



September 19, 2019

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

Re: K182631

Trade/Device Name: "SupaScoota" Motorized vehicle - Spartan (Sumo) / Spartan SP (Sumo SP)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: August 20, 2019
Received: August 20, 2019

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. 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,

For: Vivek Pinto, Ph.D.
Director (Acting)
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K182631

Device Name
"SupaScoota" Motorized Vehicle : Spartan(Sumo), Spartan SP(Sumo SP)

Indications for Use (Describe)
As a motorized portable electric vehicle for indoor or outside use by persons with medical conditions requiring assistance.

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
PRASStaff@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."

<i>SupaScoota</i>	K182631	Page
	510(k) Summary	1 / 8

1 Submitter:

Company Name: Eurogreen International Inc.
Company Address: No.48, Ln.220, Sec.1, Fuzun Rd., Yuanlin Township, Changhua County, 51055, Taiwan
Telephone: +886-4-8319633
Fax: +886-4-8332226
Contact person: David Hsieh
Summary Preparation Date: September 17, 2019

2 Device Name:

Trade Name: "SupaScoota" Motorized vehicle, Spartan(Sumo)/ Spartan SP(Sumo SP)
Classification Name: Motorized three-wheeled vehicle
Regulation Number: 890.3800
Product Code: INI
Device Class: Class 2
Panel: Physical Medicine

3 Predicate Device:

K143557, Eurogreen International Inc., "SupaScoota" Motorized vehicle SP-01

4 Indications for Use:

"SupaScoota" Motorized vehicle, Spartan(Sumo)/ Spartan SP(Sumo SP), as a motorized portable electric vehicle for indoor or outside use by persons with medical conditions requiring assistance.


5 Device Description:

A battery operated lightweight portable mobility device designed for personal travel indoors and limited outdoor use and available in 4 wheel configurations. It is used in a sitting position and operated by a hand controlled throttle located on the handle bars. Braking is automatically controlled when releasing the throttle by the electronic controller and magnetic motor brake.

<i>SupaScoota</i>	K182631	Page
	510(k) Summary	2 / 8

The product is supplied ready to use with a battery and charger and it can be disassembled and folded for transport.

Steel frame, battery cycle life of Sealed Lead Acid battery is 400 charging times, 24V15ah Lithium battery is 1000 charging times, 24V12ah Lithium battery is 800 charging times.

Specification	Spartan(Sumo)	Spartan SP(Sumo SP)
Photograph		
Number of wheels	4 wheels	
Front wheel size	200 x 65 mm (8x2.5")	
Rear wheel size	200 x 65 mm (8x2.5")	260 x 85mm (10 x 3")
Ground clearance	65 mm (2.6")	
Length	1100 mm (43.7")	1130 mm (44.5")
Width	630 mm (24.8")	660 mm (26")
Weight of front frame (without seat)	13.5 kgs (29.7 lbs)	
Weight of front frame (without seat and front wheels)	11.3 kgs (25 lbs)	
Weight of back frame (without seat)	12.2 kgs (27 lbs)	13.4 kgs (29.5 lbs)
Weight of Seat (include seat frame & arm rest)	10.6 kgs (23.3 lbs)	
Max Loading (on level ground)	200 kgs (440 lbs)	
Turn Radius	1000 mm (39.4")	
Motor Output	2 x 180 W	
Transmission	Worm Drive Gearbox	

