May 10, 2021

Dongguan Prestige Sporting Goods Co., Ltd.
Ms. SK
Manager
SK Medical Device International Corp.
Suite 52, Floor 16, No. 119 Xing Guang Ying Jing, Shui Ying Road
Guangzhou, 510663
China

Re: K190737
Trade/Device Name: Solax Electric Scooter (Models: S204311M, S204161, S204143)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: February 3, 2021
Received: February 9, 2021

Dear Ms. SK:

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 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

Enclosure

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)*
K190737

Device Name
Solax Electric Scooter (Models: S204311M, S204161, S204143)

Indications for Use *(Describe)*
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.

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 for K190737

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
- Tel: 13763128800
- Fax: 86-769-85922505
- Contact Person: Zhang Zhao (General Manager)
- E-mail: leon@wisefame.com

2. Application Correspondent:

- Contact Person: Ms. SK
- SK Medical Device International Corp.
- Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China
- Tel: +86-18620793542
- Email: medical-device@qq.com

3. Subject Device Information

Trade Name:	Solax Electric Scooter

	Model: S204311M, S204161, S204143
Common Name:	Scooter
Classification name:	Vehicle, Motorized 3-Wheeled
Review Panel:	Physical Medicine
Product Code:	INI
Regulation Class:	2
Regulation Number:	890.3800

4. Predicate Device Information

Sponsor	Dongguan Prestige Sporting Goods Co., Ltd.
Device Name	Solax Electric Scooter Model: S302121, S302131, S302141, S302151
Common Name:	Scooter
Classification name:	Vehicle, Motorized 3-Wheeled
Review Panel:	Physical Medicine
510(k) Number	K172440
Product Code	INI
Regulation Number	890.3800
Regulation Class	2

5. Device Description

The Solax Electric Scooter (Models: S204311M, S204161, S204143) is an indoor/outdoor electric scooter that is intended to be used by individuals that are able to walk, but suffer from mobility limitations. It has the following main components: two 6 inch solid front tires, two 7 inch solid rear tires, two anti-tip tires, control panel, steering handles, seat folding lever, backrest, arm rest, seat, steering column, seat frame, front/ rear covers, folding release lever, angle adjustment lever, height adjustment lock, carry handle, an off-board charger and aluminum alloy made frame, It is powered by two Li-ion DC rechargeable batteries with 18 km (on level surface) which maximum speed up to 6 km/hr.

The movement of the scooter is controlled by the steering handles and control panel. 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.

6. Intended Use / Indications 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.

7. Performance Summary

The following performance, safety and biocompatibility tests were conducted with Solax Electric Scooter:

- ISO 7176-1: 2014, Wheelchairs - Part 1: Determination of static stability
- ISO 7176-2:2017, 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: 2018, 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
- 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 3.1, 2013
- IEC 62366 Medical devices – Application of usability engineering to medical devices Edition 1.0,2007

The materials and manufacturing used for the Solax Electric Scooter are identical to those of the predicate device, 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

8. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Solax Electric Scooter 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	**Predicate Device**	**Subject Device**	**Remark**
Proprietary name	Solax Electric Scooter	Solax Electric Scooter	--
Model	S302121, S302131, S302141, S302151	S204311M, S204161, S204143	--
510K Number	K172440	K190737	--
Common or Usual name	Electrical scooter	Electrical scooter	--
Intended 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.	SE
Indications 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.	SE
Rx or OTC?	OTC	OTC	SE
Size (unfold)	930*450*865mm	S204311M: 980*450*940mm S204161: 930*450*860mm	SE Note 1

		S204143: 980*450*880mm	
Tires	6 inches for front wheel (solid wheel) 7 inches for rear wheel (solid wheel)	6 inches for front wheel (solid wheel) 7 inches for rear wheel (solid wheel)	SE
Speed	6 km/h (3.7mph)	6 km/h (3.7mph)	SE
Safe Gradient / Maximum Gradient	0-12º	S204311M: 0-13° S204161, S204143: 0-15°	SE Note 1
Range	15 km (9.32mile)	15 km (9.32mile)	SE
Turning circle	1.55 m	S204311M: 1.55m (with a speed less than 3km/h is recommend) S204161, S204143: 1.35 m (with a speed less than 3km/h is recommend)	SE Note 1
Base weight(not including battery)	24 kg	S204311M: 24kg S204161, S204143: 24.7 kg	SE Note 1
Battery weight	1.84 kg	1.84 kg	SE
Brake	Electromagnetic	Electromagnetic	SE
Drive system	PG 45A / Rear wheel drive	PG 45A / Rear wheel drive	SE
Maximum capacity	125 kg Approx.	125 kg Approx.	SE Note 1
Ground clearance	36 mm	S204311M: 38mm S204161, S204143: 58mm	SE Note 1
Obstacle Climbing Ability	38 mm	S204311M: 40mm S204161, S204143: 60mm	SE Note 1
Frame design - Construction	X type	X type	SE
Frame design - Materials	aluminum alloy frame	aluminum alloy frame	SE
Folding mechanism	Manual folding and remote folding	Manual folding for S204311M, S204161, S204143	SE Note 2

Remote control	None	Yes	SE Note 2
Battery	Lithium battery 24V/10AH	Lithium battery 24V/10AH	SE
Motor	24V 120W	24V 120W	SE
Battery charger	DC24V/2A	DC24V/2A	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

Comparison in Detail(s):

Note 1:

The design and technological characteristics of the Solax Electric Scooter is basically similar to the predicate device chosen. There are minor differences between the devices including overall dimensions, Safe Gradient, Base weight, Maximum capacity, Ground clearance, Obstacle Climbing Ability. There is no deleterious affection of safety and effectiveness about 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 Solax Electric Scooter (models: S204311M, S204161, S204143) is substantially equivalent to the Solax Electric Scooter (models: S302121, S302131, S302141, S302151) (K172440).

Note 2:

Although the “Folding mechanism” and “Remote control” is a little different with predicate device, but these difference will not affect the basic safety and indications for use of subject device, they are not necessary function which will not raise any safety issue and effectiveness issue.

9. Date of the summary prepared: May 6, 2021