December 23, 2025

Guangdong Prestige Technology Co., Ltd.
% Cassie Lee
Official Correspondent
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road,
Huangpu District
Guangzhou, Guangdong 510000
China

Re: K252835
Trade/Device Name: Electric Scooter (S202572J, S2060, M2089, S2050)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: December 1, 2025
Received: December 1, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252835

Please provide the device trade name(s).

Electric Scooter (S202572J, S2060, M2089, S2050)

Please provide your Indications for Use below.

It is a motor driven, indoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary for K252835

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 890.92.

1. Submitter's Information

Company Name: Guangdong Prestige Technology Co., Ltd.
Address: No.8, Road.1, 3rd Ind. District, Houjie Qiaotou, Houjie Town, Dongguan City, Guangdong Province, China
Establishment Registration Number: 3008841035
Postal Code: 523950
Phone: +86 0769-85922501
Fax: +86 0769-85922505
Contact Person (including title): Zhang Zhao (General Manager)
E-mail: leon@solaxtech.com

Application Correspondent:

Contact Person: Ms. Cassie Lee
Company: Share Info (Guangzhou) Medical Consultant Ltd.
Address: No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District, Guangzhou, China
Tel: +86 20 8200 6973
Email: 382198657@qq.com

2. Subject Device Information

Type of 510(k) Submission: Traditional
Common Name: Electric Scooter
Trade Name: Electric Scooter
Model: S202572J, S2060, M2089, S2050
Classification Name: Vehicle, Motorized 3-Wheeled
Regulation Description: Motorized three-wheeled vehicle.
Review Panel: Physical Medicine
Product Code: INI
Regulation Class: 2
Regulation Number: 21 CFR 890.3800

3. Predicate Device Information

Predicate Device

510k number: K190737
Trade Name: Solax Electric Scooter
Model: S204311M, S204161, S204143

Classification name: Vehicle, Motorized 3-Wheeled

Regulation Description: Motorized three-wheeled vehicle.

Review Panel: Physical Medicine

Product Code: INI

Regulation Class: 2

Regulation Number: 21 CFR 890.3800

4. Device Description

The Electric Scooter (model: S202572J, S2060, M2089, S2050) is an indoor electric scooter that is battery operated.

The Electric Scooter (Model: S202572J, S2060, M2089, S2050) is with 125 kg weight capacity. It is basic conventional rear wheels drive, rigid frame vehicle that are battery powered. It consists primarily of a fold-able frames (S202572J: carbon fiber frame, S2060, M2089, S2050: aluminum alloy frame), a sealed trans-axle motors drive system, electromagnetic braking system, electric motor controller and a Li-ion batteries with an off-board battery charger. It is powered by 25.2 V/10 AH rechargeable Lithium batteries with 15 km which maximum speed up-to 6 km/hr. The direction control lever to control the direction of the Electric Scooter.

For model S202572J, when pushing the right acceleration push rod forward with the right finger, the electric scooter moves forward, when pushing the left acceleration push rod forward with the left finger, the electric scooter moves backward, the electromagnetic brake will be actuated when the acceleration push rod is released and the electric scooter will stop. It consists of four parts which are chair part, control part, folding part and drive part. Overall, it mainly has a basic carbon fiber frame, two front wheels, two rear wheels, two anti-tip wheels, a seat, a control panel, an electric motor, an electromagnetic brake, two armrests and a Lithium battery with an off-board charger. The control panel has eight buttons, the acceleration push rod, a display screen showing the device status and NFC unlocking sensing area.

For model S2060, when pushing the right acceleration push rod backward with the right finger, the electric scooter moves forward, when pushing the left acceleration push rod backward with the left finger, the electric scooter moves backward, the electromagnetic brake will be actuated when the acceleration push rod is released and the electric scooter will 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 control panel, an electric motor, an electromagnetic brake and a Lithium battery with an off-board charger. The control panel has five buttons, the acceleration push rod, a display screen showing the device status and NFC unlocking sensing area.

For model M2089, when pushing the right acceleration push rod forward with the right finger, the electric scooter moves forward, when pushing the left acceleration push rod forward with the left finger, the electric scooter moves backward, the electromagnetic brake will be actuated when the acceleration push rod is released and the electric scooter will 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, four backline anti-tip wheels, a seat, a control panel, an electric motor, an electromagnetic brake, two armrests and a Lithium battery with an off-board charger. The control panel has five buttons, the acceleration push rod, a display screen showing the device status.

For model S2050, when pushing the right acceleration push rod forward with the right finger, the electric scooter moves forward, when pushing the left acceleration push rod forward with the left finger, the electric scooter moves backward, the electromagnetic brake will be actuated when the acceleration push rod is released and the electric scooter will 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 control panel, an electric motor, an electromagnetic brake and a Lithium battery with an off-board charger. The control panel has a battery level indication area, a speed control knob, a horn button, a power control keyhole and the acceleration push rod.