Reverse	Forward/Reverse Switch	
Brakes	Dynamic Braking and Electromagnetic Brake	
Battery-SLA	24V-15ah / 9.2kg (20 lbs)	
Battery-Lithium (optional)	24V-15ah / 4.0kg (9 lbs) or 24V-12ah / 3.3kg (7.3 lbs)	
Charger-SLA battery	Off board 24 volt 2 amp	
Charger-Lithium battery	Off board 24 volt 4 amp	
Max Speed	6.2 kph (3.9 mph)	8.2 kph (5 mph)
2 nd speed choice	4.2 kph (2.6 mph)	5.5 kph (3.4 mph)
Slope Grade Ability	150 kg-8 degree, 175 kg-6 degree	150 kg-7 degree, 175 kg-4 degree
Travel Distance (with standard SLA battery)	Up to 10 km (6.2 miles)	
Travel Distance -with 15ah Lithium battery -with 12ah Lithium battery	Up to 13 km (8 miles) Up to 11 km (6.8 miles)	
Arm Rests	Distance between armrests 45-57cm (18-22.4")	
Brake distance-Normal operation (Horizontal-Forward-Max speed)	1.0-1.5 m/s	1.0-1.5 m/s
Time to brake (1~1.5M)	0.6~0.7 seconds	0.8~0.9 seconds
Operating surface & environment	Use it on firm, even surfaces. Such as concrete, asphalt and indoor flooring; not operate it in sand, loose soil or over rough terrain.	
Frame material	Steel	

6 Technological characteristics:

Unique one piece folding frame available in several models to suit different users and applications. The compact design and minimal component weight are of significant benefit to the elderly who are independent and have a need to transport the scooter in their motor vehicle. The electronically controlled speed reduction system which operates when turning is a valuable safety features for elderly users.

It's a rear wheel drive scooter with four wheels, weight capacity 200kgs, average travel distance with 24V15ah Sealed Lead Acid battery is 10 km, with Lithium

<i>SupaScoota</i>	K182631	Page
	510(k) Summary	4 / 8

batteries 24V15ah is 13km, 24V12ah is 11km, the maximum speed is 6.2kph for Spartan(Sumo), 8.2kph for Spartan SP (Sumo SP)

7 Substantial Equivalence comparison:

The “SupaScoota” Motorized vehicle, Spartan(Sumo)/ Spartan SP(Sumo SP) and the “SupaScoota” Motorized vehicle SP-01 (K143557) have the same design, intended use, classification name and product code.

Per the 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], we choose Eurogreen International Inc., our own devices, to be our predicate device. The reasons are Eurogreen International Inc. had 510(k) already, same intended use and technological characteristics to the new subject devices.

The device features and use parameters of the Eurogreen International Inc. "SupaScoota" Motorized Vehicle model SP01 (K143557) are the same. Both are battery operated and have brake systems. Batteries capacity and battery chargers are the same and are provided with the scooters.

<i>SupaScoota</i>	K182631	Page 5 / 8
	510(k) Summary	

	EUROGREEN International Inc.	EUROGREEN International Inc.	Differences
K number	K182631	K143557	-
Identification	Subject devices	Predicate device	
Indication for Use	As a motorized portable electric vehicle for indoor or outside use by persons with medical conditions requiring assistance.	As a motorized portable electric vehicle for indoor or outside use by persons with medical conditions requiring assistance.	Same
Model Type	Spartan(Sumo) Spartan SP(Sumo SP)	"SupaScoota" Motorized Vehicle-SP01	-
Front wheel size	200 x 65mm (8 x 2.5")	200 x 65mm (8 x 2.5")	Same
Rear wheel size	Spartan(Sumo): 200 x 65mm (8 x 2.5") Spartan SP(Sumo SP): 260 x 85mm (10 x 3")	260 x 85mm (10 x 3")	It does not affect the safety and performance. (Ref. Appendix 7.3~7.4)
Ground clearance	65mm (2.6")	65mm (2.6")	Same
Length	1110~1130mm (43.7~44.5")	1100mm (43")	It does not affect the safety and performance.
Width	630~660mm (24.8~26")	600mm (26")	It does not affect the safety and performance.
Weight of front frame (without seat)	13.5kg (29.7 lbs)	10.9kg (24 lbs)	It does not affect the safety and performance.
Weight of front frame (without seat & front wheels)	11.3kg (25 lbs)	8.7kg (19 lbs)	It does not affect the safety and performance.
Weight of back frame (without seat)	12.2~13.4kg (27~29.5 lbs)	11.4kg (25 lbs)	It does not affect the safety and performance.
Weight of Seat (include seat frame & arm rest)	10.6kg (23.3 lbs)	8.6kg (19 lbs)	It does not affect the safety and performance

