



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: K173313

Trade/Device Name: "SupaChair" Powered Wheelchair: COMBI 18, COMBI 18SP, COMBI 20,  
COMBI 20SP

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](mailto: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)

K173313

Device Name

"SupaChair" Powered Wheelchair: COMBI 18, COMBI 18SP, COMBI 20, COMBI 20SP

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 18, 2017

### 5.1 Applicant Information

Type of Submission	Original Application- Traditional 510(k)
Applicant Name	EUROGREEN INTERNATIONAL INC.
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Phone	+886-4-8319633
Fax	+886-4-8332226
Contact Person	David Hsieh
Contact Title	General Manager
Contact E-mail	<a href="mailto:sales@lawia.com">sales@lawia.com</a>

### 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	COMBI 18/ COMBI 20/ COMBI 18SP/ COMBI 20SP

Drive wheel size	200mm (8") 260mm (10")
Caster wheel size	178mm (7") 200mm (8")
Overall Length	1180mm (46.5")
Overall Width	580~620mm (22.8~25.2")
Overall Height	1010mm (39.8")
Standard Seat Width	450~490mm (17.7~19.3")
Standard Seat Depth	450mm (17.7")
Backrest height	470mm (18.5")
Weight capacity	150kg (330 lbs)
Total weight with batteries (SLA)	37.3~39.8kg (82~87.5 lbs)
Weight of motor mount complete	14.9~17.4kg (32.8~38.2 lbs)
Heaviest Piece	14.9~17.4kg (32.8~38.2 lbs)
Breaks down into	6 pieces
Maximum speed SLA battery	6.5~9kph (4~5.6mph)
Turning Radius	900~1100mm (35.4~43.3")
Ground clearance	83mm (3.3")
Battery (SLA/Lithium)	24V-15ah
Weight of battery (SLA/Lithium)	9.2/4 kg (20/9 lbs)
Slope grade ability	8~9 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	160~215mm (6.3~8.5")
Brake	Dynamic braking and electromagnetic brake
Brake distance-Normal operation (Horizontal-Forward-Max speed)	1.0~1.5 m/s *Adjustable from software according to market demand.*
Attendant joystick (Optional)	Detachable joystick either mount on power chair or handle bar.

	COMBI 18	COMBI 20	COMBI 18SP	COMBI 20SP
Drive wheels size	200mm (8")	200mm (8")	260mm (10")	260mm (10")
Caster wheels size	178mm (7")	178mm (7")	200mm (8")	200mm (8")
Overall length	1180mm (46.5")	1180mm (46.5")	1180mm (46.5")	1180mm (46.5")
Overall width	580mm (22.8")	620mm (25.2")	580mm (22.8")	620mm (25.2")
Overall height	1010mm (39.8")	1010mm (39.8")	1010mm (39.8")	1010mm (39.8")
Standard seat width	450mm (17.7")	490mm (19.3")	450mm (17.7")	490mm (19.3")
Standard seat depth	450mm (17.7")	450mm (17.7")	450mm (17.7")	450mm (17.7")
Back rest height	470mm (18.5")	470mm (18.5")	470mm (18.5")	470mm (18.5")
Weight capacity	150kg (330 lbs)	150kg (330 lbs)	150kg (330 lbs)	150kg (330 lbs)
Total weight with batteries (SLA)	37.3kg (82 lbs)	37.7kg (83 lbs)	39.7kg (87 lbs)	39.8kg (87.5 lbs)
Weight of motor mount complete	14.9kg (32.8 lbs)	15kg (33 lbs)	17.3kg (38 lbs)	17.4kg (38.2 lbs)
Heaviest piece	14.9kg (32.8 lbs)	15kg (33 lbs)	17.3kg (38 lbs)	17.4kg (38.2 lbs)
Breaks down into	6 pieces	6 pieces	6 pieces	6 pieces
Maximum speed SLA battery	6.5kph (4mph)	6.5kph (4mph)	9kph (5.6mph)	9kph (5.6mph)
Turning radius	900mm (35.4")	1100mm (43.3")	900mm (35.4")	1100mm (43.3")
Ground clearance	83mm (3.3")	83mm (3.3")	83mm (3.3")	83mm (3.3")
Battery (SLA/Lithium)	24V15ah	24V15ah	24V15ah	24V15ah
Weight of battery (SLA/Lithium)	9.2/4kg (20/9 lbs)	9.2/4kg (20/9 lbs)	9.2/4kg (20/9 lbs)	9.2/4kg (20/9 lbs)

