July 22, 2025

Suzhou Master Machinery Manufacturing Co., Ltd.
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd., Pudong
Shanghai, 200120
China

Re: K251638
Trade/Device Name: Mobility Scooter (MS160C)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: May 29, 2025
Received: May 29, 2025

Dear Boyle 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 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.	K251638

Please provide the device trade name(s).

Mobility Scooter (MS160C)

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

K251638

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's information

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Tel: 86-512-57452882
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Contact: Siqi.Shangguan
Date of Preparation: Jul.10, 2025

Designated Submission Correspondent

Mr. Boyle Wang
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2.0 Device information

Trade name: Mobility Scooter
Common name: Scooter
Classification name: Motorized Three-Wheeled Vehicle
Model(s): MS160C

3.0 Classification

Production code: INI
Regulation number: 21 CFR 890.3800
Classification: Class II
Panel: Physical Medicine

4.0 Predicate device information

Manufacturer: Zhejiang Innuovo Rehabilitation Devices Co.,Ltd.
Trade/Device: Mobility Scooter (Model: W3468)

510(k) number: K220207

5.0 Indication for Use Statement

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.

6.0 Device description

The product is a Mobility Scooter which provides transport for the disabled and the elderly and to be used both indoors and outdoors.
This scooter is a battery powered four wheeled vehicle. It consists two Lead-acid batteries (in the battery box) with an off-board battery charger, frame, a seat, a back support, control panel (including the key switch, throttle control lever, horn button, speed adjustment dial, and the battery condition meter) , two foldable handles, two rear drive wheels with motor/ e-magnetic brake components, two front wheels, anti-tip devices, an external battery charger, a control panel and a motor controller. For convenience of transportation and reduction of possible damage, the battery and the seat unit can be dismantled and separately packaged.

The front wheels of the scooter are 8 inches and the rear wheels are 9 inches.
The motor of the scooter is 24VDC,150W,4200RPM; the Lead-acid Battery is 12 V, 22 Ah, 18.7 Ah; the charger is 24V/2A.
Max. loading cannot be over than 180kg.
The maximum distance travelled with a fully charged battery is 17.5km and the maximum forward speed is 1.6m/s(5.8km/h).
Braking time is less than 2 seconds, braking distance is ≤1.0 meters.

7.0 Summary of Non-Clinical Testing

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 7176-1:2014 Wheelchairs - Part 1: Determination of static stability
ISO 7176-2:2017 Wheelchairs - Part 2: Determination of dynamic stability of electrically powered 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 overall dimensions, mass and manoeuvring 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 strengths
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 16840-10:2021 Wheelchair seating - Part 10: Resistance to ignition of postural support devices - Requirements and test method
ISO 7176-22:2014 Wheelchairs - Part 22: Set-up procedures
ISO 7176-25:2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs
IEC 60601-1-2:2020 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC TR 60601-4-2 Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Biocompatibility of patient-contacting parts

Patient-contacting material are carried out biocompatibility assessment in accordance with lSO 10993-1: 2018, including:
Cytotoxicity per ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
Skin Sensitization per ISO 10993-10:2021 Biological Evaluation of Medical Devices - Part 10: Tests For Skin Sensitization.
Irritation per ISO 10993-23:2021 Biological Evaluation of Medical Devices - Part 23: Tests For Irritation.

8.0 Summary of Clinical Testing

No clinical study implemented for the scooter.

9.0 Technological Characteristic Comparison Table

Table 1 - General Comparison

Item	Subject Device K251638	Predicate Device K220207	Remark
Product Code	INI	INI	Same
Regulation No.	21 CFR 890.3800	21 CFR 890.3800	Same
Class	II	II	Same
Product name	Scooter (Model: MS160B)	Scooter (Model: W3468)	-
Intended Use/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 environment	Indoor and outdoor use	Indoor and outdoor use	Same
Patient Population	This product is suitable for disabled people with mobility difficulties and elderly people.	This product is suitable for disabled people with mobility difficulties and elderly people.	Same
Product structure	It consists two Lead-acid batteries (in the battery box) with an off-board battery charger, frame, a seat, a back support, control panel (including the key switch, throttle control lever, horn button, speed adjustment dial, and the battery condition meter), two foldable handles, two rear drive wheels with motor/ e-magnetic brake components.	It has a base with Steal frame, two front wheels, two rear wheels, a seat, a tiller console, electric motor, electromagnetic brake, front light, USB charging port (Transfer power only), 2 rechargeable Lead-acid Batteries with an off-board charger	Similar
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	Same
Number of wheels	4	4	Same
Main frame material	Aluminium alloy	Steel	Different
Motor	Brushless motor, DC24V * 180W * 1 pcs	Brushless motor, 250W	Minor differences in the dimensions will not impact the safety and effectiveness of the substantial equivalence.
Battery	Lead Acid DC 12 V,22 Ah, 18.7 Ah 2 pc	Lead Acid12V x 2 (22Ah) 2pc	
Battery charger	Off-board charger 24V/2A	Off-board charger 24V/2A	

