



December 8, 2025

Foshan Dahao Medical Technology Co., Ltd.  
% Sandra Jiang  
Regulatory Affairs Consultant  
Shanghai SUNGO Management Consulting Co., Ltd.  
Room 1401, Dongfang Building, 1500# Century Ave  
Shanghai, 200122  
China

Re: K252862  
Trade/Device Name: Electric Wheelchair (DH01126)  
Regulation Number: 21 CFR 890.3860  
Regulation Name: Powered Wheelchair  
Regulatory Class: Class II  
Product Code: ITI  
Dated: September 9, 2025  
Received: September 9, 2025

Dear Sandra Jiang:

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](mailto: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: 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.

K252862

?

Please provide the device trade name(s).

?

Electric Wheelchair (DH01126)

Please provide your Indications for Use below.

?

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.

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)

?

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## **K252862 510(K) Summary**

(As requirement by 21 CFR 807.92)

*Date prepared: 21<sup>st</sup>, August, 2025*

### **A. Applicant:**

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### **B. Device:**

Trade Name: Electric Wheelchair

Device Model: DH01126

#### Regulatory Information

Classification Name: Wheelchair, Powered

Classification: Class II

Product code: ITI

Regulation Number: 21 CFR 890.3860

Review Panel: Physical Medicine

### **C. Predicate device:**

510(K) Number: K241529

Manufacturer: Zhejiang Nysin Medical Co., Ltd.

Device Name: Powered Wheelchair (NXN20-209)

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**D. Device Description:**

The subject Electric Wheelchair is a wheeled personal mobility device that incorporates a seat-support system for a person with a disability or a person without the full capacity to walk designed to be propelled by power from electric motors. The electronic control of speed and direction can be performed by the occupant with the help of controlling joystick. The device can be quickly folded and disassembled, which makes it convenient to be stored or placed at the trunk of vehicles while traveling.

The subject Electric Wheelchair are intended to provide mobility to a disabled or elderly limited to a seated position. It is of indoor and outdoor type, suitable for the use indoor and flat path near buildings, but not on grass, gravel roads, large slopes or motorway, neither on muddy, rugged, soft, narrow, icy road, bad roads such as dangerous roads without guardrails or waterways.

The DH01126 Electric Wheelchair consists of two parts, the wheelchair main body and the electrical part. The main body includes a main foldable frame, two armrests, a backrest, a seat cushion, two rear driving wheels and two front wheels. The electrical part is composed of two 24V DC motors, two brakes, lithium battery, a controller and an off-board charger.

The device is powered by Li-ion 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 wheelchair. The further the joystick is pushed from its central position, the faster the wheelchair moves, when it is released, it will automatically reset and brake.

The DC brushless motor and brake system are fixed on the rear wheels.

The max loading of both models is 100KG. Only for one person sit.

**E. Indication for Use**

The proposed 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.

**F. Comparison with the predicate device**

**Table 1 - General Information Comparison**

<b>Item</b>	<b>Proposed Device</b>	<b>Predicate Device</b>	<b>Discussion/Conclusion</b>
Product Code	ITI	ITI	Same
Regulation No.	21 CFR 890.3860	21 CFR 890.3860	Same

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Device classification	Class II	Class II	Same
Product Name	Electric Wheelchair	Powered Wheelchair	Same
Intended 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.	The device 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
Use Environment	Indoor and outdoor use	Indoor and outdoor use	Same
Patient Population	The device is suitable for disabled people with mobility difficulties and elderly people.	The device is suitable for disabled people with mobility difficulties and elderly people.	Same
Product Structure	Consist of two foldable armrests, a backrest, a seat cushion, a safety belt, a foldable frame, two rear driving wheels with hub motor/electromagnetic brake assemblies, two pivoting casters, a piece of Li-ion battery pack, an off-board battery charger, a control panel, and an electric motor controller.	Consist of two foldable armrests, a backrest, a seat cushion, a safety belt, a foldable frame, two rear driving wheels with hub motor/electromagnetic brake assemblies, two pivoting casters, two Li-ion batteries, an off-board battery charger, a control panel, and an electric motor controller.	Same
Driving System	Direct drive on the rear wheels	Direct drive on the rear wheels	Same
Number of wheels	4	4	Same
Motor	Brushless DC motor, 24V/150W, 2pcs	Brushless motor, 24V/200W, 2pcs	<b>Analysis:</b> Minor differences in the specification of electric parts will not impact the
Battery	Lithium-ion battery 24V10Ah*1	Lithium-ion battery 24V12Ah*2	
Battery Charger	Off-board charger: Input: 100-240VAC,	Off-board charger: Input: 100-240 VAC	

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	50/60Hz, 2A Output: 29.4V, 2.0A	Output: DC 24V, 3A	safety and effectiveness of the substantial equivalence.
Main Frame Material	Carbon Fiber	Carbon Fiber	Same

**Table 2 - Technical Parameters Comparison**

Item	Subject Device	Predicate Device	Discussion/Conclusion
Overall length	860mm	930mm	<b>Analysis:</b> Dimensions and mass of the subject electric wheelchair have been tested according to ISO 7176-5. Such minor differences of the parameters won't will not affect the safety or effectiveness of the device
Overall width	600mm	585mm	
Storage length	620mm	740mm	
Storage width	260mm	265mm	
Storage height	700mm	720mm	
Weight	14kg	13.75kg	
Front Wheels	6.5 inch PU tire	7-inch PU solid tires	Similar
Rear Wheels	12-inch PU solid tires	12-inch PU solid tires	Same
Cruising Range	12.4 km	16.5 km	<b>Analysis:</b> Cruising range of the subject electric wheelchair have been tested according to ISO 7176-4. Such minor differences of the parameters won't will not affect the safety or effectiveness of the device.
Obstacle Climbing (mm)	20	25	<b>Analysis:</b> The obstacle climbing ability of the subject wheelchair has been tested according to ISO 7176-10. Such difference will not affect the

