January 9, 2026

Suzhou Sweetrich Vehicle Industry Technology Co., Ltd.
℅ Ariel Xiang
Shanghai Sungo Management Consulting Co. Ltd.
14th Floor, 1500# Century Avenue
Shanghai, Shanghai 200122
China

Re: K253075
Trade/Device Name: mobility scooter (Air Classic); mobility scooter (Air Traveller); mobility scooter (Air Traveller 2.0)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: December 10, 2025
Received: December 10, 2025

Dear Ariel Xiang:

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.	K253075 ?

Please provide the device trade name(s). ?

mobility scooter (Air Classic);
mobility scooter (Air Traveller);
mobility scooter (Air Traveller2.0)

Please provide your Indications for Use below. ?

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.

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

Document Prepared Date: 2025/12/10

1. Applicant Information

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2. Subject Device

Mobility Scooter
Model: Air Classic,Air Traveller,Air Traveller2.0
Classification regulations:21 CFR 890.3800
Product code:INI
Classification:Class II

3. Substantial Equivalence Information

Suzhou Sweetrich Vehicle Industry Technology Co., Ltd.
Mobility Scooter (S1 SPORT, S1 PLUS, MAX SPORT),K231472
Classification regulations:21 CFR 890.3800
Product code:INI
Classification:Class II

4. Device Description

The Mobility Scooter(Air Classic, Air Traveller, and Air Traveller 2.0) feature a base with an aluminum frame and an ABS body shell. They come equipped with one or two front wheels, two rear wheels, two armrests, a seat, a control panel, direction handles, electrical machinery, an electromagnetic brake, and rechargeable lithium-ion batteries with an off-board charger.The movement of the scooter is controlled by control panel and direction handles.
The device is installed with an electromagnetic brake.Seat and handlebar can be folded.The maximum load capacity is 120KG.

5. 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.

6. Product parameters

Attribute	Subject device	Predicate device	Results
Manufacturer	Suzhou Sweetrich Vehicle Industry Technology Co., Ltd.	Suzhou Sweetrich Vehicle Industry Technology Co., Ltd.	/
Proprietary name, model	Electrical Scooter Air Classic,Air Traveller,Air Traveller2.0	Electrical Scooter SI SPORT, SI PLUS, MAX SPORT	/
510(k) number	K253075	K231472	/
Device classification name	Class II	Class II	Same
Classification regulations	21 CFR 890.3800	21 CFR 890.3800	Same
Product code	INI	INI	Same
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	Air Classic: 3, including one front wheels and two rear wheels Air Traveller&Air Traveller2.0: 4, including two front wheels and two rear wheels	4, including two front wheels and two rear wheels	Similar
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
Brake distance	＜1m	≤1m	Same
Frame style	Foldable seat, removable battery pack, disassemble for transport	Foldable seat, removable battery pack, disassemble for transport	Same
Battery	Llithium-ion battery 24V/12AH	lead-acid 24V/12AH	Different,The lithium battery has passed the IEC 62133-2 test,the subject device also

Attribute	Subject device	Predicate device	Results
			complies with ISO 7176-25,these difference will not cause new safety and effectiveness concerns raised.
Max loading weight	120 kg/265 lbs approx	120 kg/265 lbs approx	Same
Max speed	Air Classic:1.73m/s(6.2km/h) Air Traveller&Air Traveller2.0: 1.78m/s(6.4 km/h)	6.4 km/h	Same
Charger	DC 24V/2A	DC 24V/2A	Same
Main frame material	Aluminium	Carbon Steel	Different material used for frame, that such difference will not impact the safety and effectiveness of the subject device as the performance tests are conducted according to ISO 7176 series.
Front wheel size/type	Air Classic: 150*38mm ,PU Solid tire Air Traveller&Air Traveller2.0: 178*48mm, PU Solid tire	8” (215 x 70 mm) Solid tire	This difference will not cause new safety and effectiveness concerns raised.
Rear wheel size/type	Air Classic: 190*50 PU Solid tire Air Traveller&Air Traveller2.0: 188*48mm PU Solid tire	8” (215 x 70 mm) Solid tire	
Overall Dimension (length*width*height)	Air Classic:1115*505*881mm Air Traveller&Air Traveller2.0: 1193*495*858mm	1210*662*925mm (Model: S1 SPORT & S1 PLUS) 1260*662*925mm (Model: MAX SPORT)	Minor difference on scooter dimension will not cause different performance. All safety and performance