Table 2 - Performance Comparison

Item	Subject Device	Predicate Device K220207	Remark

Dimensions (mm)	1150x511x900	1075 x 510 x 930	Minor differences in the dimensions will not impact the safety and effectiveness of the substantial equivalence.
Folded dimensions (mm)	1100x500x390	Not Publicly Available	Minor differences in the folded dimensions will not impact the safety and effectiveness of the substantial equivalence.
Weight, w/ Battery	110.2lbs. /50kg	127.9lbs. /58kg	Both the proposed and predicate devices meet the performance testing standards ISO 7176 series.
Frame design	Foldable/ The electric scooter is an auxiliary walking tool powered by electricity. It can be folded after removing the battery, convenient for transport and storage.	Foldable/ The electric scooter is an auxiliary walking tool powered by electricity. It can be folded after removing the battery, convenient for transport and storage.	Same
Seating Design	The seat height is adjustable to suit different users, and the armrests can be adjusted in width or flipped up to facilitate getting on and off. The seat can be easily removed for folding and transportation.	The seat height is adjustable to suit different users, and the armrests can be adjusted in width or flipped up to facilitate getting on and off. The seat can be easily removed for folding and transportation.	Same
Folding mechanism	A foldable seat frames (The backrest could be folded to seat)	A foldable seat frames (The backrest could be folded to seat)	Same
Front wheel(inch)	8 (PU tire)	9	Different sizes of wheel will not affect safety and performance of the subject device as all related stability tests are performed according to standard ISO 7176 series.
Rear tire (inch)	9 (PU tire)	9	Same
Anti-tip Wheels (inch)	2.5	2.5	Same

Cruising Range(km)	17.5	20km	The difference will not raise any new safety and effectiveness concerns.
Obstacle climbing(mm)	10	Not Publicly Available	The difference will not raise any new safety and effectiveness concerns.
Ground clearance	63mm	85mm	The device has been tested according to ISO7176 series standards and the test records support its safety and effectiveness.
Max. loading (kg)	396.83 lbs(180kg)	352.7lbs(160kg)	The difference will not raise any new safety and effectiveness concerns.
Slope Grade Ability	14 degree	9 degree	Larger safe operational incline of subject brings more convenient for the use environment
Min. Turning radium	1500mm	1800mm	The little difference in the turning radius will not raise any new safety and effectiveness concerns.
Minimum braking distance	1.0m for the speed of 5.78 km/h 1s	≤1.5m for the speed of 6.4km/h 1s	The subject device complies with the requirements of ISO 7176-3
Max Speed Forwards	1.6 m/s (5.78 km/h)	1.8 m/s (6.4 km/h)	The devices are evaluated according to standard ISO 7176-6:2018, so the different will not impact the safety and effectiveness
Max. Speed Backward	0.6 m/s (2.16 km/h)	Not Publicly Available	
Controller	Dynamic DR50-B01	Dynamic PG45A	Although different controller is used, both the control system, including the electromagnetic brakes and the user interface are similar. Bothof the control systems are evaluated according to standard ISO7176-14:2008 and software validation requirement and there are no new safety and effectiveness concerns due to the difference.

Wheel Lock (type)	Electromagnetic brake	Electromagnetic brake	Same

Table 3 - Safety Comparison

Item	Proposed Device	Predicate Device	Remark
Materials contacting user	Hand grips: PVC; Backrest (Back support): PVC, sponge; Armrest (Arm support): PVC, sponge; Seat: PVC, sponge; Foot support pad: PEVA; Throttle controller lever: ABS.	Hand grips: PVC; Backrest (Back support): PVC, sponge; Armrest (Arm support): PVC, sponge; Seat: PVC, sponge; Foot support pad: PEVA; Throttle controller lever: ABS.	Same
Biocompatibility of materials contacting user	Comply with ISO 10993-1, FDA Guidance	Comply with ISO 10993-1, FDA Guidance, Tests included: Cytotoxicity (ISO 10993-5:2009), Skin Sensitization test (ISO 10993-10:2021) Intracuaneous Reacitivity Test (ISO 10993-23:2021)	Same

Summary of substantial equivalence discussion:

Despite of the above slight differences, the two devices all completed the performance tests in accordance with ISO 7176 series standards. There are no safety and effectiveness aspects concerned. 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 slight differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

10.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicated device in K220207 and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.