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			safety and effectiveness of the device.
Static stability forward	23.1°	18.9°	<b>Analysis:</b> The static stability of both proposed device and predicate devices is similar. Both devices have been evaluated according to ISO 7176-1 standard, therefore, such minor difference will not affect the safety and effectiveness of the device.
Static stability rearward	15.9°	18.2°	
Static stability sideways	Left: 23.2° Right: 23.0°	20.7°	
Max. Loading (kg)	100kg	110kg	<b>Analysis:</b> The max. loading of the proposed device have been evaluated according to ISO 7176 standard, therefore, such minor difference will not affect the safety and effectiveness of the device.
Min. Turning radium	825mm	870mm	<b>Analysis:</b> Both devices have been evaluated according to ISO 7176-5 standard, therefore, such minor difference will not affect the safety and effectiveness of the device.
Min. braking distance	0.6m	1.76m	<b>Analysis:</b> Both devices have been evaluated according to ISO 7176-3 standard, therefore, such minor difference will not affect the safety and effectiveness of the device.
Max Speed Forwards	1.3m/s	1.66m/s	<b>Analysis:</b>

			<p>The specification of both proposed device and predicate device is similar.</p> <p>Both devices have been evaluated according to ISO 7176-6 standard, therefore, such minor difference will not affect the safety and effectiveness of the device.</p>
Speed control method	Joystick control	Joystick control	Same

**Table 3 - Safety Comparison**

Item	Proposed Device	Predicate Device	Discussion/ Conclusion
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5, ISO10993-10 and ISO10993-23 requirements.	Comply with FDA Guidance	Same
EMC	IEC 60601-1-2& ISO7176-21	IEC 60601-1-2& ISO7176-21	Same
Performance	ISO7176 series	ISO7176 series	Same
Label and labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	Same

### **G. Summary of substantial equivalence discussion**

The proposed DH01126 Electric Wheelchair complies with the requirements of ISO 7176-1:2014, ISO 7176-2:2017, ISO 7176-3:2012, ISO 7176-4:2008, ISO 7176-5:2008, ISO 7176-6:2018, ISO 7176-7:1998, ISO 7176-8:2014, ISO 7176-9:2009, ISO 7176-10:2008, ISO 7176-11:2008, ISO 7176-13:1989, ISO 7176-14:2008, ISO 7176-15:1996, ISO 7176-16/ISO 16840-10, ISO 7176-21:2009, ISO 7176-22:2014, ISO 7176-25:2013, IEC 60601-1-2:2020, IEC TR 60601-4-2:2016, ISO 10993-1:2018, ISO10993-5:2009, ISO 10993-10:2021 and ISO 10993-23:2021.

The instructions for use, design and technological characteristics of the subject Electric Wheelchair are similar to the predicate device. The design principles of the controller and driving system are the same, and both meet the requirements of the ISO 7176-14:2008. Software validation has been carried out on both control systems. Brake system and speed

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control are designed in the same way as well, and both meet the requirements of the ISO 7176-3:2012. Although technical parameter, such as device dimensions, weight, static and dynamic stability, maximum obstacle climbing etc., as listed in Table 2 are slightly different, such minor differences will not impact the safety and effectiveness of the subject device or raise new safety and effectiveness concerns because both devices been tested according to ISO 7176 series standard and the test results showed that the devices comply with those requirements.

The biocompatibility of the predicate device and subject device meet the requirements of the ISO 10993-5:2009, ISO 10993-10:2021 and ISO 10993-23:2021. The flame retardant test of the seat cushion/back cushion and armrest of both subject device and predicate device is carried out according to the ISO 7176-16 and ISO 16840-10 test. Therefore, both devices are assured to be under the same safety level.

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

#### **H. Summary of Non-clinical Tests**

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 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- 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: Tests for Irritation
- 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: 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

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- 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 7176-21:2009 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 wheelchair
- ISO 16840-10:2021/AMD-1 2024 Wheelchair seating - Part 10: Resistance to ignition of postural support device - Requirements and test method
- IEC 60601-1-2:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance
- IEC 60601-4-2 Medical electrical equipment – Part 4-2: Guidance and interpretation for electromagnetic immunity of medical electrical equipment and medical electrical systems

#### **I. Biocompatibility of Patient-contacting material**

Biocompatibility of patient-contacting material are evaluated in accordance with ISO 10993-1: 2018. Although there are risks related to cytotoxicity, sensitization and irritation, the risk level is very low as the patient-contacting parts of the power wheelchair are made from materials in common use for other consumer products with a similar nature of contact, in addition, the product quality is controlled and managed by design, manufacturing, quality control, safety instructions, or warning information, hence the biological safety of the power wheelchair is acceptable without further biocompatibility testing on some parts contacted with the user during operation procedure of the product.

#### **J. Summary of Clinical Testing**

No clinical or animal study is available for our device. Clinical testing was not required to demonstrate the substantial equivalence of the power wheelchair to its predicate device.

#### **K. Conclusion**

The differences between DH01126 Electric Wheelchair and its predicate devices do not introduce a new intended use and do not raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended. From the results of nonclinical testing described, it can be concluded that the subject device electric wheelchair is substantially equivalent to the legally marketed predicate device.