April 8, 2021

Dongguan Prestige Sporting Goods Co., Ltd.
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road
Huangpu District
Guangzhou, Guangdong 510663
China

Re: K202632
Trade/Device Name: Electric wheelchair, Models: S7204, S7205
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: January 8, 2021
Received: January 11, 2021

Dear Cassie Lee:

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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
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and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K202632

Device Name
Electric wheelchair, Models: S7204, S7205

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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510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

- 510(k) Owner's Name: Dongguan Prestige Sporting Goods Co., Ltd
- Establishment Registration Number: 3008841035
- Address: 3rd industrial, Qiaotou Area, Houjie Town, Dongguan City, Guangdong province, China, 523950
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- Fax: 86-769-85922505
- Contact Person: Zhang Zhao (General Manager)
- E-mail: leon@solaxtech.com

Application Correspondent:

- Contact Person: Ms. Cassie Lee
- Guangzhou GLOMED Biological Technology Co., Ltd.
- Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China
- Tel: +86 20 8266 2446
- Email: regulatory@glomed-info.com

2. Subject Device Information

- Trade Name: Electric wheelchair, Model: S7204, S7205
- Common Name: Powered Wheelchair
- Classification name: Wheelchair, Powered
- Review Panel: Physical Medicine Device
- Product Code: ITI
- Regulation Class: II
- Regulation Number: 890.3860

3. Predicate Device Information

- Sponsor: Eurogreen International Inc.
- Device Trade name: "SupaChair" Powered Wheelchair: Safari, Safari Sport, Mini
- Common name: Powered Wheelchair
- Classification name: Wheelchair, Powered
- 510K Number: K173315
- Medical specialty (Panel): Physical Medicine Device
- Regulation number: 890.3860
- Product Code: ITI
- Classification: Class II

Predicate Device 2

- Sponsor: Permobil AB
- Device Trade name: M300 & M400
- Common name: Powered Wheelchair
- Classification name: Wheelchair, Powered
- 510K Number: K123290
- Medical specialty (Panel): Physical Medicine Device
- Regulation number: 890.3860
- Product Code: ITI
- Classification: Class II

4. Device Description

The Electric wheelchair (Model S7204, S7205) is a power wheelchair intended to provide mobility to persons restricted to a sitting position.
The Electric wheelchair (Model S7204, S7205) is about 136 kg weight capacity. It is basic conventional rear wheels drive, rigid frame vehicle that are battery powered. It consists primarily of a welded-aluminum frames, sealed transaxle motors drive system, electromagnetic braking system, electric motor controller and Li-ion batteries with an off-board battery charger. It is powered by rechargeable batteries with 45 km which maximum speed up to 7 km/h. The controller with a joystick attaches to either armrest and allows the rider to control the movement and velocity of the powered wheelchair. When the joystick is released, the electromagnetic brake will be actuated and the power wheelchair is slow to stop.
It consists of three parts which are chair part, control part and drive part. Overall it mainly has a basic aluminum alloy frame, two front wheels, two rear wheels, two anti-tip wheels, a seat, a footrest, an controller, an electric motor, an electromagnetic brake and a Lithium battery with an off-board charger.
The result of "tiltover" tests performed laterally (12°), posteriorly (16°), and anteriorly (12°) with a user of maximum allowable weight in the least stable configuration: No overturn performed laterally, posteriorly, and anteriorly with 136kg in the least stable configuration.

5. Intended Use / Indications for Use

The device is a power wheelchair intended to provide mobility to persons restricted to a sitting position

6. Tests Summary

The following performance and safety tests were conducted with Electric wheelchair:

• ISO 7176-1: 2014, Wheelchairs - Part 1: Determination of static stability
• ISO 7176-2: Third edition 2017-10, Wheelchairs - Part 2:Determination of dynamic stability of electrically powered wheelchairs
• ISO 7176-3: 2012, Wheelchairs - Part 3: Determination of effectiveness of brakes
• ISO 7176-4: Third edition 2008-10-01, Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
• ISO 7176-5: Second edition 2008-06-01, Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space
• ISO 7176-6: Third edition 2018-06 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs
• ISO 7176-7: First Edition 1998-05-15, Wheelchairs - Part 7: Measurement of seating and wheel dimensions
• ISO 7176-8: 2014, Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths
• ISO 7176-9: 2009, Wheelchairs - Part 9: Climatic tests for Powered Wheelchairs
• ISO 7176-10: 2008, Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
• ISO 7176-11: Second edition 2012-12-01, Wheelchairs - Part 11: Test dummies
• ISO 7176-13: First edition 1989-08-01, Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces
• ISO 7176-14: 2008, Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods
• ISO 7176-15: 1996, Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
• ISO 7176-16: Second edition 2012-12-01, Wheelchairs - Part 16: Resistance to ignition of postural support devices
• ISO 7176-21: Second edition 2009-04-01 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
• ISO 7176-22: Second Edition 2014-09-01 Wheelchairs - Part 22: Set-Up Procedures
• IEC 62304: 2006 (First Edition), Medical device software, Software life- cycle processes
• IEC 60601-1-6: Medical electrical equipment– Part1-6: General requirements for safety– Collateral Standard: Usability Edition 3.0, 2010
• IEC 62366 Medical devices – Application of usability engineering to medical devices Edition 1.0, 2007

The materials and manufacturing used for the Electric wheelchair are identical to those of the predicate device K122749, which were demonstrated to conform with the following biocompatibility standards:

• ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity
• ISO 10993-10: 2009, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Electric wheelchair is substantially equivalent to the predicate devices quoted above.