The model S202572J, S2060, M2089, S2050 are identical in circuit structure and key components (such as battery, charger, controller, motor) except for some differences shown in the appearance and function.

About appearance of the four models, the model S202572J and model S2060 are different in the material of the frame, the control panel, the size of tires, the overall size and the backrest shape. The model S2050 and model S2060 are different in the shape of seat bracket, the control panel and the backrest shape. The model M2089 and model S2060 are different in the shape of seat bracket, the pedal, the overall size and the backrest shape. The model S2060, S2050 have no armrest, while the model S202572J, M2089 have two armrests.

About function of the four models, the folding method of model M2089 are different from the model S202572J, S2060, S2050. The tiller height of model S202572J, S2060, S2050 is adjustable, while the tiller height of model M2089 is non-adjustable.

5. Intended Use / Indications for Use

It is a motor driven, indoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

6. Tests Summary

6.1 Summary of Non-Clinical Tests

Electric Scooter (Model: S202572J, S2060, M2089, S2050) has been evaluated the safety and performance by lab bench testing as following:

- Biocompatibility Testing

The patient-contacting materials of Electric Scooter (model: S202572J, S2060, M2089, S2050) have the same nature of tissue contact and contact duration as the Mobile scooter (K122749).

- Electromagnetic compatibility (EMC)

EMC testing was conducted on the proposed device. The system was shown to comply with IEC 60601-1-2:2020, ISO 7176-21, and IEEE ANSI C63.18-2014 for electromagnetic compatibility.

- Performance testing

Performance test and functional tests were conducted on the proposed device in accordance with product design specifications. Data generated from the test met the predetermined acceptance criteria. The following includes:
The device complied with requirements for ISO 7176-1 static stability; ISO 7176-2 dynamic stability; ISO 7176-3 effectiveness of brakes; ISO 7176-4 theoretical distance rang; ISO 7176-5 dimensions, mass and manoeuvring space; ISO 7176-6 maximum speed, acceleration and deceleration; ISO 7176-7 static dimensions of the device; ISO 7176-8 static, impact and fatigue strengths; ISO 7176-9 climatic tests; ISO 7176-10 obstacle-climbing ability; ISO 7176-11 dummies; ISO 7176-13 coefficient of friction of test surfaces; ISO 7176-14 power and control systems; ISO 7176-15 information disclosure, ISO 7176-21 documentation and labelling; ISO 7176-22 set-up procedures.

- Resistance to Ignition Testing

The seat cushion, backrest and armrests of this device were tested for resistance to ignition, and the test results all met the criteria requirements of ISO 16840.

- Software Verification and Validation

The Software verification and validation is in compliance with FDA Guidance-Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

- Cybersecurity

The subject device no any external interfaces, according to FDA guidance “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”, no need cybersecurity evaluation.

6.2 Summary of Clinical Performance Test
No clinical study is included in this submission.

7. Comparison to predicate device and conclusion

Compare with the predicate devices:

Elements of Comparison	Subject Device	Predicate Device	Remark
Company	Guangdong Prestige Technology Co., Ltd.	Dongguan Prestige Technology Co., Ltd.	--
Trade Name	Electric Scooter	Solax Electric Scooter	--
Model	S202572J, S2060, M2089, S2050	S204311M, S204161, S204143	--
Classification Name	Vehicle, Motorized 3-Wheeled	Vehicle, Motorized 3-Wheeled	Same
510K Number	K252835	K190737	--
Common or Usual name	Electric Scooter	Solax Electric Scooter	
Product Code	INI	INI	Same
Regulation Number	21 CFR 890.3800	21 CFR 890.3800	Same
Regulation Description	Motorized three-wheeled vehicle.	Motorized three-wheeled vehicle.	Same
Intended use	It is a motor driven, indoor 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.	Similar. The difference between the subject device and the predicate device is that the subject device can only be used indoors, while the predicate device can be used indoors and outdoors. Therefore, the expected use of the predicate device includes the content of the subject device. So, the difference will not raise any safety or effectiveness issue.
Use condition	Indoor use	Indoor and outdoor use	Similar. The predicate device contains the conditions of use of the subject device and is within the scope of the predicate device, so it does not affect the safety and effectiveness of the device.
Intended user	Disabled or elderly person limited to a seated position.	Disabled or elderly person limited to a seated position	Same

