May 21, 2019

Dongguan Prestige Sporting Goods Co., Ltd
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
Suite 306, Kecheng Mansion, No.121 Science Road
Guangzhou Science Park
Guangzhou, 510663 Cn

Re: K182576
Trade/Device Name: Solax Powered Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: April 21, 2019
Received: April 26, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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 Pinto, PhD
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K182576

Device Name
Solax Powered Wheelchair, model: S7102

Indications for Use *(Describe)*
The intended use of the Solax Powered Wheelchair 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.

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.***

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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

- Company Name: Dongguan Prestige Sporting Goods Co., Ltd.
- Establishment Registration Number: 3008841035
- Address: 3rd industrial, Qiaotou Area, Houjie Town, Dongguan City, Guangdong province, China, 523950
- Phone: 13763128800
- Fax: 86-769-85922505
- Contact Person (including title): Zhang Zhao (General Manager)
- E-mail: leon@wisefame.com

## 2. Application Correspondent

- Contact Person: Ms. Cassie Lee
- Guangzhou GLOMED Biological Technology Co., Ltd.
- Tel: +86-20-61099984
- Email: regulatory@glomed-info.com

## 3. Subject Device Information

- Type of 510(k) submission: Traditional
- Device Common or Usual Name: Powered Wheelchair
- Trade Name: Solax Powered Wheelchair, model: S7102
- Regulation Name / Classification Name: Wheelchair, Powered
- Medical specialty (Panel): Physical Medicine Device
- Regulatory Class: II
- Classification Product Code: ITI
- Regulation Number: 890.3860

## 4. Predicate Device Information

- Sponsor: MERITS Health Products, Inc.
- Device Trade name: MP3C Power Base Chair, Model: MP3C
- Common name: Powered Wheelchair
- Classification name: Wheelchair, Powered
- 510K Number: K011687
- Medical specialty (Panel): Physical Medicine
- Regulation number: 890.3860
- Product Code: ITI
- Classification: Class II

## 5. Device Description

The Solax Powered Wheelchair (Model S7102) 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 Solax Powered Wheelchair (Model S7102) is with 100 kg (220 lbs) weight capacity. It is basic conventional rear wheels drive, rigid frame vehicle that are battery powered. It consists primarily of a foldable welded-aluminum frames, two sealed transaxle motors drive system, electromagnetic braking system, electric motor controller and two Li-ion batteries with an off-board battery charger. It is powered by rechargable batteries with 27.65 km which maximum speed upto 6.2 km/hr. 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 four parts which are chair part, control part, folding 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, a remote for folding/unfolding the device and a Lithium battery with an off-board charger.

## 6. Intended Use / Indications for Use

The intended use of the Solax Powered Wheelchair 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.

## 7. Performance Summary

The following performance and safety tests were conducted with Solax Powered 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 manoeuvring 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 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

**8. Comparison to predicate device and conclusion**

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Solax Powered 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** |
|---|---|---|---|
| **Submitter** | Dongguan Prestige Sporting Goods Co., Ltd. | MERITS Health Products, Inc. | -- |
| **Proprietary name** | Solax Powered Wheelchair | MP3C Power Base Chair | -- |
| **Model** | S7102 | MP3C | -- |
| **510K Number** | K182576 | K011687 | -- |
| **Common or Usual name** | Powered Wheelchair | Powered Wheelchair | SE |
| **Intended use** | The intended use of the Solax Powered Wheelchair 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 intended use of the MP3C 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. | SE |
| **Intended Use** | Over-the-counter | Over-the-counter | SE |
| **Size (unfold)** | 690mm x 600mm x 910mm | 960 x 610 x 1040mm | SE Note1 |
| **Tires** | 6 inches for front wheel (solid wheel)<br>9 inches for rear wheel (solid wheel) | 8 inches for front wheel (foam wheel)<br>10 inches for rear wheel (foam wheel) | SE Note1 |

| | | | |
|---|---|---|---|
| **Maximum speed forward** | 6.2 km/h | 8 km/h | SE Note2 |
| **Energy consumption** | 27.65 km | ~ 32 km | SE Note2 |
| **Minimum braking distance from max speed** | 0.8 m | 0.53m | SE Note1 |
| **Base weight (not including battery)** | 52kg | 54kg | SE Note1 |
| **Brake** | Electromagnetic | Electromagnetic | SE |
| **Drive system** | PG VR2 60A / Rear wheel drive | PG VR2 50A / Rear wheel drive | SE Note2 |
| **Maximum capacity** | 100 kg Approx. | 135 kg Approx. | SE Note2 |
| **Obstacle Climbing Ability** | 50mm | 50mm | SE |
| **Battery** | Lithium 25.9V30AH | 12V/U1*2 PCS | SE Note3 |
| **Motor** | 24V 200W | 24V 200W | SE |
| **Battery charger** | DC24V/2A off-board | 5 Amp off-board | SE Note3 |

**Comparison Discussion:**

**Note1:**
Although the “Size”, “Base Wight” and “Turning Circle” are a little different from the predicative device, they all comply with ISO 7176-5 Requirement. Although the “Tires” is a little different from the predicative device, they all comply with ISO 7176-7 Requirement. So the differences will not raise any safety or effectiveness issues.

**Note2:**
Although the “Maximum speed forward” is a little different from the predicative device, they all comply with ISO 7176-6 Requirement. Although the “Energy consumption” and “Maximum capacity” are a little different from the predicative device, they all comply with ISO 7176-4 Requirement. Although the “Drive System” is a little different from the predicative device, they all comply with ISO 7176-14 Requirement. So the differences will not raise any safety or effectiveness issues.

**Note3:**
Although the “Battery” and “Battery Charger” are a little different from the predicative device, they all comply with ISO 7176 Requirement. So the differences will not raise any safety or effectiveness issues.

**Final Conclusion**
The subjective device “Solax Powered Wheelchairs, model S7102” are Substantially Equivalent to the predicate device as described herein.

**8. Date of the summary prepared: 2019-05-16**