July 19, 2023

Suzhou Sweetrich Vehicle Industry Technology Co., Ltd.
℅ Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K231472
Trade/Device Name: Mobility Scooter (S1 SPORT, S1 PLUS, MAX SPORT)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: May 22, 2023
Received: May 22, 2023

Dear Ivy Wang:

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
OHT5: Office of Neurological
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)*
K231472

Device Name
Mobility Scooter (S1 SPORT, S1 PLUS, MAX SPORT)

Indications for Use *(Describe)*
The mobility Scooter 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.

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
PRAStaff@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."

510(k) Summary

I. Applicant

Name: Suzhou Sweetrich Vehicle Industry Technology Co., Ltd.

Address: No. 68 Xinfa Road, Suzhou Industrial Park, Suzhou, Jiangsu, China

Name of contact person: Chen Lezhang

Telephone: +86 139 1626 7666

Email: lezhang@sweetrich.cn; qc@sweetrich.cn

Date prepared: 2023-05-18

II. Submission Correspondent

Ms. Ivy Wang

Shanghai Sungo Management Consulting Company Limited

Tel: +86-21-5881 7802

Email: zxfda@sungoglobal.com

III. Device

Device trade name: Mobility Scooter

Model: SI SPORT, SI PLUS, MAX SPORT

Regulatory Information:

Classification name: Vehicle, motorized 3-wheeled

Regulation class: 2

Regulation number: 21CFR 890.3800

Panel: Physical Medicine

Product code: INI

IV. Predicate device

K182471

Device Name: Scooter

Model: KPL001

Tianjin Kepler Vehicle Industry Co. Ltd.

V. Device description

The Mobility Scooter, Model S1 SPORT, S1 PLUS, MAX SPORT, has a base with Steel frame, two front wheels, two rear wheels, a seat, a tiller console, electric motor, electromagnetic brake, 2 rechargeable Lead-ac id Batteries with an off-board charger. The movement of the scooter is controlled by the rider who operates the throttle lever, speed control dial and handle on the tiller console. The device is installed with an electromagnetic brake that will engage automatically when the scooter is not in use and the brake cannot be used manually. The Scooter only can be operated on the flat road.

The controller panel shape is slightly different among the three models, S1 SPORT, S1 PLUS, MAX SPORT. The S1 PLUS has a wind board on the triller, while the other two models do not have. The length of model MAX SPORT is 5cm longer than the other two models.

VI. Indication for use

The mobility scooter 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.

VII. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- ISO 7176-1:2014 Wheelchairs - Part 1: Determination of static stability
- ISO 7176-2:2017 Wheelchairs - Part 2: Determination of dynamic stability of electric wheelchairs
- ISO 7176-3:2012 Wheelchairs - Part 3: Determination of effectiveness of brakes
- ISO 7176-4:2008 Wheelchairs - Part 4: Energy consumption of electric wheelchairs

and scooters for determination of theoretical distance range

- ISO 7176-5:2008 Wheelchairs - Part 5: Determination of dimensions, mass and maneuvering space
- ISO 7176-6:2018 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs
- ISO 7176-7:1998 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 strength
- ISO 7176-9:2009 Wheelchairs - Part 9: Climatic tests for electric wheelchairs
- ISO 7176-10:2008 Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
- ISO 7176-11:2012 Wheelchairs -- Part 11: Test dummies
- ISO 7176-13:1989 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: 2012 Second edition 2012-12-01 Wheelchairs - Part 16: Resistance to ignition of postural support devices
- ISO 7176-21:2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters
- ISO 7176-22: 2014 Wheelchairs - Part 22: Set-up procedures
- ISO 7176-25:2013 Wheelchairs - Batteries and chargers for powered wheelchairs
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2014.

VIII. Comparison with the predicate device

Table 1 General Comparison

Attribute	Subject device	Predicate device	Results

Attribute	Subject device	Predicate device	Results
Manufacturer	Suzhou Sweetrich Vehicle Industry Technology Co., Ltd.	Tianjin Kepler Vehicle Industry Co. Ltd.	/
Proprietary name, model	Electrical Scooter SI SPORT, SI PLUS, MAX SPORT	Scooter, KPL001	/
510(k) number	K231472	K182471	/
Device classification name	Class II	Class II	Same
Classification regulations	21 CFR 890.3800	21 CFR 890.3800	Same
Product code	INI	INI	Same
Similarities			
Indication for use	It 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.	It 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.	Same
Use condition	indoor and outdoor use	indoor and outdoor use	Same
Number of wheels	4, including two front wheels and two rear wheels	4, including two pivoting casters and two rear drive wheels	Same
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	Same
Brake	Electromagnetic	Electromagnetic	Same
Time to brake	< 1 s	< 1 s	Same
Main frame material	Carbon Steel	Carbon Steel	Same
Frame style	Foldable seat, removable battery pack, disassemble for transport	Foldable seat, removable battery pack, disassemble for transport	Same
Battery	lead-acid 24V/12AH	lead-acid 24V/12AH	Same
Max loading weight	120 kg/265 lbs approx	120 kg/265 lbs approx	Same
Charger	DC 24V/2A	DC 24V/2A	Same
Rear wheel size/type	8” (215 x 70 mm) Solid tire	8” (215 x 70 mm) Solid tire	Same
Differences			
Controller	DR50 Dynamic	PG45A	Different.
Maximum distance	17 km	15 km	Different

