December 17, 2020

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: K200857
Trade/Device Name: Electric wheelchair (Model: S7012)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: September 27, 2020
Received: October 1, 2020

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, Ph.D.
Assistant Director, Acute Injury Devices Team
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200857

Device Name
Electric wheelchair (Model: S7012)

Indications for Use *(Describe)*
The Electric wheelchair is a motor driven transportation vehicle with the intended use to provide mobility to a disabled or elderly limited 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

K200857

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
- Tel: 13763128800
- 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: S7012)
- Common Name: Powered Wheelchair
- Classification name: Wheelchair, Powered
- Review Panel: Physical Medicine Device
- Product Code: ITI
- Regulation Class: 2
- Regulation Number: 890.3860

3. Predicate Device Information

- Sponsor: Kunshan Aoshida Electric Technology Co., Ltd.
- Device Trade name: A08 powered Wheelchair
- Common name: Powered Wheelchair
- Classification name: Wheelchair, Powered
- 510K Number: K163204
- Medical specialty (Panel): Physical Medicine Device
- Regulation number: 890.3860
- Product Code: ITI
- Classification: Class 2

4. Device Description

The Electric wheelchair (Model S7012) is to provide mobility to adults, limited to a seated position that have capability to operate a few simple controls and the ability to control a powered wheelchair. The

device and accessories (remote controller, AC power wire, charger, and battery) are reusable.

The Electric wheelchair (Model S7012) is about 125 kg weight capacity and size is about 840mm x 640mm x 930mm if unfold and about 700mm x 640mm x 370mm if fold. It is basic conventional rear wheels drive, rigid frame vehicle that are battery powered. It consists primarily of a foldable 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 has some components as two front wheels, two rear wheels, two anti-tip wheels, a seat, a footrest, and has a remote for folding/unfolding the device.

Its basic function is powered by rechargeable batteries with 15 km which has a maximum speed up to 6 km/h. The controller with a joystick attaches to either armrest 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. The joystick can move up and down, left and right. There is a speed button to adjust the speed, and the speed indicator can display the speed. In addition, there is a remote control to control the folding and unfolding of the device. And no any new features of the device.

5. Intended Use / Indications for Use

The Electric wheelchair is a motor driven transportation vehicle with the intended use to provide mobility to a disabled or elderly limited to a seated 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 7176-2:2001, Wheelchairs - Part 2: Determination of dynamic stability of 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 maneuvering space

• ISO 7176-6: 2001, Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of Powered 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 Electric 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 Electric 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 Electric 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 reference 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**	**Remark**
Company	Dongguan Prestige Sporting Goods Co., Ltd.	Kunshan Aoshida Electric Technology Co., Ltd.	--
Trade Name	Electric wheelchair (Model S7012)	A08 power wheelchair	--
Classification Name	Wheelchair, Powered	Wheelchair, Powered	SE
510K Number	K200857	K163204	--
Product Code	ITI	ITI	SE
Common or Usual name	Powered Wheelchair	Powered Wheelchair	SE
Intended use/ Indications for Use	The Electric wheelchair is a motor driven transportation vehicle with the intended use to provide mobility to a disabled or elderly limited to a seated position.	This device is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.	SE
Size (unfold)	840mm x 640mm x 930mm	890 mm *603 mm *670 mm	SE Note 1

Overall length	840mm	890 mm (35")	SE Note 1
Overall width	640mm	603 mm (23.7")	SE Note 1
Stowage length	700mm	324 mm (12.8")	SE Note 1
Stowage width	640mm	603 mm (23.7")	SE Note 1
Stowage height	370mm	670 mm (26.4")	SE Note 1
Total mass	25.84 kg	28 kg (61.7 lbs)	SE Note 1
Mass of heaviest part	24kg	24 kg (53 lbs)	SE
Seat plane angle	5°	2 °	SE Note 1
Effective seat depth	430mm	430 mm (17")	SE
Effective seat width	430mm	450 mm (17.7")	SE Note 1
Seat surface height at front edge	520mm	470 mm (18.5")	SE Note 1

Back support angle	10°or 18°	20 °	SE Note 1
Back support height	450mm	470 mm (18.5")	SE Note 1
Foot support to seat distance	410mm	400 mm (15.7")	SE Note 1
Arm support height	225mm	200 mm (7.9")	SE Note 1
Front of arm support to back support	315mm	350 mm (13.8")	SE Note 1
Minimum turning diameter	1550mm	1600 mm	SE Note 1
Tires	6 inches for front wheel (solid wheel) 7 inches for rear wheel (solid wheel)	7" x 2"inches for front wheel (solid wheel) 10" x 2.35" for rear wheel (solid wheel)	SE Note 1
Speed	6 km/h (3.7mph)	7 km/h (4.4mph)	SE Note 2
Safe Gradient / Maximum	0-8°	0-12º	SE Note 2

Gradient			
Range	16 km (9.32mile)	20 km (12.43mile)	SE Note 2
Turning Radius	0.73 m	0.8 m	SE Note 2
Base weight (not including battery)	24 kg approx.	24.0 kg	SE
Battery weight	1.84 kg	4.00kg	SE Note 1
Brake	Electromagnetic	Electromagnetic	SE
Drive system	PG 45A / Rear wheel drive	PG 45A / Rear wheel drive	SE
Maximum capacity	125 kg	100 kg	SE Note 2
Ground clearance	100 mm	63.5 mm	SE Note 2
Obstacle Climbing Ability	40 mm	25 mm	SE Note 2
Battery	Lithium battery 24V/10Ah	Lithium battery 24V/20AH	SE Note 3
Motor	24V 137W	24V 250W	SE Note 3

Battery charger	DC 24V/2A	DC24V/2A	SE
Frame design	Rigid frame	Rigid frame	SE
Folding mechanism	X type	Inverted Y-type	SE Note 4
Material	Aluminum	Aluminum	SE
Remote control	Yes	Yes	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.	SE
Electrical Safety	ISO 7176 series	ISO 7176 series	SE
EMC	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”, “Total mass”, “Seat plane angle”, “Effective seat width”, “Seat surface height at front edge”, “Back support angle”, “Back support height”, “Foot support to seat distance”, “Arm support height”,

“Front of arm support to back support”, “Minimum turning diameter”, “Tires” 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”, “ Turning Radius”, “Maximum capacity”, “ Ground clearance” and “Obstacle Climbing Ability” 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” and “Motor” of the subject device are a little different from the predicate device, but both of them are comply with the standards IEC 62133 and ISO 7176, it will not raise any safety or effectiveness issue.

Note 4:

Although the “Folding mechanism” of the subject device are a little different from the predicate device, but both of them are comply with the standards ISO 7176, it will not raise any safety or effectiveness issue.

Final Conclusion:

The subject device Electric wheelchair (Model: S7012) is Substantially Equivalent to the predicate devices.

8. Date of the summary prepared

December 15, 2020