510(k) Summary

Max Loading(on level ground)	200kg (440 lbs)	125kg (275 lbs)	These are options according the customer needs. All models have pass the loading test. (Ref. Appendix 7.3~7.4)
Turn Radius	1000mm (39.4")	975mm (38.5")	-
Motor Output	2 x 180 W	2 x 180 W	Same
Transmission	Worm Drive Gearbox	Worm Drive Gearbox	Same
Reverse	Forward/Reverse Switch	Forward/Reverse Switch	Same
Brakes	Dynamic braking and electromagnetic brake	Dynamic braking and electromagnetic brake	Same
Battery	SLA: 24V-15ah/9.2kg (20 lbs) Lithium (Optional) : 24V-15ah/4kg (9 lbs) or 24V-12ah/3.3kg (7.3 lbs)	SLA: 24V-15ah/9.2kg (20 lbs) Lithium (Optional) : 24V-15ah/4kg (9 lbs)	Same
Charger	SLA: Off board 24 volt 2 amp Lithium: Off board 24 volt 4 amp	SLA: Off board 24 volt 2 amp Lithium: Off board 24 volt 4 amp	Same
Max Speed	6.2~8.2kph (3.9~5mph)	9kph (5.6mph)	-
2 nd speed choice	4.2~5.5kph (2.6~3.4mph)	6kph (3.7mph)	-
Slope Grade Ability	Spartan(Sumo): 150kg: 8 degree 175kg: 6 degree Spartan SP(Sumo SP): 150kg: 7 degree 175kg: 4 degree	9 degree (Max.)	It does not affect the safety and performance.
Travel Distance	SLA: Up to 10km (6.2 miles) Lithium-24V15ah: Up to 13km (8 miles) Lithium-24V12ah: Up to 11km (6.8miles)	SLA: Up to 14km (8.5miles) Lithium: Up to 18km (11miles)	-

Arm Rests (Distance between armrests)	45~57cm (18~22.4")	45~55cm (18~22")	-
Speed Reduction System	Reduces operating speed to a safe level when turning	Reduces operating speed to a safe level when turning	Same
Brake distance-Normal operation (Horizontal-Forward-Max speed)	1.0~1.5 m/s	1.0-1.5 m/s	Same
Controller	Eurogreen SF-1307-24V	Eurogreen SF-1306-24V	Same
Time to brake (1~1.5M)	0.6~0.9 seconds	0.8~0.9 seconds	-
Operating surface & environment	Use it on firm, even surfaces. Such as concrete, asphalt and indoor flooring; not operate it in sand, loose soil or over rough terrain.	Use it on firm, even surfaces. Such as concrete, asphalt and indoor flooring; not operate it in sand, loose soil or over rough terrain.	Same
Frame material	Steel	Steel	Same

8 Safety and Effectiveness:

The substantially equivalence to Eurogreen International Inc "SupaScoota" Motorized Vehicle model SP01 (K143557). The comparison table above list the primary technical aspects and specifications that are pertinent to motorized four-wheeled vehicle. The "SupaScoota" Motorized vehicle is as safe and effective as the predicate devices.

9 Non-clinical Testing

"SupaScoota" Motorized vehicle has done the series test to confirm 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

<i>SupaScoota</i>	K182631	Page
	510(k) Summary	8 / 8

- 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 7176-16 : Resistance to ignition of postural support devices
- 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.
- ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.
- ISO 10993-10 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin delayed-type hypersensitivity

10 Conclusion:

"SupaScoota" Motorized vehicle 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.