December 4, 2025

Zhejiang Taotao Vehicle Co.,Ltd.
℅ Eva Li
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.
Shanghai, 200122
China

Re: K252588
Trade/Device Name: Mobility Scooter (T5)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: November 4, 2025
Received: November 4, 2025

Dear Eva Li:

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.	K252588 ?
Please provide the device trade name(s).	?
Mobility Scooter (T5)	
Please provide your Indications for Use below.	?
It is 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

Application Information: Zhejiang Taotao Vehicle Co.,LTD.
Device Name： Mobility Scooter
Model: T5
Classification: II
Product Code: INI
Regulation:890.3800
Panel: Motorized three-wheeled vehicle

Date prepared： Aug 5,2025

Substantial Equivalence Information:
510Knumber: K231428
Device Name: Mobility Scooter
Model: W3431D
Zhejiang Innuovo Rehabilitation Devices Co.,Ltd.

1. Product Parameter

Table 1 General Comparison

Elements of Comparison	Subject Device (K252588)	Predicate Device (K231428)	Remark
Manufacturer	Zhejiang Taotao Vehicle Co.,LTD.	Zhejiang Innuovo Rehabilitation Devices Co.,Ltd	NA
Device name	Mobility Scooter	Mobility Scooter	Same
Model(s)	T5	W3431D	--
Indications 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
Overall dimension	1240mm*610mm*875mm	1020 mm x 500 mm x 840 mm	Similar
Frame Material	Steel	Steel	
Frame style	Foldable tiller, removable battery pack, disassemble for transport	Foldable seat, removable battery pack, disassemble for transport	Similar
Rear Wheels Quantity	2	2	Same
Ground clearance	20 mm	45 mm	Similar

Max Loading(on level ground)	150kg	120kg	Similar
Min Turn Radius	2175mm	1650mm	Similar
Motor output	24 V 350W	24 V 180W	Similar
Drive System	Rear Wheel Drive	Rear Wheel Drive	Same
Brakes	Electromagnetic brake	Electromagnetic brake	Same
Battery	Li-ion Battery 25.6Vdc 15Ah	Lead-acid 12V12Ah*2	Similar
Charger	29.4V/2A	24V/2A	Similar
Max Speed	7.92 km/h	6 km/h	Same
Max Slope	6°	9°	Similar
Travel Distance	18.5 km	15 km	Similar
Time to brake	< 1 s	0.7-1s	Similar
Brake Distance-Normal operation (Horizontal-Forward-Max speed)	≤1.3m	≤1.5m	Similar
Total mass	54 kg	42kg	Similar
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
Folding mechanism	foldable column, removable basket	Foldable seat, removable battery pack	different
Stowage size （H*L*W）	600*1240*560mm	No revelation	N/A
Front Tire Diameter	9inch	190 x 55 mm(15inch)	different
Rear Tire Diameter	9inch	190 x 55 mm(15inch)	different

Analysis: Subject device control system has passed the requirements of ISO 7176 series and test results meet its design specification.

Table 2 safety comparison

Item	Proposed Device	Predicate Device	Results
Biocompatibility	All user directly contacting materials are compliance with ISO10993-1	All user directly contacting materials are compliance with ISO10993-1	Same
EMC	ISO7176-21& IEC 60601-1-	ISO7176-21& IEC 60601-1-	Same

	2:2014+A1:2020	2:2014+A1:2020	
Performance	ISO7176 series	ISO7176 series	Same
Label and labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	Same

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
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 7176-5,	The dimensions, mass has been determined after the testing according to the ISO 7176-5,	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	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	Same

	of ISO 7176-9	specified in Clause 8 of ISO 7176-9	
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
ISO7176-16	The performance of resistance to ignition meet the requirements of ISO 7176-16	The performance of resistance to ignition meet the requirements of ISO 7176-16	Same
ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21, IEC 60601-1-2:2014+A1:2020	The EMC performance results meet the requirements of ISO 7176-21, IEC 60601-1-2:2014+A1:2020	Same
ISO 7176-22	The performance of resistance to ignition meet the requirements of ISO 7176-22	The performance of resistance to ignition meet the requirements of ISO 7176-22	Same
ISO7176-25	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	Same

Substantial Equivalence Discussion

The proposed 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 7176-16, ISO 7176-21, ISO 7176-22, ISO 7176-25, and FDA guidance Submission for Scooter.

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

The performance testing demonstrates that the subject device is substantially equivalent to the predicate devices regarding Static ability (Scooter tipping angle), The Dynamic stability (Safe Gradient Maximum Gradient), Brake performance, Theoretical distance range, Dimension and weight, Maximum speed, Dimension of wheel Static, impact and fatigue strengths, Climatic tests, Obstacle-climbing ability, Dummy, friction of test surfaces, Power and control systems, Documentation and labeling, Resistance to ignition, Electromagnetic Compatibility and Electrical Safety, Batteries and chargers.
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. Substantially Equivalency Conclusion

Based on the comparison and analysis above, the subject device is determined to be Substantially Equivalent (SE) to the predicate devices, W3431D Scooter from Zhejiang Innuovo Rehabilitation Devices Co.,Ltd. K231428.