May 7, 2025

Wuyi Aichi Industry & Trade Co., Ltd.
% Boyle Wang
Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd., Pudong
Shanghai, 200120
China

Re: K242975
Trade/Device Name: Mobility Scooter (Model X-01, X-02)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: April 7, 2025
Received: April 7, 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,

Julia E. Slocomb -S 2025.05.07 15:06:14 -04'00'

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

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.

Submission Number *(if known)*

K242975

Device Name

Mobility Scooter (Model X-01, X-02)

Indications for Use *(Describe)*

It is a motor driven, indoor 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K242975

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

Name: Wuyi Aichi Industry&Trade Co.,Ltd.
Address: Yongwu road, Southeast Industrial Zone, Wuyi, Zhejing Province, 321200 China
Tel: 86-13506793848
Fax: 86-579-87486410
Contact: Mr.LYU Wei
Date of Preparation: Sep.07, 2024

Designated Submission Correspondent

Mr. Boyle Wang
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device information

Trade name: Mobility Scooter
Common name: Scooter
Classification name: Motorized Three-Wheeled Vehicle
Model(s): X-01, X-02

3.0 Classification

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

4.0 Predicate device information

Manufacturer: Nanjing Jin Bai He Medical Apparatus Co., Ltd.
Trade/Device: Scooter (Model: FDB01)

510(k) number: K201196

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 Mobility Scooter, is an indoor/outdoor electric scooter that is intended to be used by individuals that are able to walk but suffer from mobility limitations.

The scooter is classified as type Class A with 120 kg including occupant and any carried items weight capacity. It is basic conventional rear wheels drive, rigid frame vehicle that are battery powered. It consists of sealed transaxle motors drive system, electromagnetic braking system, electric motor controller and two lead-acid batteries with an off-board battery charger. It is powered by rechargeable battery with 15 km theoretical distance range which maximum speed up to 7 km/h.

The motor of electric wheelchair is DC24V 120W; the battery is 24V 12AH,Lead-acid battery; the charger is DC 24V, 2A.
Max. loading can not be over than 265lbs(120kg).
Max. distance of travel on the fully charged battery is 19.2km and Max. speed forward is 1.94m/s (7 km/h).
The braking time is about 1.93s, and the braking distance is 1.16m.

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 7176-21:2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
ISO 7176-22:2014 Wheelchairs - Part 22: Set-up procedures
ISO 7176-25:2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs
IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 12184 :2014 Electrically powered wheelchairs, scooters and their chargers- Requirements and test methods

Biocompatibility of patient-contacting parts

Patient-contacting material are carried out biocompatibility assessment in accordance with ISO 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

Table1-General Comparison

Item	Subject device	Predicate device	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: X-01, X-02)	Scooter (Model: FDB01)	-
510(k) No.	K242975	K201196	-
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 is basic conventional rear wheels drive, rigid frame vehicle that are battery powered. It consists of sealed transaxle motors drive system, electromagnetic braking system, electric motor controller and two lead-acid batteries with an off-board battery charger.	It has a base with metal alloy frame, two front wheels, two rear wheels, two anti-tip wheels, a seat, an adjustable steering column, a tiller console, an electric motor, an electromagnetic brake, 2 rechargeable lead-acid cell 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	Aluminium alloy	Same
Motor	Brushless motor, DC24V* 250W*1 pcs	Brush differential rear axle. 24V *180W	Minor differences in the dimensions will not impact the safety and effectiveness of the substantial equivalence.
Battery	12V12Ah Lead-acid cell, 2 pcs	24V 6AH Lithium-ion, 2 pcs	
Battery charger	Off-board charger Input: 100-240 VAC Output: DC 24V, 2A	Off-board charger Input: 100-240 VAC Output: DC 24V, 6 Amp	

