January 15, 2026

Foshan Dahao Medical Technology Co., Ltd.
℅ Luna Hu
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.
Shanghai, 200122
China

Re: K251458
Trade/Device Name: Electric Wheelchair (DH01168)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: December 17, 2025
Received: December 17, 2025

Dear Luna Hu:

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,

Digitally signed by
MARY S. KESZLER -S
Date: 2026.01.15
13:36:51 -05'00'

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251458

Please provide the device trade name(s).

Electric Wheelchair (DH01168)

Please provide your Indications for Use below.

This 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.

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

K251458

Document Prepared Date: 2025/05/08

1. Applicant

Company name: FOSHAN DAHAO MEDICAL TECHNOLOGY CO., LTD
Address: Building 1, 2nd Floor of Building 2, 3rd Floor of Building2, Building 3, 4, 5, 6, 7, No.9 of Fanye Road, Leping Town, Sanshui District, Foshan City, Guangdong Province, P.R. China

Contact Person: Ms. Bao Yixie

Tel: 86-13760674304

Submission Correspondent:

Primary Contact: Luna Hu

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Secondary Contact: Raymond Luo

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2. Device

Trade name: Electric Wheelchair

Classification name: Powered wheelchair

Model: DH01168

Regulatory Information

Classification: Class II

Product code: ITI

Regulation Number: 890.3860

Review Panel: Physical Medicine

3. Predicate Device

Manufacturer: NANJING E-TAKE MEDICAL APPARATUS CO., LTD.

Product Name: Electric Wheelchair (MODEL H)

510(K) #: K242989

4. Indication for Use

This 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.

5. Device Description

The product is intended only carry one person and used as a means of transportation for people with disabilities or incomplete walking ability (excluding obesity).

The electric wheelchair is classified as class A, which is suitable for use on flat walking paths indoors and near buildings.

The maximum occupant mass is 100kg.

The Electric Wheelchair is a battery powered four wheeled vehicle.

It consists one Lithium battery with an off-board battery charger, frame, controller, motors, seat, back support, control device (including the battery power indicator, ON/OFF button, horn button, speed indicator, speed control button, joystick, lighting switch, USB interface), arm supports, two rear wheels, two casters(front wheels), Foot support, anti-tip devices.

The wheelchair can easily fold and unfold for transportation or storage.

The controller handle (joystick) is equipped on the control pad that attaches to the right arm rest. While there is a bluetooth music play function equipped on the left arm rest. The bluetooth function does not connect to the controller, so it will not affect the normal operation of the wheelchair at all.

6. Non-clinical Test Conclusion

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 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2021 Biological Evaluation of Medical Devices -- Part 10: Tests For Skin Sensitization
- ISO 10993-23:2021 Biological Evaluation of Medical Devices -- Part 23: Test for Intracutaneous Reactivity
- 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 maneuvering space
- ISO 7176-6:2018, Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electrically powered 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 7176-25:2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs
- 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
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

7. Clinical Test Conclusion

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.

8. Comparison technological characteristics with the predicate device

Table 1 General Comparison

Elements of Comparison	Subject Device	Predicate Device (K242989)	Remark
Manufacturer	FOSHAN DAHAO MEDICAL TECHNOLOGY	NANJING E-TAKE MEDICAL APPARATUS	--

	CO., LTD	CO., LTD	
Device name	Electric Wheelchair	Electric Wheelchair	--
Model(s)	DH01168	MODEL H	--
Indication for use	This 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.	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.	Same
Intended user	disabled or elderly person limited to a seated position	disabled or elderly person limited to a seated position	Same
Use condition	Indoor and outdoor use	Indoor and outdoor use	Same
Number of wheels	6, including two front wheels and two rear wheels, two anti-tip wheels	6, including two front wheels and two rear wheels, two anti-tip wheels	Same
Function of wheels	Front wheels: driven wheels suitable for rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed and direction Anti-tip wheels: preventing the wheelchair from tipping turning over when driving on the slope. Non-adjustable	Front wheels: driven wheels suitable for rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed and direction Anti-tip wheels: preventing the wheelchair from tipping turning over when driving on the slope. Non-adjustable	Same
Movement control method	By joystick control	By joystick control	Same
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	Same
Brake system	Automatic electromagnetic brake system	Automatic electromagnetic brake system	Same
Battery charger	Off-board charger Input: 100-240VAC, 50/60Hz, 3.15A Output: 29.4V, 3.0A;	Off-board charger Input: 100-240VAC, 50-60Hz 1.2-0.5A Output: 24 Vdc, 2A;	Different
Max Loading(on level ground)	100KG	120KG	Different
Max obstacle climbing	S mode:30mm D mode:35mm ECO mode:40mm	25mm	Different
Total mass	40KG	23KG	Different
Overall dimension (mm)	1060*610*1020	1130*660*950	Different

Stowage Dimension (mm)	830*610*540	890*360*900	Different
Front wheel	9inch/Pneumatic tires	7inch/Solid tires	Same
Rear wheel	12.5inch/Pneumatic tires	24inch/Solid tires	Different
Max Speed (forward)	5.4km/h(1.5m/s)	6.84km/h(1.9m/s)	Different
Max Speed (backward)	1.44km/h(0.4m/s)	3.24km/h(0.9m/s)	Same
Maximum safe operational incline degree	6°	6°	Same
Brake Distance-Normal operation (Horizontal-Forward-Max speed)	1.0m	1.1m	Similar
Battery	Lithium-ion battery; Rechargeable, 24V, 15.6Ah, 374.4Wh	Lithium-ion battery; Rechargeable, 24V 10Ah	Different
Maximum distance of travel on the fully charged battery	22.6km	8.2km	Different
Motor	Brushless DC motor; 24VDC 150W*2	Brushless DC motor; 24VDC 200W*2	Different
Electronic controller	XA5-C30	Micon CON7084-WB controller	Different
Turn Radius	825mm	925mm	Similar

Difference analysis

The design and technological characteristics of the proposed Electric Wheelchair is similar to the predicate device. There are minor differences between the devices in battery charger, max Loading, max obstacle climbing, size, weight, wheel size, max speed, brake distance, turn radius, motor output, travel distance and controller model. 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 Electric Wheelchair is substantially equivalent (SE) to The Electric Wheelchair (K242989).

Table 2 safety comparison

Item	Subject Device	Predicate Device (K242989)	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	ISO7176 series	ISO7176 series	Same
Label and labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	Same

Item	Subject Device	Predicate Device (K242989)	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	The test results shown that the device under tests could continue to function	Same

	according to manufacturer's specification after being subjected to each of the tests specified in Clause 8 of ISO 7176-9.	according to manufacturer's specification after being subjected to each of the tests 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
ISO7176-21	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

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device K242989.