### 510(k) Summary

Slope grade ability	9 degree	9 degree	8 degree	8 degree
Travel distance SLA/Lithium	Up to 10/16.5km (Up to 6.2/10.2mile)	Up to 10/16.5km (Up to 6.2/10.2mile)	Up to 10/16.5km (Up to 6.2/10.2mile)	Up to 10/16.5km (Up to 6.2/10.2mile)
Battery charger SLA	2A off board	2A off board	2A off board	2A off board
Battery charger Lithium	4A off board	4A off board	4A off board	4A off board
Armrest height	160-215mm (6.3-8.5")	160-215mm (6.3-8.5")	160-215mm (6.3-8.5")	160-215mm (6.3-8.5")
Brake	Dynamic braking and electromagnetic brake	Dynamic braking and electromagnetic brake	Dynamic braking and electromagnetic brake	Dynamic braking and electromagnetic brake
Brake distance-Normal operation (Horizontal-Forward-Max speed) <small>*Adjustable from software according to market demand.*</small>	1.0-1.5 m/s	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 handle bar.			



### 5.3 Equivalence comparison to marketed device

#### Technological characteristics :

Per the 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], we choose OTTO BOCK Healthcare, LP to be our predicate device. The reasons are OTTO BOCK Healthcare, LP had 510k already, similar intended use and technological characteristics to our subject devices.

The device features and use parameters of the OTTO BOCK Healthcare, LP, A-200 Powered Wheelchair (K052706) are very similar. Both are battery operated and have brake systems. Batteries capacity and battery chargers are similar and provided with the powered wheelchair. Use parameters are very similar, varying only in minor parameters such as the grade climbable by the respective wheelchairs.

	EUROGREEN International Inc.	OTTO BOCK Healthcare, LP	Differences
K number	K173313	K052706	-
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."	Provide mobility to persons physically challenged and limited to sitting positions.	Similar
Model Type	COMBI 18/ COMBI 20/ COMBI 18SP/ COMBI 20SP	A-200	-
Drive wheel size	200 mm (8") 260 mm (10")	-	Smaller wheel for lower speed and better output for torque.

Caster wheel size	178 mm (7") 200 mm (8")	-	Not effect to output
Overall Length	1180 mm (46.5")	1000 mm	Similar
Overall Width	580~620 mm (22.8~25.2")	570 mm	Similar
Overall Height	1010 mm (39.8")	-	Similar
Standard Seat Width	450~490 mm (17.7~19.3")	340~480 mm	Similar
Standard Seat Depth	450 mm (17.7")	340~500 mm	Similar
Back rest height	470 mm (18.5")	550/500/450 mm	Similar
Weight Capacity	150 kg (330 lbs)	100 kg	These are options according the customer needs. All models passed the loading test. (Appendix 7.3~7.6)
Total Weight With Batteries (SLA)	37.3~39.8 kg (82~87.5 lbs)	66 kg	It doesn't affect the safety and performance.
Weight of Motor mount complete	14.9~17.4 kg (32.8~38.2 lbs)	-	-
Heaviest Piece	14.9~17.4 kg (32.8~38.2 lbs)	-	-
Breaks Down Into	6 pieces	-	-
Maximum Speed SLA battery	6.5~9 kph (4~5.6 mph)	6 km/h	Similar
Turning Radius	900~1100 mm (35.4~43.3")	870 mm	Similar
Ground Clearance	83 mm (3.3")	-	-
Battery (SLA/Lithium)	24V 15ah	28 Ah (C5) AGM batteries	It doesn't affect the safety.
Weight of battery (SLA/Lithium)	9.2 kg/4kg (20/9 lbs)	-	It doesn't affect the safety.

Slope Grade Ability	8~9 degree	12%	Similar
Travel Distance SLA/Lithium	Up to 10/16.5 km (Up to 6.2/10.2 mile)	15 km	It doesn't affect the safety and performance.
Battery Charger SLA	2A Off Board	-	It doesn't affect the safety and performance.
Battery Charger Lithium	4A Off Board	-	-
Armrest Height	160~215 mm (6.3~8.5")	225~350 mm	Similar
Brake	Dynamic Braking and Electromagnetic Brake	-	Similar
Brake distance- Normal operation (Horizontal-Forward-Max speed) <small>*Adjustable from software according to market demand.*</small>	1.0~1.5 m/s	-	It doesn't affect the safety and performance. (Ref. Appendix 7.3~7.6)
Attendant joystick (Optional)	Detachable joystick either mount on power chair or handle bar.	-	

#### 5.4 Safety and Effectiveness

The substantially equivalence to other commercially product (powered wheelchair) OTTO BOCK HEALTHCARE, LP, A-200 Powered Wheelchair (K052706). 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.

<i>SupaChair</i>	Section 5	Page
	510(k) Summary	9 / 10

## 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
- 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.

<i>SupaChair</i>	Section 5	Page
	510(k) Summary	10 / 10

## 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.