Maximum capacity	125 kg	125 kg Approx.	Same
Remote control	No	No	Same
Drive system	PG 45A / Rear wheel drive	PG 45A / Rear wheel drive	Same
Brake system	Electromagnetic	Electromagnetic	Same
Motor	24 V/150 W	24V 120W	Similar. Although the “motor” of the subject device is slightly different from that of the predicate device, they both comply with EMC standards and ISO 7176-14 standards, so this difference does not affect the safety and effectiveness.
Battery	Lithium Battery 25.2 V, 10 Ah	Lithium battery 24V/10AH	Similar. Although the "Battery" is slightly difference between the subject device and predicate device, it is complied with the standards IEC 62133-2, ISO 7176-4, and ISO 7176-14, it will not affect the safety and effectiveness.
Battery weight	1.7 kg	1.84 kg	Similar. Although the “Battery weight" is slightly difference between the subject device and predicate device, it is complied with the standards IEC 62133-2 ISO7176-5, and ISO 7176-14, the difference will not affect the safety and effectiveness.
Battery charger	Off-board charger 29.4 VDC, 2 A	DC24V/2A	Similar. Although the "Battery charger " is slightly difference between the subject device and predicate device, it is complied with the standards IEC 60601-1, it will not affect the safety and effectiveness.
Frame design	Rigid frame	Rigid frame	Same
Frame design - Material	S202572J: Carbon fiber S2060, M2089, S2050: Aluminum alloy	Aluminum alloy	Different. The frame material for model S2060, M2089 and S2050 is consistent with that of the predicate device. The frame material for model S202572J is different

			from that of the predicate device, but both comply with the requirements of the ISO 7176 series standards and have the same durability level as the predicate device. Therefore, the use of different frame materials does not raise new safety and efficacy issues.
Folding mechanism	Manually fold or unfold	Manual folding for S204311M, S204161,S204143	Same
Tires	S202572J: 7 inches for front wheel (solid tire) 7 inches for rear wheel (solid tire) 66.67 mm for anti-tip wheel S2060, M2089, S2050: 8 inches for front wheel (solid tire) 8 inches for rear wheel (solid tire) 66.67 mm for anti-tip wheel	6 inches for front wheel (solid wheel) 7 inches for rear wheel (solid wheel)	Similar. Although the “Tires" is difference between the subject device and predicate device, it is complied with the standard ISO 7176 series, the difference will not affect the safety and effectiveness.
Base weight (not including battery)	S202572J: 13.3 kg S2060: 18.2 kg M2089: 14.3 kg S2050: 18.2 kg	S204311M: 24 kg S204161, S204143: 24.7 kg	Different. Although the “Base weight" is difference between the subject device and predicate device, the subject device is lighter than the predicate device and offers better portability. Furthermore, the subject device complies with the requirements of the standard ISO 7176-5. So, the difference in this parameter does not affect the safety and effectiveness.
Overall dimension (L × W × H)	S202572J: 955 x 520 x 950 mm S2060: 1030 x 460 x 968 mm M2089: 1008 mm x 545 mm x 935 mm S2050: 1030 mm x 460 mm x 968 mm	S204311M: 980 x 450 x 940 mm S204161: 930 x 450 x 860 mm S204143: 980 x 450 x 880 mm	Different. These parameters differ between the subject device and the predicate device, but the subject device complies with the requirements of standard ISO 7176-5, and. In addition, minor variations in physical characteristics do not affect critical functions or normal use, so these parameter
Turning Diameter	S202572J: 2960 mm S2060, S2050: 2800 mm M2089: 2730 mm	S204311M: 1.55 m (with a speed less than 3 km/h is recommend) S204161, S204143: 1.35 m (with a speed less than	

		3 km/h is recommend)	differences do not affect the safety and effectiveness.
Ground clearance	S202572J: 40 mm S2060, S2050: 50 mm M2089: 65 mm	S204311M: 38 mm S204161, S204143: 58 mm	
Cruising Range	15 km (9.32 mile)	15 km (9.32 mile)	Same
Max Speed forward	6 km/h (3.7mph)	6 km/h (3.7mph)	Same
Maximum obstacle climbing	25 mm	S204311M: 40 mm S204161, S204143: 60 mm	Different. Although this parameter is difference between the subject device and predicate device, it is complied with the standard ISO 7176-10. The difference in this parameter does not affect the safety and effectiveness.
Maximum safe operational incline degree	12°	S204311M: 0-13° S204161, S204143: 0-15°	Similar. This parameter is slightly different but similar to that of the predicate device, and it complies with the standards ISO 7176-1, ISO 7176-2 and ISO 7176-3, so this difference does not affect the safety and effectiveness.

Final Conclusion:

The subject device is as safe, as effective, and performs as well as the legally marketed predicated devices K190737.

8. Date of the summary prepared: December 19, 2025