



September 29, 2026

Nanjing Mijo Technology Co., Ltd.
% Andrew Wang
Consultant
Shanghai Sungo Management Consulting Co., Ltd.
14th Floor, Dongfang Bldg., 1500# Century Ave.
Shanghai, China

Re: K262213
Trade/Device Name: Power Mobility Scooter (MA03)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: June 30, 2026
Received: June 30, 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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

for 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

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.

K262213

?

Please provide the device trade name(s).

?

Power Mobility Scooter (MA03)

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 ([21 CFR 801 Subpart D](#))

☒ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☐ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

?

510(k) Summary

Document Prepared Date: 2026-06-25

1. Applicant Information

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2. Subject Device

Power Mobility Scooter

Model: MA03

Classification regulations: 21 CFR 890.3800

Product code: INI

Classification: Class II

3. Substantial Equivalence Information

Predicate Device:

Power Mobility Scooter (MJMA01), K253936

Reference Device:

Wu's Electrical Scooter (WT-M4JKx), K192308

4. Device Description

The product is intended for medical purposes to provide mobility to persons restricted to a sitting position.

The mobility scooter is classified in the Class B and the maximum occupant mass is 182kg.

The scooter is a battery powered four wheeled vehicle.

It consists one Lithium-ion battery with an off-board battery charger, frame, controllers, motor, seat, back support, control device (including battery indicator, switch, speed adjustment button, horn button, throttle control lever-forward/back, tiller, charger socket, two rear wheels, two front wheels, front lights, foot support, anti-tip devices.

The armrest is not standard equipment on the MA03 model, but it is available as an option.

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

Table 1 General Comparison

Elements of Comparison	Subject Device (K262213, MA03)	Predicate Device (K253936, MJMA01)	Reference Device (K192308)	Remark
Manufacturer	Nanjing MIJO Technology Co., Ltd	Nanjing MIJO Technology Co., Ltd	Wu's Tech Co., Ltd.	--
Device name	Power Mobility Scooter	Power Mobility Scooter	Wu's Electrical Scooter	--
Model	MA03	MJMA01	WT-M4JKx	--
Indications for use	It is a motor-driven indoor and outdoor transportation vehicle intended to provide mobility to a disabled or elderly person limited to a seated position.	It is a motor-driven indoor and outdoor transportation vehicle intended to provide mobility to a disabled or elderly person limited to a seated position.	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.	Same
Overall dimensions (L × W × H, mm)	880 × 570 × 920	1000 × 600 × 900	1210 × 580 × 1040	Similar
Frame material	Carbon fiber	Aluminum alloy	Not disclosed in the public 510(k) Summary	Different
Front-wheel diameter	178 mm	193 mm	10.2 in (approximately 259 mm)	Similar
Number of front wheels	2	2	2	Same
Rear-wheel diameter	208 mm	193 mm	10.2 in (approximately 259 mm)	Similar
Number of rear wheels	2	2	2	Same
Ground clearance	64 mm	50 mm	45 mm	Similar
Maximum occupant mass	182 kg	120 kg	182 kg (400 lb)	Different
Minimum turning radius	975 mm	1125 mm	1400 mm	Similar
Motor output	24 V, 180 W	24 V, 250 W	24 V, 470 W	Different
Drive system	Rear-wheel drive	Rear-wheel drive	Direct-drive rear wheels with differential gear	Same
Brake system	Electromagnetic brake	Electromagnetic brake	Electromagnetic brake	Same
Battery	Lithium-ion battery 24 V, 10.4 Ah × 1	Lithium-ion battery 24 V, 5.8 Ah × 2	12 V, 36 Ah × 2	Different

Elements of Comparison	Subject Device	Predicate Device (K253936, MJMA01)	Reference Device (K192308)	Remark
Battery charger output	24 V, 2 A	29.4 V, 2 A	24 V, 5 A	Different
Maximum forward speed	6.12 km/h	6.84 km/h	9.5 km/h	Similar
Maximum safe slope	8°	10°	6°	Different
Theoretical distance range	10.1 km	16.3 km	29 km	Different
Minimum braking distance - normal operation (horizontal, forward, maximum speed)	1.0 m	≤1.2 m	1.4 m	Similar
Total mass	17 kg	29 kg	85.5 kg	Different
Intended operating surface and environment	Indoor use and restricted outdoor use on pavements or paved footpaths only.	Indoor use and restricted outdoor use on pavements or paved footpaths only.	Indoor use	Same
Remote control	No	No	No	Same
Armrest	No	No	Yes	Same

Difference Analysis

The subject device and the primary predicate device have the same intended use of providing indoor and restricted outdoor mobility to disabled or elderly persons who are limited to a seated position. Both devices are battery-powered, four-wheeled mobility scooters that use a rear-wheel-drive system, an electromagnetic braking system, a user-operated throttle control, an off-board battery charger, and anti-tip devices. The selected predicate model, MJMA01, is not equipped with armrests, which is consistent with the subject device. Therefore, the subject device and the primary predicate device have the same fundamental scientific technology.

