March 27, 2026

Foshan Dahao Medical Technology Co.,Ltd.
Klem Hou
RA Manager
Building 1, 2" Floor of Building2, 3"" Floor of Building 2,
Building3, 4,5,6,7, No.9 of Fanye Road, LepingTown, Sanshui
Foshan, Guangdong
China

Re: K253307
Trade/Device Name: Electric wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: September 26, 2025
Received: September 29, 2025

Dear Klem Hou:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253307

Device Name
Electric wheelchair (Models: DH01120, Model DH01105(4))

Indications for Use *(Describe)*
The Electric 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.

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.

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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

1. Submission sponsor

Name:Foshan Dahao Medical Technology Co.,Ltd.

Address:Building 1, 2" Floor of Building2, 3"" Floor of Building 2,Building3, 4,5,6,7, No.9 of Fanye Road, LepingTown, Sanshui District, Foshan City, Guangdong Province,P.R.China

Contact person:Zehui Huang

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2. Submission correspondent

Contact person:Klem Hou

Title:RA manager

Tel: +8613537831351

Email: Klem@zhijiabm.com

3. Device

Name of Device: Electric wheelchair

Model(s): DH01120, Model DH01105(4)

Classification Name: Powered Wheelchair

Regulatory Class: II

Product Code: ITI

Regulation Number: 21 CFR 890.3860

4. Predicate device(s)

Manufacturer	Predicate Device	510(k) Number
Yurob Rehabilitation Medical Co.,Ltd.	Electrically Power Wheelchairs	K232193

5. Device description

This Electric wheelchair is a motor driven, indoor and outdoor transportation vehicle, which a device for assisting action handicapped people and disabled people to move. It is suitable for disabled people with mobility difficulties and elderly people.

The Electric wheelchair is composed of frame, motor, controller, lithium battery and seat cushion.

The Electric wheelchair is powered by lithium battery which can be recharged by an off-board battery charger that can be plugged into an AC socket outlet when the device is not in use.

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

6. Indications for Use

The Electric 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.

7. Comparison of Technological Characteristics with the Predicate Device(s)

The Electric wheelchair has the same intended use, mode of action and operational characteristics as the predicate devices. Any minor differences between the subject device and the listed predicate devices do no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate device for its intended use.

Therefore, The Electric wheelchair may be found substantially equivalent to its predicate devices.

The Electric wheelchair is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance:

1) K232193 (Predicate Device), " Electrically Power Wheelchairs ", manufactured by " Yurob Rehabilitation Medical Co.,Ltd."

Comparison Elements	Subject Device (K253307)	Predicate Device (K232193)	Remark

Comparison Elements	Subject Device (K253307)	Predicate Device (K232193)	Remark
Device name	Electric wheelchair	Electrically Power Wheelchairs	--
Model	DH01105,DH01105(4)	YLB-W-0812-A01, YLB-W-0812-A02, YLB-W-0812-A03	--
Product code	ITI	ITI	SE
Classification	Class II	Class II	SE
Indications for use	The Electric 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.	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.	SE
Use condition	indoor and outdoor use	indoor and outdoor use	SE
Number of wheels	4,including two front wheels and two rear wheels	4,including two front wheels and two rear wheels	SE
Function of wheels	Front wheels:driving wheels to control rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed and direction	Front wheels:driving wheels to control rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed and direction	SE
Movement control method	By Joystick control	By Joystick control	SE
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	SE
Brake system	Automatic electromagnetic brake system	Automatic electromagnetic brake system	SE
Braking distance	≤1.0m	≤1.5m	SE Note 1

Comparison Elements	Subject Device (K253307)	Predicate Device (K232193)	Remark
Maximum safe operational incline degree	6°	6°	SE
Max speed forward	4.5km/h	Up to 6 km/h	SE Note 2
Max speed backward	Less than 3 km/h (0.8 m/s)	Less than 3 km/h (0.8 m/s)	SE
Max loading weight	100Kg	120 Kg (654 lbs)	SE Note 3
Maximum distance of travel on the fully charged battery	20Km	20Km	SE
Maximum obstacle climbing	25mm	40 mm	SE Note 4

Comparison in Detail(s):

Note 1: Braking distance

Minor difference on Braking distance will not cause new safety and effectiveness concerns raised as Braking distance have been evaluated according to standard ISO 7176 series.

The Braking distance differences between the subject and predicate devices does not raise new concerns of safety and effectiveness for the clinical use.

Note 2: Max speed forward

The Max speed of the subject device is a little lower than that of predicate device which is not important for that the maximum distance of travel on the fully charged battery is same with the little lower maximum speed.

The Max speed differences between the subject and predicate devices does not raise new concerns of safety and effectiveness for the clinical use.

Note 3: Max loading weight

The Max loading weight of the subject device is a little lower than that of the predicate device.The Max loading weight of the subject device is shown in the user manual and patients with more than

the max loading weight is prohibited to use the device.

The Max loading weight differences between the subject and predicate devices does not raise new concerns of safety and effectiveness for the clinical use.

Note 4: Maximum obstacle climbing

The Maximum obstacle climbing of the subject device is a little lower than than that of the predicate device.

The Maximum obstacle climbing differences between the subject and predicate devices does not raise new concerns of safety and effectiveness for the clinical use.

8. Test Summary of Non-clinical Testing

The Electric Wheelchair has been evaluated the safety and performance by lab bench testing according to the following standards.

1) Performance test

The test results meet the specification of the product and the relevant standards are listed below.

- 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: 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: Resistance to ignition of postural support devices
- ISO 7176-22: 2014 Wheelchairs - Part 22: Set-up procedures
- ISO 7176-31：2023 Wheelchairs - Part 31: Lithium-ion battery systems and chargers for powered wheelchairs - Requirements and test methods
- Software validation

2) Electromagnetic Compatibility and Electrical Safety

EMC testing has been performed to, and passed, the following standards:

- ISO 7176-21: 2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
- IEC 60601-1-2:2014/AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- ANSI C63.18-2014 Ad Hoc Test Method for Estimating Electromagnetic Immunity of Medical Devices to Radiated Radio-Frequency (RF) Emissions from RF Transmitters
- IEC 61000-4-39:2017 Testing and measurement techniques - Radiated fields in close proximity - Immunity test

4) Biocompatibility

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

9. Summary of Clinical Test

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.

10. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, the Electric Wheelchair is to be concluded substantial equivalent to its predicate device.