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
Company	Dongguan Prestige Sporting Goods Co., Ltd.	Eurogreen International Inc.	Permobil AB	--
Trade Name	Electric wheelchair	"SupaChair" Powered Wheelchair: Safari, Safari Sport, Mini	M300 & M400	--
Model	S7204, S7205	Safari	--	--
Classification Name	Wheelchair, Powered	Wheelchair, Powered	Wheelchair, Powered	SE
510K Number	K202632	K173315	K123290	--
Product Code	ITI	ITI	ITI	SE
Common or Usual name	Powered Wheelchair	Powered Wheelchair	Powered Wheelchair	SE
Intended use/Indications for Use	The device is a power wheelchair intended to provide mobility to persons restricted to a sitting position.	The device is a power wheelchair intended to provide mobility to persons restricted to a sitting position.	The intended use of the M300 & M400 powered wheelchair is to provide outdoor and indoor mobility to persons limited to a seated position that are capable of operating a powered wheelchair.	SE
Size	For model S7204: 1000mm x 680mm x 1330mm For model S7205: 1000mm x 700mm x 1340mm	870mm*600mm*840mm	1256 mm x 620mm x 1260 mm	SE Note 1
Overall length	For model S7204: 1000mm For model S7205: 1000mm	870mm	1256 mm	SE Note 1
Overall width	For model S7204: 680mm For model S7205: 700mm	600mm	620mm	SE Note 1

Total mass	For model S7204: 150kg approx. For model S7205: 145kg approx.	37.7kg	155kg (342 lbs)	SE Note 1
Mass of heaviest part	For model S7204: 134kg approx. For model S7205: 129kg approx.	17.9kg	Not public	SE Note 1
Effective seat depth	480mm	400mm	Not public	SE Note 1
Effective seat width	520mm	410mm	Not public	SE Note 1
Back support height	810mm	370mm	Not public	SE Note 1
Front of arm support to back support	250mm	200mm	Not public	SE Note 1
Minimum turning diameter	1200mm	700mm	Not public	SE Note 1
Tires	6" for front wheel (solid wheel) 14" for middle wheel (solid wheel) 6" for rear wheel (solid wheel)	Drive wheels size: 200mm (8") Caster wheels size: 178mm (7")	Caster wheel: 200x50 mm Drive wheel: 3.00-8''	SE Note 1
Speed	7km/h(4.3mph)	6.5kph (4mph)	Up to 12 km/h (7,5 mph)	SE Note 2
Safe Gradient / Maximum Gradient	10°	9º	Not public	SE Note 2
Range	45km	SLA: 10km Lithium: 16.5km	Up to 25 km	SE Note 2
Turning Radius	700mm	700mm	800mm	SE
Base weight (not including battery)	For model S7204: 134kg approx. For model S7205: 129kg approx.	28.5kg	Not public	SE Note 1
Battery weight	16 kg	SLA: 9.2kg Lithium: 4kg	Not public	SE Note 1
Brake	Electromagnetic	Electromagnetic	Electronic braking via drive motors and magnetic	SE
Drive system	Dynamic	Dynamic	Not public	SE
Maximum capacity	136 kg	150 kg	136 kg	SE
Ground clearance	50mm	70mm	77 mm	SE Note 2

Minimum Braking Time	1.54s	Not public	Not public	SE Note 4
Minimum Braking Distance	1.5m	Not public	Not public	SE Note 4
Brake distance-Normal operation (Horizontal-Forward-Max speed)	1.5-1.8m	1.0-1.5m	Not public	SE Note 4
Battery	Li-ion Battery 25.2V 30AH*2	SLA/Lithium: 24V 15Ah	Not public	SE Note 3
charger	24V 15A	SLA: 2A off board Lithium: 4A off board	Not public	SE Note 3
Frame design	Rigid frame	Rigid frame	Not public	SE
Material	Aluminum	Aluminum	Not public	SE
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	Not public	SE
Electrical Safety	ISO 7176 series	ISO 7176 series	ISO 7176 series	SE
EMC	ISO 7176 - 21	ISO 7176 - 21	ISO 7176 - 21	SE

Comparison in Detail(s):

Note 1:
Although “Size”, “Overall length”, “Overall width”, “Stowage length”, “Stowage width”, “Stowage height”, “Mass of heaviest part” “Total mass”, “Effective seat width”, “Back support height”, “Effective seat depth”, “Minimum turning diameter”, “Tires”, “Base weight”, “Front of arm support to back support” and “Battery weight” which are parameters required in ISO 7176-5 and ISO 7176-7 of the subject device are different from the predicate devices, however, these are some mechanical parameters, and they are very similar, Besides, the subtle changes of the physical characteristics will not affect the critical functions or the normal use, so these parameters’ differences will not raise any safety or effectiveness issue.

Note 2:
Although the “Speed”, “ Safe Gradient / Maximum Gradient”, “ Range”, “ Ground clearance” of the subject device are different from the predicate device, as they very similar and all also comply with ISO 7176 series standards requirements, it will not affect the main function and the intended use of the device, so these parameters’ differences will not raise any safety or effectiveness issue.

Note 3:
Although the “Battery”, “Charger” of the subject device are a little different from the predicate device, but both of them are comply with the standards IEC 62133, it will not raise any safety or effectiveness issue.

Note 4:

Although the “Minimum Braking Time”, “Minimum Braking Distance” and “Brake distance-Normal operation (Horizontal-Forward-Max speed)” of the subject device are a little different from the predicate device, but both of them are comply with the standards ISO 7176-3, it will not raise any safety or effectiveness issue.

Final Conclusion:
The subject device Electric wheelchair (Model: S7204, S7205) is Substantial Equivalent to the predicate devices K173315 and K123290.

8. Date of the summary prepared

March 11, 2021