The subject device differs from the predicate device in overall dimensions, wheel diameters, ground clearance, turning radius, and total mass. These dimensional and configuration differences could potentially affect maneuverability, static and dynamic stability, obstacle negotiation, and transportation or handling of the device. The subject device was evaluated in its final production-equivalent configuration in accordance with the applicable provisions of ISO 7176-1, ISO 7176-2, ISO 7176-5, ISO 7176-7, ISO 7176-8, and ISO 7176-10. The test results demonstrated acceptable static and dynamic stability, dimensional characteristics, structural strength, fatigue resistance, and obstacle-climbing performance. Therefore, these differences do not adversely affect the safety or effectiveness of the subject device.

The frame of the subject device is manufactured from carbon fiber, whereas the frame of the predicate device is manufactured from aluminum alloy. The difference in frame material could potentially affect structural strength, impact resistance, fatigue durability, and the mode of structural failure. However, the safety of the finished mobility scooter is determined by the structural performance of the complete device rather than by material identity alone. The subject device was subjected to the applicable static strength, impact strength, and fatigue strength tests specified in ISO 7176-8 at the required test loads. The completed device maintained its structural integrity and functional performance following testing. The carbon-fiber frame therefore does not raise different questions of safety or effectiveness.

The maximum occupant mass of the subject device is 182 kg, compared with 120 kg for the predicate device. The increased occupant mass could affect structural loading, stability, braking performance, propulsion-system loading, and battery consumption. These potential effects were evaluated by conducting the applicable ISO 7176 performance tests using the specified maximum occupant mass or the corresponding test load required by the applicable standard. The subject device met the applicable acceptance criteria for static stability, dynamic stability, braking effectiveness, structural strength and fatigue, power and control systems, and maximum speed. K192308 is cited only as a reference device to demonstrate that a maximum occupant mass of 182 kg is an established performance characteristic for a legally marketed mobility scooter. Substantial equivalence remains primarily supported by comparison with K253936 and by the performance testing conducted on the subject device.

The subject device uses a 24 V, 180 W motor, one 24 V, 10.4 Ah lithium-ion battery, and an off-board charger, whereas the predicate device uses a 24 V, 250 W motor, two 24 V, 5.8 Ah lithium-ion batteries, and a charger with different output characteristics. These differences could affect propulsion performance, energy consumption, theoretical driving range, charging performance, electrical safety, and thermal performance. The subject device was evaluated in accordance with ISO 7176-4, ISO 7176-6, ISO 7176-14, ISO 7176-21, and ISO 7176-25. The results demonstrated that the propulsion, control, battery, charger, maximum-speed, range, and electromagnetic-compatibility performance of the subject device met the applicable requirements and the manufacturer's specifications. Therefore, the differences in the motor, battery, and charger do not raise different questions of safety or effectiveness.

The maximum forward speed of the subject device is 6.12 km/h, which is lower than the 6.84 km/h maximum speed of the predicate device. At its measured maximum forward speed of 1.7 m/s on a horizontal surface, the subject device demonstrated a braking distance of 1.0 m during normal braking operation. No abnormal behavior, including tipping, sliding, brake failure, or veering, was observed during the braking tests. The subject device also met the applicable requirements for reverse-command braking, emergency braking, and downhill braking under the tested conditions. These results demonstrate that the braking system provides adequate stopping performance for the subject device's specified speed and maximum occupant mass.

The maximum safe slope specified for the subject device is 8°, compared with 10° for the predicate device. The subject device therefore has a more restrictive labeled operating limitation. The subject device was tested for braking and stability under the applicable inclined-plane conditions, and the 8° maximum safe slope is disclosed in the labeling. The difference does not increase user exposure to slope-related hazards when the device is operated in accordance with the Instructions for Use.

The theoretical driving range of the subject device is 10.1 km, compared with 16.3 km for the predicate device. Driving range is a performance characteristic and does not alter the intended use or fundamental operating principle of the device. The subject device provides a battery-status indication, and the specified driving range and charging instructions are disclosed in the labeling. Accordingly, the shorter theoretical driving range does not raise different questions of safety or effectiveness.

Based on the same intended use, the same fundamental scientific technology, the comparison with the primary predicate device, and the results of the applicable nonclinical performance testing, the identified technological differences do not raise different questions of safety or effectiveness. The submitted test results demonstrate that the subject device is as safe and effective as the legally marketed predicate device.

