



March 27, 2026

Yurob Rehabilitation Medical Co., Ltd.
% Ariel Xiang
Official Correspondent
Shanghai SUNGO Management Consulting Co., Ltd.
Rm. 1401, Dongfang Bldg., 1500# Century Ave.
Shanghai, 200122
China

Re: K253980

Trade/Device Name: Electrically Powered Wheelchair (Model YC-01)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: February 27, 2026
Received: March 2, 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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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: 2026.03.27
15:07:45 -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

510(k) Number (if known)
K253980

Device Name
Electrically Powered Wheelchair (Model YC-01)

Indications for Use (Describe)

The Electrically Powered Wheelchair 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.

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510(K) Summary

Document Prepared Date: 2026/03/27

A. Applicant

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B. Device

Trade Name: Electrically Powered Wheelchair

Common Name: Powered wheelchair

Model: YC-01

Regulatory Information

Classification Name: Powered Wheelchair Classification: Class II.

Product code: ITI

Regulation Number: 890.3860

Review Panel: Physical Medicine

C. Predicate device

510K number: K232193

Yurob Rehabilitation Medical Co.,Ltd.

Device Name : Electrically Power Wheelchair

Model: YLB-W-0812-A01, YLB-W-0812-A02, YLB-W-0812-A03

D. 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.

E. Device Description

The device consists of front wheel, drive wheel, frame, controller, motor, armrest, backrest, seat cushion, pedal, battery box and charger.

Electrically Powered Wheelchair is powered by Li-ion Battery pack (25.55V 10.4Ah*2) with 11.8 km range, which can be recharged by an off-board battery charger that can be plugged into an AC socket outlet (100-240V, 50/60Hz) when the device is not in use. The materials of frame is Carbon fiber.

The patient can activate the controller handle (joystick) to control the speed and direction of the wheelchair movement. In addition, when the patient releases the joystick, the joystick will return back to the central position and the wheelchair will be automatically stopped soon due to automatic electromagnetic brake system. Once the joystick is activated again move to other position, the wheelchair will be re-energized.

The max loading of the device is 136KG. Only for one person to sit.

F. Comparison with predicate Device

Table 1 General Comparison

Elements of Comparison	Proposed device (K253980)	Predicate Device (K232193)	Remark
Manufacturer	Yurob Rehabilitation Medical Co.,Ltd.	Yurob Rehabilitation Medical Co.,Ltd.	

Common or Usual name	Power Wheelchair	Power Wheelchair	S.E.
Model(s)	YC-01	YLB-W-0812-A02	--
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.	S.E.
Use condition	indoor and outdoor use	indoor and outdoor use	S.E
Number of wheels	4,including two front wheels and two rear Wheels	4,including two front wheels and two rear Wheels	S.E
Function of wheels	Front wheels: driven wheels suitable for rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed and direction	Front wheels: driven wheels suitable for rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed and direction	S.E
Movement control method	By Joystick control	By Joystick control	S.E
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	S.E
Brake system	Automatic electromagnetic brake system	Automatic electromagnetic brake system	S.E
Braking distance	≤1 m	≤1.5 m	S.E

Maximum safe operational incline (degrees)	6°	6°	S.E
Armrest	PU	PU	S.E
Main frame material	Carbon fiber	Aluminum Alloy	Similar: All performed according to standard ISO 7176 series and biocompatibility. the results have proved that the difference will not raise new issues of safety or effectiveness.
Back cushion	Nylon	Polyester fabric	Similar: Following biological evaluation, the difference will not raise new issues of safety or effectiveness.
Seat cushion	Nylon	rubber patch cloth and Oxford fabric	

Overall Dimension (length*width*height)	980*630*870mm	920*550*890mm	Analysis: Larger size is designed for bearing more loading weight. All safety and performance have been validated with the maximum rated weight dummy.
Folded Dimension (length*width*height)	980*310*750mm	660*320*720mm	Analysis: Difference on folded dimension will not affect safety and performance of the subject device.
Front wheel size/type	8" PU Solid tire	7" PU Solid tire	Analysis: Different sizes of front wheel will not affect safety and performance of the subject device as all related stability tests are performed according to standard ISO 7176 series.
Rear wheel size/type	12" Pneumatic tire	12" Pneumatic tire	S.E
Max speed forward	Up to 6 km/h	Up to 6 km/h	S.E

<p>Max Speed backward</p>	<p>Less than 3 km/h (0.73m/s)</p>	<p>Less than 3 km/h (0.8 m/s)</p>	<p>Analysis: Minor difference on max speed of wheels will not cause different performance. Both meet the require of ISO 7176-3 standard for brake performance. It will not cause new safety and effectiveness concerns.</p>
<p>Max loading weight</p>	<p>136 Kg (≈300lbs)</p>	<p>120 Kg (≈265lbs)</p>	<p>Analysis: Minor difference on mas loading weight. The test dummies used in the testing of ISO 7176 series are meet the requirements of ISO 7176-11.</p>
<p>Battery</p>	<p>Li-ion battery rechargeable, 25.55VDC 10.4Ah *2</p>	<p>Li-ion battery rechargeable, 25.2VDC 10.4Ah *2</p>	<p>Analysis: The battery capacity will impact</p>

<p>Battery charger</p>	<p>Off-board charger Input: 100-240VAC, 50-60Hz, 1.8A Output: 24VDC, 3.0A</p>	<p>Off-board charger Input: 100-240V, 50/60Hz, 1.5A, Output: 24V 2A</p>	<p>the travel distance, which will not cause new safety and effectiveness concerns raised. The performance of batteries and charger of device meet the Requirements of ISO 7176-25.</p>
<p>Maximum distance of travel on the fully charged battery</p>	<p>11.8km</p>	<p>20km</p>	<p>Analysis: The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet its design specification.</p>

