May 20, 2026

Suzhou Sweetrich Vehicle Industry Technology Co., Ltd.
℅ Andrew Wang
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, 1500# Century Ave.
Shanghai, Shanghai 200122
China

Re: K260717
Trade/Device Name: Mobility Scooter (Air Carbon)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: March 5, 2026
Received: March 5, 2026

Dear Andrew 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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260717

Device Name
Mobility Scooter (Air Carbon)

Indications for Use *(Describe)*
This 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.

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510(k) Summary

Document Prepared Date: 2026-05-14

1. Applicant Information

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2. Subject Device

Device Name: Mobility Scooter
Model: Air Carbon
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI

3. Predicate Device

Mobility Scooter (Air Classic, Air Traveller, Air Traveller2.0), K253075

4. Device Description

The Mobility Scooter(Air Carbon) features a base with a carbon fiber frame and an ABS body shell. It comes equipped with two front wheels, two rear wheels, two armrests, a seat, a control panel, direction handles, motor, an electromagnetic brake, and rechargeable Li-ion battery pack 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. And the device can be folded. The maximum load capacity is 120KG.

5. Indication for Use

This 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.

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	Mobility Scooter Air Carbon	Mobility Scooter Air Classic, Air Traveller, Air Traveller2.0	/
510(k) number	K260717	K253075	/
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	4, including two front wheels and two rear 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	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
Brake distance	1.64m	＜1m	Same
Frame style	Foldable seat, removable battery pack, disassemble for transport	Foldable seat, removable battery pack, disassemble for transport	Same

Attribute	Subject device	Predicate device	Results
Battery	Li-ion Battery Pack 24V 6.4Ah	Llithium-ion battery 24V/12AH	The subject device complies with ISO 7176- 25: 2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs and EMC testing, these differences do not affect safety and effectiveness.
Max loading weight	120 kg/265 lbs approx	120 kg/265 lbs approx	Same
Max speed	1.73m/s (6.2km/h)	Air Classic:1.73m/s(6.2km/h) Air Traveller&Air Traveller2.0: 1.78m/s(6.4 km/h)	Same
Charger	DC 24V/2A	DC 24V/2A	Same
Main frame material	Carbon fiber	Aluminium	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	PU Solid tire, 7inch (=177.8mm)	Air Classic: 150*38mm ,PU Solid tire Air Traveller&Air Traveller2.0: 178*48mm, PU Solid tire	Minor difference on wheel size will not cause new safety and effectiveness concerns raised.
Rear wheel size/type	PU Solid tire, 8inch (=203.2mm)	Air Classic: 190*50 PU Solid tire Air Traveller&Air Traveller2.0: 188*48mm PU Solid tire	

Attribute	Subject device	Predicate device	Results
Overall Dimension (length*width*height)	1030*517*920mm	Air Classic:1115*505*881mm Air Traveller&Air Traveller2.0: 1193*495*858mm	Minor difference on scooter dimension will not cause different performance. All safety and performance have been validated with the maximum rated weight dummy.
Maximum distance of travel on the fully charged battery	11.7km	Air Classic:16km Air Traveller&Air Traveller2.0: 18.1km	Minor difference on travel distance will not cause new safety and effectiveness concerns raised.
Turning Radius	1375mm	Air Classic:1035mm Air Traveller&Air Traveller2.0：1600mm	Minor difference on turning radius will not cause new safety and effectiveness concerns raised.
Ground clearance	34mm	Air Classic:19mm Air Traveller&Air Traveller2.0: 59mm	Minor difference on ground clearance will not cause new safety and effectiveness concerns raised.
Maximum obstacle climbing	30mm	Air Classic:20mm Air Traveller&Air Traveller2.0: 15mm	The difference on maximum obstacle climbing will not cause new safety and effectiveness concerns raised.
Slope grade ability	8 °	10 °	Minor difference on slope grade ability will not cause different performance. No safety or effectiveness concerns raised.
Controller	24V30A/180W-300W	24V32A,180W-300W	Both meet the requirements of the ISO 7176-14. Not cause new safety and effectiveness concerns raised.

Attribute	Subject device	Predicate device	Results
Motor	Brushless motor, 24V180W	Air Classic: Brushless motor,24V/250W Air Traveller&Air Traveller2.0: Brushless motor,24V/180W	Same
Base weight (not including battery)	14.16kg	Air Classic:25.47kg Air Traveller&Air Traveller2.0: 22.46kg	Minor difference on scooter weight will not cause different performance. No safety or effectiveness concerns raised.

Substantial Equivalence Discussion:

The mobility scooter complied with the requirements of ISO 7176-1:2014, ISO 7176-2:2017, ISO 7176-3:2012, ISO 7176-4:2008, ISO 7176-5:2008, ISO 7176-6:2018, ISO 7176-7:1998, ISO 7176-8:2014, ISO 7176-9:2009, ISO 7176-10:2008, ISO 7176-11:2012, ISO 7176-13:1989, ISO 7176-14:2022, ISO 7176-15:1996, ISO 7176-16:2012, ISO 7176-21:2009, ISO 7176-22:2014, ISO 7176-25:2013, IEC 60601-1-2:2020, ISO 10993-1.

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. Brake system and speed control are designed in the same way as well, and both meet the requirements of the ISO 7176-3:2012. 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 ISO10993-1.

In conclusion, the technological characteristics, features, specifications, 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

Item	Proposed Device	Predicate Device	Remark
EMC	ISO7176-21 & IEC 60601-1-2	ISO7176-21 & IEC 60601-1-2	Same
Performance	ISO7176 series	ISO7176 series	Same
Label and labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	Same

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 7176-14:2022 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 16840-10:2021 Wheelchair seating - Part 10: Resistance to ignition of postural support devices –Requirements and test method
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 60601-1-2:2020.

Item	Proposed 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.	Same
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.	Same

Item	Proposed Device	Predicate Device	Results
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.	Same
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.	Same
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	Same
ISO7176-6	The dimensions, mass has been determined after the testing according to the ISO 7176- 6	The dimensions, mass has been determined after the testing according to the ISO 7176-6	Same
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	Same
ISO7176-8	All test results meet the requirements in Clause 4 of ISO 7176-8	All test results meet the requirements in Clause 4 of ISO 7176-8	Same
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	Same
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,	Same
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	Same
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	Same

Item	Proposed Device	Predicate Device	Results
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	Same
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	Same
ISO7176-16/ ISO 16840-10	The performance of resistance to ignition meet the requirements of ISO 16840-10	The performance of resistance to ignition meet the requirements of ISO 16840-10	Same
ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21	Same
ISO 7176-25	The performance of batteries and chargers for powered wheelchairs meet the requirements of ISO 7176-25	The performance of batteries and chargers for powered wheelchairs meet the requirements of ISO 7176-25	Same

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 devices have the same technological characteristics, features, specifications, mode of operation, and intended use of the device. To ensure all the key characteristic of the products can meet the requirements, testing was done and all the results indicate the positive conclusion. Based on the analysis above, we confirm these two devices are substantially equivalent.