake
Controller	Dynamic LiNX LE
Brake distance-Normal operation (Horizontal-Forward-Max speed)	1.0-1.5 m/s
Attendant joystick (Optional)	Detachable joystick either mount on power chair or attendant control handle.

510(k) Summary

	SAFARI	SAFARI SPORT	MINI
Drive wheels size	200mm (8")	260mm (10")	200mm (8")
Caster wheels size	178mm (7")	200mm (8")	100mm (4")
Overall length	870mm (34.3")	910mm (35.8")	850mm (33.5")
Overall width	600mm (23.6")	610mm (24")	550mm (21.7")
Overall height	840mm (33")	865mm (34")	800mm (31.5")
Standard seat width	410mm (16.2")	410mm (16.2")	400mm (15.8")
Standard seat depth	400mm (15.8")	400mm (15.8")	380mm (15")
Back rest height	370mm (14.6")	370mm (14.6")	320mm (12.6")
Weight capacity	150kg (330 lbs)	150kg (330 lbs)	150kg (330 lbs)
Total weight with batteries (SLA)	37.7kg (83 lbs)	40kg (88 lbs)	39.1kg (86 lbs)
Weight of motor mount complete	17.9kg (39.4 lbs)	20.2kg (44 lbs)	20.5kg (45 lbs)
Heaviest piece	17.9kg (39.4 lbs)	20.2kg (44 lbs)	20.5kg (45 lbs)
Breaks down into	2 pieces	2 pieces	2 pieces
Weight of seat (included armrest)	10.6kg (23.4 lbs)	10.6kg (23.4 lbs)	9.4kg (20.7 lbs)
Maximum speed SLA battery	6.5kph (4mph)	9kph (5.6mph)	5.2kph (3.2mph)
Turning radius	700mm (27.6")	730mm (28.7")	590(565)mm/23.2" (22.2")
Ground clearance	70mm (2.76")	105mm (4.1")	42mm (1.6")
Battery (SLA/Lithium)	24V 15ah	24V 15ah	24V 15ah
Weight of battery (SLA/Lithium)	9.2/4kg (20/9 lbs)	9.2/4kg (20/9 lbs)	9.2/4kg (20/9 lbs)
Slope grade ability	9 degree	8 degree	4 degree (6 degree with back anti-tip)
Travel distance SLA/Lithium	Up to 10/16.5km (Up to 6.2/10.2mile)	Up to 10/16km (Up to 6.2/10mile)	Up to 10/16.5km (Up to 6.2/10.2mile)

Battery charger SLA	2A off board	2A off board	2A off board
Battery charger Lithium	4A off board	4A off board	4A off board
Armrest height	200mm (7.9")	200mm (7.9")	200mm (7.9")
Brake	Dynamic braking and electromagnetic brake	Dynamic braking and electromagnetic brake	Dynamic braking and electromagnetic brake
Controller	Dynamic LiNX LE	Dynamic LiNX LE	Dynamic LiNX LE
Brake distance-Normal operation (Horizontal-Forward-Max speed)	1.0-1.5 m/s	1.0-1.5 m/s	1.0-1.5 m/s
Attendant joystick (Optional)	Detachable joystick either mount on power chair or attendant control handle.		

5.3 Equivalence comparison to marketed device

Technological characteristics :

Per the 510(k) Program: *Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*, we choose C.T.M. Homecare Product, Inc. Power Chair Model HS-1500 (K073686) to be our primary predicate device. The reasons are C.T.M. Homecare Product, Inc. Model HS-1500 had 510k already, similar intended use and technological characteristics to our subject devices.

The device features and use parameters of the C.T.M. Homecare Product, Inc. Power Chair Model HS-1500 (K073686) are very similar. Both are battery operated and have brake systems. Batteries capacity and battery chargers are similar and provided with the powered wheelchairs. Use parameters are very similar, varying only in minor parameters such as the grade climbable by the respective wheelchairs.