Attribute	Subject device	Predicate device	Results
of travel on the fully charged battery			
Overall Dimension (length*width*height)	1210*662*925mm (Model: S1 SPORT & S1 PLUS) 1260*662*925mm (Model: MAX SPORT)	1030mm*630mm * 920mm	Different
Brake distance	≤1m	1m	Different
Turning Radius	1080-1200 mm	1300 mm	Different
Ground clearance	40-50 mm	45 mm	Different
Maximum obstacle climbing	20 mm	50 mm	Different
Slope grade ability	6 °	0-12°	Different
Front wheel size/type	8” (215 x 70 mm) Solid tire	7” (190 x 54 mm) Solid tire	Different
Max speed	6.4 km/h	6.6 km/h	Different
Motor	24 V 300W	24 V 180W	Different
Base weight (not including battery)	46 kg	50 kg	Different
Battery Weight	9 kg	10.2 kg	Different

Difference Analysis:

The design and technological characteristics of the subject device is basically similar to the predicate device chosen. There are minor differences between the devices including controller, travel distance, overall dimensions, front tire size, speed, turning radius, basic weight, battery weight, Brake distance, slope grade ability, obstacle climbing ability, Ground clearance and motor. There is no deleterious effect on safety and effectiveness due to the differences, and these minor differences do not influence the intended use function and use of the device. Moreover, the non-clinical tests and the predicate comparisons demonstrate that these differences in their technological characteristics do not raise any questions as to the safety and effectiveness.

Therefore, the subject device is substantially equivalent to the Scooter (K182471).

Table 2 Safety comparison

Attribute	Subject device	Predicate device	Results
Biocompatibility	All user directly contacting materials are compliance with	All user directly contacting materials are compliance	S.E.

Attribute	Subject device	Predicate device	Results
	ISO10993-5, ISO10993-10, ISO 10993-23 requirements.	with ISO10993-5 and ISO10993-10 requirements.	
EMC	ISO7176-21	ISO7176-21	S.E.
Performance	ISO7176 series	ISO7176 series	S.E.
Label and labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	S.E.

Table 3 Safety comparison

Attribute	Subject device	Predicate device	Results
ISO7176-1	The Static stability has been determined after the testing according to the ISO 7176-1, and test results meet its design specification.	The Static stability has been determined after the testing according to the ISO 7176-1, and test results meet its design specification.	S.E.
ISO7176-2	The dynamic stability has been determined after the testing according to the ISO 7176-2, and test results meet its design specification	The dynamic stability has been determined after the testing according to the ISO 7176-2, and test results meet its design specification	S.E.
ISO7176-3	The effectiveness of brakes has been determined after the testing according to the ISO 7176-3, and test results meet its design specification.	The effectiveness of brakes has been determined after the testing according to the ISO 7176-3, and test results meet its design specification.	S.E.
ISO7176-4	The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet its design specification.	The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet its design specification.	S.E.
ISO7176-5	The dimensions, mass has been determined after the testing according to the ISO 7176-5.	The dimensions, mass has been determined after the testing according to the ISO 7176-5.	S.E.
ISO7176-6	The maximum speed, acceleration and deceleration of scooter has been determined after the testing according to the ISO 7176-6	The maximum speed, acceleration and deceleration of scooter has been determined after the testing according to the ISO 7176-6	S.E.
ISO7176-7	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7	S.E.
ISO7176-8	All test results meet the	All test results meet the	S.E.

Attribute	Subject device	Predicate device	Results
	requirements in Clause 4 of ISO 7176-8	requirements in Clause 4 of ISO 7176-8	
ISO7176-9	The test results shown that the device under tests could continue to function according to manufacturer's specification after being subjected to each of the tests specified in Clause 8 of ISO 7176-9	The test results shown that the device under tests could continue to function according to manufacturer's specification after being subjected to each of the tests specified in Clause 8 of ISO 7176-9	S.E.
ISO7176-10	The obstacle-climbing ability of device has been determined after the testing according to the ISO 7176-10.	The obstacle-climbing ability of device has been determined after the testing according to the ISO 7176-10.	S.E.
ISO7176-11	The test dummies used in the testing of ISO 7176 series are meet the requirements of ISO 7176-11.	The test dummies used in the testing of ISO 7176 series are meet the requirements of ISO 7176-11.	S.E.
ISO7176-13	The coefficient of friction of test surfaces has been determined, which could be used in other 7176 series tests involved	The coefficient of friction of test surfaces has been determined, which could be used in other 7176 series tests involved	S.E.
ISO7176-14	All test results meet the requirements in Clause 7, 8, 9, 10, 11, 12, 13, 14, 15, 17 of ISO 7176-14	All test results meet the requirements in Clause 7, 8, 9, 10, 11, 12, 13, 14, 15, 17 of ISO 7176-14	S.E.
ISO7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	S.E.
ISO 7176-16	The performance of resistance to ignition meets the requirements of ISO 7176-16.	The performance of resistance to ignition meets the requirements of ISO 7176-16.	S.E.
ISO7176-21	The EMC performance results meet the requirements of ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21	S.E.
ISO7176-22	All performed tests are set up as requirements of ISO 7176-22	All performed tests are set up as requirements of ISO 7176-22	S.E.
ISO7176-25	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	S.E.

IX. Summary of clinical testing

No clinical study is included in this submission.

X. Conclusions

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device K182471.