June 3, 2026

Yurob Rehabilitation Medical Co., Ltd.
℅ Ariel Xiang
Official Correspondent
Shanghai SUNGO Management Consulting Co., Ltd.
Rm. 1401, Dongfang Bldg., 1500# Century Ave.
Shanghai,
China

Re: K253600
Trade/Device Name: Scooter (YD-03)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: May 7, 2026
Received: May 8, 2026

Dear Ariel Xiang:

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,

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

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)*

K253600

Device Name

Scooter (YD-03)

Indications for Use *(Describe)*

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

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.

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510K Summary
K253600

Prepared Date: 2025/1/14

Application Information:

Yurob Rehabilitation Medical Co.,Ltd.

Address: No.93 Dianxing Road, Dianshanhu Town, Kunshan City, Jiangsu Province, China
Contact Person: Pan daoping

Tel: +86 13918374973

Proposed Device:

Device Name: Scooter

Common name: Mobility Scooter/ Scooter

Model: YD-03

Classification: II

Product Code: INI

Regulation:890.3800

Panel: Motorized three-wheeled vehicle

Predicate Device

510Knumber: K240008

Device Name: Scooter

Model: W3331

Zhejiang Innuovo Rehabilitation Devices Co.,Ltd.

Device Description

YD-03 is a Mobility Scooter which provides mobility to persons with mobility difficulties, the elderly, and the weak.
The Mobility Scooter is classified in the Class B and the maximum loading weight is 136kg.
The scooter is a battery powered four-wheeled vehicle. It consists Lithium-ion battery with an off-board battery charger, frame, motor, seat cushion, backrest, armrest, controller and dashboard (including speed knob, battery gauge, power key switch, horn button, forward/reverse lever, charger port) two rear wheels, two front wheel, foot pad.
For convenience of transportation and reduction of possible damage, the battery and armrest can be dismantled and separately packaged. User can also easily assemble these parts without

use of the tools.

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.

1. Product Parameter

Table 1 General Comparison

Elements of Comparison	Subject Device	Predicate Device (K240008)	Remark
Manufacturer	Yurob Rehabilitation Medical Co.,Ltd	Zhejiang Innuovo Rehabilitation Devices Co.,Ltd.	--
Device name	Scooter	Scooter	--
Model(s)	YD-03	W3331	--
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
Overall dimension (mm)	1070×570×900	1110 x 560 x 840	Similar
Frame Material	Magnesium alloy+Carbon fiber	Steel	Different
Front wheel diameter	8 inch PU tire	196mm × 66mm	Minor
Front Wheels Quantity	2	1	Same
Rear wheel diameter	8inch	196mm × 66mm	Similar
Rear Wheels Quantity	2	2	Same
Ground clearance	80mm	35mm	Different
Max Loading(on level ground)	136KG	120KG	Similar
Turn Radius	1750mm	925mm	Different
Motor output	24 V 150W	LINIX 24 V 180W	Different
Brakes	Electromagnetic brake	Electromagnetic brake	Same
Battery	Li-ion battery 24V, 10.4Ah	Lead-acid 12V12Ah*2	Different
Charger	24V, 3A	24V, 2A	Similar
Max Speed	6.84km/h	6.83km/h	Same

Max Slope	10°	Dynamic Stability: 6。 Static Stability: 8。	Different
Travel Distance	16.3km	15km	Different
Distance between armrests	41cm	37-50.5 cm	Different
Controller	YLB-KZQ-JN-FY05	British PG 45A	Different
Time to brake	< 1 s	< 1 s	Same
Brake Distance-Normal operation	＜1m	≤1.3m	Similar
Total mass	21KG	40KG	Different
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	No	No	Same

Difference analysis

The design and technological characteristics of the proposed device scooter is similar to the predicate device. There are minor differences between the devices in frame material, size, load capacity, weight, ground clearance, turn radius, drive system, battery type,charger, controller, motor output,max slope, travel distance, Distance between Armrests, brake distance and time to brake. All of the parameters with differences have been tested according to ISO7176 series standards and the test records support its safety and effectiveness. There is no deleterious effect on safety and effectiveness due to the minor differences do not influence the intended use of the device. Therefore, the proposed Scooter is substantially equivalent (SE) to The Scooter (K240008).

Table 2 safety comparison

Item	Subject Device	Predicate Device (K240008)	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 60601-1-2:2014+A1:2020 &IEC TR 60601-4-2:2016	ISO7176-21& IEC 60601-1-2:2014+A1:2020	Same
Performance	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	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	Same

	7176-15, ISO 16840-10, ISO 7176-22, ISO 7176-25	7176-14, ISO 7176-15, ISO 16840-10, ISO 7176-22, ISO 7176-25	
Battery Safety	IEC 62133-2	IEC 62133-2	Same
Software Verification	IEC 62304 &FDA Guidance	IEC 62304 &FDA Guidance	Same
Label and labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	Same

Item	Subject Device	Predicate Device (K240008)	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 maximum speed, acceleration and deceleration has been determined after the testing according to the ISO 7176-6.	The maximum speed, acceleration and deceleration 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 functionaccording 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	All test results meet the requirements in Clause 7, 8, 9, 10, 11, 12, 13, 14, 15,	Same

	of ISO 7176-14.	17 of ISO 7176-14.	
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
ISO16840-10	The performance of resistance to ignition meet the requirements of ISO ISO16840.	The performance of resistance to ignition meet the requirements of ISO 7176-16.	Same
ISO7176-21 and IEC 60601-1-2	The EMC performance results meet the requirements of ISO 7176-21, IEC 60601-1-2:2014+A1:2020 and IEC TR 60601-4-2:2016.	The EMC performance results meet the requirements of ISO 7176-21, IEC 60601-1-2:2014+A1:2020.	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

2. Non-Clinical Test summary

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:

- ISO10993-5 Biological evaluations of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation
- From the test result, we can find the material are safety and can meet the requirements.
- ISO 7176-1:2014 Wheelchairs - Part 1: Determination of static stability
- ISO 7176-2:2017 Wheelchairs - Part 2: Determination of dynamic stability of electric 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 dimensions, mass and maneuvering 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 strength
- 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 7176-14:2022 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
- ISO 7176-22：2014 Wheelchairs-Part 22: Set-up proceduresd
- ISO 7176-25： 2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs.
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2020 and IEC TS 60601-4-2:2024
- ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software-Software life cycle processes
- IEC 62133-2 dition1.0 2017-02 Secondary cells and batteries containing alkaline or other non- acid electrolytes–Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications–Part 2: Lithium systems

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 electric wheelchair to its predicate device.

4. Substantially Equivalent Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Carbon fiber +Magnesium alloy scooter, model: YD-03, is as safe, effective and performs as well as the legally marketed predicate device cleared under K240008.