April 22, 2026

Wuyi Aichi Industry And Trade Co., Ltd.
℅ Kiwi Xu
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Bldg., 1500# Century Ave.
Shanghai, China

Re: K260237
Trade/Device Name: Mobility Scooter (X-12, X-14, X-17)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: January 26, 2026
Received: January 26, 2026

Dear Kiwi Xu:

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,

Digitally signed by
MARY S. KESZLER -S
Date: 2026.04.22
17:24:38 -04'00'

for 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

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.	K260237

Please provide the device trade name(s).

Mobility Scooter (X-12, X-14, X-17)

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)

510(k) Summary

K260237

Date: 2026.01.22

Submitter:
Name: Wuyi Aichi Industry And Trade Co., Ltd.

Address: Southeast Industrial Zone, Duan Village, Shuxi Street, Wuyi City, Jinhua, Zhejiang,

China Contact: Wei Lu

E-mail:1457644761@qq.com

Device:
510(k) number: K260237

Device Trade Name: Mobility Scooter

Model: X-12, X-14, X-17

Classification name: Motorized three-wheeled vehicle

Regulation class: 2

Regulation number: 21CFR 890.3800

Panel: Physical Medicine

Product code: INI

Predicate device:

510(k) number: K252588
Device Trade Name: Mobility Scooter Model: T5
Zhejiang Taotao Vehicle Co., LTD.

Device description:

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.

The Mobility Scooter, has a base with two front wheels, two rear wheels, two support wheels, a seat, a tiller console, an electric motor, an electromagnetic brake, 1 rechargeable battery with an off-board charger, a key switch. The movement of the scooter is controlled by the rider who operates the throttle lever, speed control dial and handle on the tiller console. The device is installed with an electromagnetic brake that will engage automatically when the scooter is not in use and the brake cannot be used manually. The scooter can only be operated on the flat road.

Indication for use:

The 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.

1. Product Parameters

Table 1 General Comparison

Attribute	Subject device	Predicate device	Results
Manufacturer	Wuyi Aichi Industry And Trade Co., Ltd.	Zhejiang Taotao Vehicle Co.,LTD.	/
Proprietary name, model	Mobility Scooter, X-12, X-14, X-17	Mobility Scooter, T5	/
510(k) number	K260237	K252588	/
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
Rear Wheels Quantity	2	2	Same
Ground clearance	38mm	20 mm	Both of the devices are evaluated according to standard ISO 7176-5, so the different will not impact the safety and effectiveness
Operating surface & 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.	Same
Remote control	None	None	Same
Total mass	24kg	54 kg	Both of the devices are evaluated according to standard ISO 7176-5, so the different static stability will not impact the safety and effectiveness
Brake	Electromagnetic	Electromagnetic	Same
Time to brake	< 1 s	< 1 s	Same
Max speed	X-12: 7.2 km/h	7.92 km/h	Both of the devices are
	X-14: 7.56 km/h X-17: 7.56 km/h		evaluated according to standard ISO 7176-6, so the different static stability will not impact the safety and effectiveness
Frame style	Foldable seat, removable battery pack, disassemble for transport.	Foldable seat, removable battery pack, disassemble for transport.	Same

Battery	Lithium-ion battery, 24V 10Ah	Lithium battery 25.6Vdc 15Ah	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.
Main frame material	Aluminium alloy	Steel	
Max Slope	10°	6°	Both of the devices are evaluated according to standard ISO 7176-2:2017, so the different static stability will not impact the safety and effectiveness
Max loading weight	X-12: 100 kg X-14: 120kg X-17: 120kg	150 kg	The subject device complies with ISO 7176- 3 testing, the difference do not affect safety and effectiveness.
Brake distance	X-12: 0.9m X-14: 1.1m X-17: 1.1m	≤1.0m	
Travel Distance	X-12: 10.7 km X-14: 22.4 km X-17: 22.4 km	18.5km	Minor difference on travel distance will not cause new safety and effectiveness concerns raised.
Overall Dimension (length*width*height)	970*520*960 mm	1240mm*610mm*875mm	Minor difference on scooter dimension will not cause different performance. All safety and performance have been validated with the maximum rated weight dummy.
Turning Radius	1425 mm	2175 mm	Minor difference on turning radius will not cause new safety and effectiveness concerns raised.

Attribute	Subject device	Predicate device	Results
Motor	24 V 180W	24 V 350W	Both of the devices are evaluated according to standard ISO 7176-1:2014, minor difference on motor power will not cause safety or effectiveness concerns raised.
Charger	Lithium-ion battery charger, Input: 100-240V, 1.5A,50/60Hz. Output: 29.4V, 2.0A	29.4V/2A	Minor difference on input current will not cause safety or effectiveness concerns raised.

Table 2 Safety comparison

Item	Subject Device	Predicate Device	Results
Biocompatibility	Conforms to FDA Regulatory	All directly tissue-contacting materials are in compliance with ISO10993-5 and ISO10993-10 requirements.	Same
Electromagnetic Compatibility (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

Item	Subject 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
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

Item	Subject Device	Predicate Device	Results
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
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
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 7176-22	The ISO 7176-series performance testing used set-up procedures according to ISO 7176-22	The ISO 7176-series performance testing used set-up procedures according to ISO 7176-22	Same
ISO 7176-25	The performance of batteries and chargers for powered wheelchairs meet the	The performance of batteries and chargers for powered wheelchairs meet the	Same

Item	Subject Device	Predicate Device	Results
	requirements of ISO 7176-25	requirements of ISO 7176-25	

Substantial Equivalence Discussion

The proposed (subject) 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 7176-22, ISO 7176-25, and 1995 FDA Guidance on 510(k) Submissions for Mechanical and Mobile scooter. The subject device also provided electromagnetic compatibility (EMC) testing according to IEC 60601-1-2 and Enhanced-level software documentation (including verification and validation testing) in accordance with FDA's 2023 Guidance on the "Content of Premarket Submissions for Device Software Functions."

The proposed device performs in a similar manner to the predicate device. All these tests have corresponding requirements/ acceptance criteria following above mentioned standards. And the test results show that the subject device is within acceptable performance specifications and thus substantially equivalent to the predicate device in performance.

The non-clinical laboratory data support the safety and performance of the subject device and demonstrate that the subject device should perform as intended in the specified use conditions.

3. 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.

4. Substantially Equivalency Conclusion

Based on the comparison and analysis above, the subject device is determined to be Substantially Equivalent (SE) to the predicate device, K252588 Mobility Scooter from Zhejiang Taotao Vehicle Co., LTD.