Attribute	Subject device	Predicate device	Results
			have been validated with the maximum rated weight dummy.
Maximum distance of travel on the fully charged battery	Air Classic:16km Air Traveller&Air Traveller2.0: 18.1km	17 km	Bigger motor capacity keeps longer travel distance. This difference will not cause new safety and effectiveness concerns raised.
Turning Radius	Air Classic:1035mm Air Traveller&Air Traveller2.0：1600mm	1080-1200 mm	Minor difference on turning radius will not cause new safety and effectiveness concerns raised.
Ground clearance	Air Classic:19mm Air Traveller&Air Traveller2.0: 59mm	40-50 mm	Minor difference on ground clearance will not cause new safety and effectiveness concerns raised.
Maximum obstacle climbing	Air Classic:20mm Air Traveller&Air Traveller2.0: 15mm	20 mm	The difference on maximum obstacle climbing will not cause new safety and effectiveness concerns raised.
Slope grade ability	10 °	6 °	Minor difference on slope grade ability will not cause different performance. No safety or effectiveness concerns raised.
Controller	24V32A,180W-300W	DR50 Dynamic	Both meet the requirements of the ISO 7176-14:2008.

Attribute	Subject device	Predicate device	Results
			Not cause new safety and effectiveness concerns raised.
Motor	Air Classic: Brushless motor,24V/250W Air Traveller&Air Traveller2.0: Brushless motor,24V/180W	24 V 300W	Minor difference on motor power will not cause safety or effectiveness concerns raised.
Base weight (not including battery)	Air Classic:25.47kg Air Traveller&Air Traveller2.0: 22.46kg	46 kg	Minor difference on scooter weight will not cause different performance. No safety or effectiveness concerns raised.

Substantial Equivalence Discussion:

The proposed device and predicate device are complying to the same ISO standards, ISO 7176-1, ISO 7176-2, ISO 7176-3, ISO 7176-4, ISO 7176-5, ISO 7176-6, ISO 7176-7, ISO 7176-8, ISO 7176-9, ISO 7176-10, ISO 7176-11, ISO 7176-13, ISO 7176-14, ISO 7176-15, ISO 16840-10,ISO 7176-21, ISO 7176-25, and FDA guidance Submission for Mobility Scooter.

The intended uses for both devices are the same. The frame style of the two devices are both foldable seat, removable battery pack and disassemble for transport, and the frame materials are the same carbon steel. Brake system and speed control are designed in the same way as well, and both meet the requirements of the ISO 7176-3:2012. The controller are designed by different company, however the design principles of the controller and Driving system are similar, and both meet the requirements of the ISO 7176-14:2008. Those dimension difference will not impact the safety and effectiveness of the subject device or raise new safety and effectiveness concerns. The biocompatibility of the Predicate device and Subject device meet the requirements of the ISO 10993-5:2009 & ISO 10993-10:2010.

In conclusion, the technological characteristics, features, specifications, materials, mode of operation, and intended use of the device 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.

7. Product Performance

7.1 Product Material Safety

To ensure the safety of the scooter material, the bio-compatibility testing was done to the products. The testing was conducted according to the following standards:

ISO10993-5 Biological evaluations of medical devices -- Part 5: Tests for In Vitro cytotoxicity

ISO 10993-10 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
From the test result, we can find the material are safety and can meet the requirements.

7.2 Performance of the products
The following performance data were provided to verify that the subject device met all design specifications and provided support of the substantial equivalence determination.
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 7176-21:2009 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
ISO16840-10:2021Wheelchairseating — Part 10: Resistance to ignition of postural support devices — Requirements and test method
Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2014.
IEC 62133-2:2021 Secondary cells and batteries containing alkaline or other non- acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems

8. Summary of clinical testing
No animal study and clinical studies are available for our device. Clinical testing was not required to demonstrate the substantial equivalence of the power wheelchair to its predicate device.

9. Conclusion
The current device and the predicate products have the same technological characteristics, features, specifications, materials, mode of operation, and intended use of the device. To ensure all the key characteristic of the products can meet the requirements, the testing was done and all the results indicate the

positive conclusion.
Based on the analysis above, we confirm these two products are substantially equivalent.