	EUROGREEN International Inc.	C.T.M. Homecare Product, Inc.	Differences
K number	K173315	K073686 Appendix 9.1	-
Identification	Subject devices	Predicate device	
Indication for Use	The device is a powered wheelchair intended to provide mobility to persons restricted to a sitting position.	The C.T.M. Power Chair HS-1500 is an indoor / outdoor powered wheelchair that provides transportation for a disabled or elderly person.	Similar
Model Type	SAFARI/SAFARI SPORT/MINI	HS-1500	-
Drive wheel size	200 mm (8"), 260 mm (10")	200 mm (8")	Similar
Caster wheel size	100 mm (4"), 178 mm (7"), 200 mm (8")	130 mm (5")	Similar
Overall length	850~910 mm (33.5~35.8")	810 mm (31.9")	Similar
Overall width	550~610 mm (21.7~24")	600 mm (23.6")	Similar
Overall height	800~865 mm (31.5~34")	935 mm (36.8")	Lower due to no headrest equipped.
Standard seat width	400~410 mm (15.8~16.2")	470 mm (18.5")	Similar
Standard seat depth	380~400 mm (15~15.8")	-	Similar
Backrest height	320~370 mm (12.6~14.6")	-	-
Weight capacity	150 kg (330 lbs)	115 kg (255 lbs)	These are options according the customer needs. All models passed the loading test. (Appendix 7.4~7.6-1)
Total weight with batteries (SLA)	37.7~40 kg (83~88 lbs)	47.8 kg (105.4 lbs)	It does not affect the safety and performance.
Weight of motor mount complete	17.9~20.5 kg (39.4~45 lbs)	-	-

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Heaviest piece	17.9~20.5 kg (39.4~45 lbs)	-	-
Breaks down into	2 pieces	-	-
Weight of seat (included armrest)	9.4~10.6 kg (20.7~23.4 lbs)	-	It does not affect the safety and performance.
Maximum speed SLA battery	5.2~9 kph (3.2~5.6 mph)	6.3 kph (4 mph)	Similar
Turning radius	590~730 mm (23.2~28.7")	695 mm (27.4")	Similar
Ground clearance	42~105 mm (1.6~4.1")	40 mm (1.6")	Similar
Battery (SLA/Lithium)	24V 15ah	12V 14ah	It does not affect the safety and performance.
Weight of battery (SLA/Lithium)	9.2 kg/4kg (20/9 lbs)	10.4 kg (23 lbs)	It does not affect the safety and performance.
Slope grade ability	4~9 degree	6 degree	Similar
Travel distance (SLA/Lithium)	Up to 10/16.5 km (Up to 6.2/10.2 mile)	8.4 km (5.2 miles)	It does not affect the safety and performance.
Battery charger SLA	2A Off Board	2A Off Board	It does not affect the safety and performance.
Battery charger Lithium	4A Off Board	-	-
Armrest height	200 mm (7.9")	-	-
Brake	Dynamic Braking and Electromagnetic Brake	Electro- Mechanical	Similar
Controller	Dynamic LiNX LE	-	-
Brake distance- Normal operation (Horizontal-Forward-Max speed)	1.0-1.5 m/s	-	It does not affect the safety and performance. (Ref. Appendix 7.4~7.6-1)
Attendant joystick (Optional)	Detachable joystick either mount on power chair or attendant control handle.		

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5.4 Safety and Effectiveness

The substantial equivalence to other commercially products (powered wheelchair) including C.T.M. Homecare Product, Inc. Power Chair Model HS-1500 (K073686). The comparison table on above list the primary technical aspects and specifications that are pertinent to powered wheelchair. The "SupaChair" powered wheelchair is as safe and effective as the predicate devices.

5.5 Non-clinical Testing

"SupaChair" powered wheelchair has done the series test to confirmation its safety and effectiveness in pre-clinical test. The tests are conducted with ISO 7176 serial standards. All test results are in compliance with it and were similar to predicate device.

- ISO 7176-1 : Static stability test
- ISO 7176-2 : Dynamic stability test
- ISO 7176-3 : Efficiency of brakes tests
- ISO 7176-4 : Theoretical distance range tests
- ISO 7176-5 : Overall dimensions, Mass, Turning, Diameter tests
- ISO 7176-6 : Maximum speed, acceleration and retardation tests
- ISO 7176-7 : Seating and wheel dimension tests
- ISO 7176-8 : Static, impact and fatigue strengths tests
- ISO 7176-9 : Climatic tests
- ISO 7176-10 : Obstacle-climbing ability tests

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- ISO 7176-11 : Test dummies
- ISO 7176-13 : Determination of coefficient of friction of test surfaces
- ISO 7176-14 : Power and control system
- ISO 7176-15 : Information disclosure, documentation and labeling
- ISO 7176-21 (EN 12184) : EMC test
- ISO 7176-25 : Batteries and chargers for powered wheelchairs
- IEC 62133 : Secondary cells and batteries containing alkaline or other non-acid electrolytes-Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.

5.6 Conclusion

"SupaChair" powered wheelchair is a safe, reliable and effective medical device, meeting all declared requirements of its intended use and the device does not introduce new risks and does not present any adverse health effects or safety risks to patients when used as intended.