Table 2 Safety Comparison

Item	Subject Device	Predicate Device (K253936, MJMA01)	Result
Biocompatibility	The directly contacting materials have been evaluated in accordance with ISO 10993-1 and the applicable biological endpoints.	The directly contacting materials were evaluated in accordance with ISO 10993-1 and the applicable biological endpoints.	Same
EMC	ISO 7176-21; IEC 60601-1-2:2014+A1:2020; and IEC TS 60601-4-2:2024	ISO 7176-21; IEC 60601-1-2:2014+A1:2020; and IEC TR 60601-4-2:2016	Same
Performance	Applicable ISO 7176 series standards	Applicable ISO 7176 series standards	Same
Labeling	Conforms to applicable FDA labeling requirements and ISO 7176-15.	Conforms to applicable FDA labeling requirements and ISO 7176-15.	Same

Item	Subject Device	Predicate Device (K253936, MJMA01)	Result
ISO 7176-1	Static stability was determined in accordance with ISO 7176-1, and the test results met the applicable acceptance criteria.	Static stability was determined in accordance with ISO 7176-1, and the test results met the applicable acceptance criteria.	Same
ISO 7176-2	Dynamic stability was determined in accordance with ISO 7176-2, and the test results met the applicable acceptance criteria.	Dynamic stability was determined in accordance with ISO 7176-2, and the test results met the applicable acceptance criteria.	Same
ISO 7176-3	The effectiveness of the brakes was determined in accordance with ISO 7176-3, and the test results met the applicable acceptance criteria.	The effectiveness of the brakes was determined in accordance with ISO 7176-3, and the test results met the applicable acceptance criteria.	Same
ISO 7176-4	The theoretical distance range was determined in accordance with ISO 7176-4, and the test results met the applicable acceptance criteria.	The theoretical distance range was determined in accordance with ISO 7176-4, and the test results met the applicable acceptance criteria.	Same

Item	Subject Device	Predicate Device (K253936, MJMA01)	Result
ISO 7176-5	Overall dimensions, mass, and maneuvering space were determined in accordance with ISO 7176-5.	Overall dimensions, mass, and maneuvering space were determined in accordance with ISO 7176-5.	Same
ISO 7176-6	Maximum speed was determined in accordance with ISO 7176-6, and the test results met the applicable acceptance criteria.	Maximum speed was determined in accordance with ISO 7176-6, and the test results met the applicable acceptance criteria.	Same
ISO 7176-7	Seating and wheel dimensions were determined in accordance with ISO 7176-7.	Seating and wheel dimensions were determined in accordance with ISO 7176-7.	Same
ISO 7176-8	Static, impact, and fatigue strengths were evaluated in accordance with ISO 7176-8, and the test results met the applicable acceptance criteria.	Static, impact, and fatigue strengths were evaluated in accordance with ISO 7176-8, and the test results met the applicable acceptance criteria.	Same
ISO 7176-9	The device continued to function according to the manufacturer's specifications after the climatic tests specified in ISO 7176-9.	The device continued to function according to the manufacturer's specifications after the climatic tests specified in ISO 7176-9.	Same
ISO 7176-10	Obstacle-climbing ability was determined in accordance with ISO 7176-10.	Obstacle-climbing ability was determined in accordance with ISO 7176-10.	Same
ISO 7176-11	The test dummies used for the applicable ISO 7176 testing conformed to ISO 7176-11.	The test dummies used for the applicable ISO 7176 testing conformed to ISO 7176-11.	Same
ISO 7176-13	The coefficient of friction of the applicable test surfaces was determined in accordance with ISO 7176-13.	The coefficient of friction of the applicable test surfaces was determined in accordance with ISO 7176-13.	Same
ISO 7176-14	The power and control systems were evaluated in accordance with ISO 7176-14, and the test results met the applicable acceptance criteria.	The power and control systems were evaluated in accordance with ISO 7176-14, and the test results met the applicable acceptance criteria.	Same

Item	Subject Device	Predicate Device (K253936, MJMA01)	Result
ISO 7176-15	Information disclosure, documentation, and labeling were evaluated in accordance with ISO 7176-15.	Information disclosure, documentation, and labeling were evaluated in accordance with ISO 7176-15.	Same
ISO 7176-16	Resistance to ignition of postural support devices was evaluated in accordance with ISO 7176-16.	Resistance to ignition of postural support devices was evaluated in accordance with ISO 7176-16.	Same
ISO 7176-21	EMC performance was evaluated in accordance with ISO 7176-21, IEC 60601-1-2:2014+A1:2020, and IEC TS 60601-4-2:2024.	EMC performance was evaluated in accordance with ISO 7176-21, IEC 60601-1-2:2014+A1:2020, and IEC TR 60601-4-2:2016.	Same
ISO 7176-25	Battery and charger performance was evaluated in accordance with ISO 7176-25, and the test results met the applicable acceptance criteria.	Battery and charger performance was evaluated in accordance with ISO 7176-25, and the test results met the applicable acceptance criteria.	Same

7. 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 scooter to its predicate device.

8. Conclusion

The subject device, Power Mobility Scooter model MA03, has the same intended use and the same fundamental scientific technology as the primary predicate device, K253936 (model MJMA01). The identified differences in design and performance characteristics have been adequately evaluated through risk management and applicable nonclinical testing. K192308 (WT-M4JKx) provides additional reference support for the 182 kg maximum occupant mass and associated braking performance. The test results demonstrate that the subject device is as safe and effective as the predicate device and that the technological differences do not raise different questions of safety or effectiveness. Therefore, the subject device is substantially equivalent to the legally marketed predicate device cleared under K253936.