Motor	Brushless DC motor; 24VDC; 200W, 2pcs	Brushless DC motor; 24VDC; 150W, 2pcs	<p>Analysis: Slight difference on motor power will not cause different performance. larger power will provide more driving force, no safety and effectiveness concerns raised.Both meet the require of ISO 7176-14 standard.</p>
Electronic controller	Brushless dual-drive rocker controller	Brushless dual-drive rocker controller	S.E
Turning Radius	590 mm	900 mm	<p>Analysis: Narrower turning radius will bring more convenience for the use environment. All relevant tests have been performed according to standards ISO 7176 series, the difference will not raise any new safety and effectiveness concerns.</p>

Maximum obstacle climbing	50 mm	40 mm	Analysis: Longer distance in the obstacle climbing will not impact the safety and effectiveness of the subject device. Both meet require of ISO 7176-10standard.
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Table 2 safety comparison

Item	Proposed Device	Predicate Device	Results
Biocompatibility	All directly user-contacting materials are low-biocompatibility-risk materials identified in Attachment G of FDA's 2023 Biocompatibility Guidance.	All directly user-contacting materials are in compliance with ISO 10993-5 and ISO10993-10 requirements.	SE
EMC	ISO 7176-21, IEC 60601-1-2, IEC TR 60601-4-2, ANSI C63.18	ISO 7176-21	SE
Performance	ISO 7176 series	ISO 7176 series	SE
Label and labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	SE

Item	Proposed Device	Predicate Device	Results
ISO 7176-1	The Static stability has been determined after the testing according to the ISO 7176-1,	The Static stability has been determined after the testing according to the ISO 7176-1,	SE

	and test results meet its design specification.	and test results meet its design specification.	
ISO 7176-2	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.	SE
ISO 7176-3	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.	SE
ISO 7176-4	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.	SE
ISO 7176-5	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.	SE
ISO 7176-6	The maximum speed has been determined after the testing according to the ISO 7176-6.	The maximum speed has been determined after the testing according to the ISO 7176-6.	SE
ISO 7176-7	The seating and wheel dimensions have been determined after the testing according to the ISO 7176-7,	The seating and wheel dimensions have been determined after the testing according to the ISO 7176-7,	SE
ISO 7176-8	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.	SE

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	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	SE
ISO 7176-10	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,	SE
ISO 7176-11	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	SE
ISO 7176-13	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	SE
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	All test results meet the requirements in Clause 7, 8, 9, 10, 11, 12, 13, 14, 15, 17 of ISO 7176-14	SE
ISO 7176-15	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	SE
Resistance to Ignition	Resistance to ignition of postural support devices — Requirements and test	The performance of resistance to ignition meet the requirements of ISO	SE

	method per ISO 16840-10:2021	7176-16	
ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21 and IEC 60601-1-2	The EMC performance results meet the requirements of ISO 7176-21	SE
Battery Safety	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25, as well as ISO 7176-31 and IEC 62133-2	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	SE

G. 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 16840-10, ISO 7176-21, ISO 7176-25, ISO 7176-31, and FDA Guidance Document for 510(k) Applications for Mechanical and Powered Wheelchairs.

The indications for use for both devices are the same. The design principles of the controller and Driving system are the same, and both meet the requirements of the ISO 7176-14. Software validation is carried out on both control systems. Brake system and speed control are designed in the same way as well, and both meet the requirements of the ISO 7176-3.

The frame material is slightly different while such differences will not impact the safety and effectiveness of the subject device or raise new safety and effectiveness concerns as well as both meet the requirements of the ISO 7176-8, ISO 7176-10 and ISO 7176-11.

The biocompatibility of the predicate device met the requirements of ISO 10993-5:2009 & ISO 10993-10:2010 , whereas the biocompatibility of subject device was established via the use of low-biocompatibility-risk materials identified in Attachment G (Section B) of FDA's 2023 Biocompatibility Guidance document, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'".

The flame-retardant test of the seat cushion/ backrest of both subject device and predicate device is carried out according to the ISO 16840-10 test. Therefore, both devices are assured to be under the same safety level.

In conclusion, the technological characteristics, features, specifications, materials, mode of operation, and intended use of the device are substantially equivalent to the predicate device quoted above. The differences between the subject device and predicate device do not raise different questions of safety or effectiveness.

H. Product Performance

The following performance data were provided to verify that the proposed device met all design specifications and provided support of the substantial equivalence determination.

- Risk Analysis developed in accordance with ISO 14971: 2019.
- Software validation
- 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 procedures
- ISO 7176-25 : 2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs.
- ISO 7176-31 : 2023 Wheelchairs - Part 31: Lithium-ion battery systems and chargers for powered wheelchairs - Requirements and test methods
- IEC 62133-2:2017+A1:2021 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
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2, ISO 7176-21, and IEC TR 60601-4-2, plus 5G cellular immunity testing per ANSI C63.18:2014

Biocompatibility of patient-contacting material

- The biocompatibility of the subject device is based on the use of low-biocompatibility-risk materials and supporting information in accordance with Attachment G of FDA's 2023 Biocompatibility Guidance.

I. 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.

J. Conclusion

The proposed device and predicate device have the same intended use and similar technological characteristics, features, specifications, materials, and mode of operation of the device. To ensure all the key characteristics of the devices can meet the requirements, the above performance testing was done and all the results support a positive conclusion. Based on the analysis above, we confirm these two devices are substantially equivalent.