Table2 Performance Comparison

Item	Subject Device	Predicate Device K201196	Remark
Dimensions (mm)	1080 X650 X940	1050 X 550 X 870	Minor differences in the dimensions will not impact the safety and effectiveness of the substantial equivalence.
Folded dimensions (mm)	1080x650x500	480 x550 x790	Minor differences in the folded dimensions will not impact the safety and effectiveness of the substantial equivalence.
Weight, w/ Battery	97lbs. /44kg	63.1lbs. /29 kg	The difference will not raise any new safety and effectiveness concerns.
Frame design	Foldable/ The scooter is driven by electricity scooter, is a transportation tool and auxiliary tools for the purpose of walking, without removing the battery can be folded, easy to carry and storage.	Foldable/ Electric scooter is driven by electricity scooter, is a transportation tool and auxiliary tools for the purpose of walking, without removing the battery can be folded, easy to carry and storage.	Same
Seating Attachment - integrated, power base, specialty power	Without any seat accessories (integrated, power base, dedicated power supply)	Without any seat accessories	Same
Folding mechanism	A foldable seat frames (The backrest could be folded to seat)	Seat can be folded; battery can be dismantled；The frame can be folded back and forth	Same
Front wheel(inch)	8 (Solid tire)	7 (Solid tire)	Larger size of the front wheel. The difference will not raise any new safety and effectiveness concerns.
Rear tire (inch)	8 (Solid tire)	8 (Solid tire)	Same
Anti-tip Wheels (inch)	2.0	2.5	Same

Cruising Range(km)	15	Not Publicly Available	The difference will not raise any new safety and effectiveness concerns.
Obstacle climbing(mm)	40	60	The smaller height in the obstacle climbing will not impact the safety and effectiveness of the subject device.
Ground clearance	40mm	50mm	The device has been tested according to ISO7176 series standards and the test records support its safety and effectiveness.
Static stability forward	15.6°	30°	Both of the devices are evaluated according to standard ISO 7176-1:2014, so the different static stability will not impact the safety and effectiveness
Static stability rearward	9.5°	20.1°	
Static stability sideways	14.1°	15.3°	
Max. loading (kg)	265lbs(120kg)	265lbs (120kg)	Same
Min. Turning radium	1400mm	1200mm	The little difference in the turning radius will bring more convenience when it turns. The difference will not raise any new safety and effectiveness concerns.
Minimum braking distance	1.16m for the speed of 7km/h 1.93s	1.1 m for the speed of 6km/h 1s	Similar
Max Speed Forwards	1.94m/s (7 km/h)	1.67m/s (6 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	0.93 m/s (3.3 km/h)	0.83m/s (3 km/h)	The devices are evaluated according to standard ISO 7176-6:2018, so the different will not impact the safety and effectiveness
Controller	British PG Controller R-series	British PG Controller PG45A	Although different controller is used, both the control system, including the

			electromagnetic brakes and the user interface are similar. Both devices have the same user interface, the patient uses the foldable tiller handle/handlebar for steering and a thumb operated potentiometer throttle control lever located at the top of the tiller to engage and disengage the scooter motion in both the forward and reverse directions. When the throttle control lever is released, the electromagnetic brake will be actuated and the scooter is slow to stop. The speed mode of the both devices was single mode and the speed control dial can control the maximum speed. Both of the control systems are evaluated according to standard ISO 7176-14:2008 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

Table3 Safety Comparison

Item	Proposed Device	Predicate Device	Remark
Materials contacting user	Armrest: PU foam Backrest: PVC Artificial Leather Seat: PVC Artificial Leather Joystick: Nylon + 30% Glass fiber Handle cover: PVC Footrest: TPR Footrest decoration: ABS	Armrest: PU Foamed; Backrest/seat: Leather package Footplates: ABS plastics	Biocompatibility evaluation has been carried out per ISO 10993-1. There are no new safety and effectiveness concerns due to the difference.
Biocompatibilit	Comply with ISO 10993-1, FDA	Comply with ISO 10993-1, FDA	Same

y of materials contacting user	Guidance, Tests included Cytotoxicity Test (ISO 10993-5:2009) Sensitization Test (ISO 10993-10:2021) Intracuaneous Reacitivity Test (ISO 10993-23:2021)	Guidance, Tests included Cytotoxicity (ISO 10993-5:2009), Sensitization and Intracutaneous Reactivity (ISO 10993-10:2010)	

Summary of substantial equivalence discussion:
Despite of the above 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 differences between the subject device and predicate devices do not raise new issues of safety or effectiveness. The 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 K201196 and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.