September 16, 2024

Ningbo Youhuan Automation Technology Co., Ltd.
℅ Boyle Wang
Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd., Pudong
Shanghai, 200120
China

Re: K240638
Trade/Device Name: Power Wheelchair (YH-E7007)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: August 21, 2024
Received: August 21, 2024

Dear Boyle Wang:

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,

Tushar Bansal -S

for Heather Dean, PhD
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240638

Device Name

Electric Wheelchair (YH-E7007)

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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510(k) Summary
K240638

Date of Preparation: February 4, 2024

Submitter's information

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Designated Submission Correspondent

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Device information

Trade name: Power Wheelchair
Common name: Power Wheelchair
Classification name: Powered Wheelchair
Model(s): YH-E7007

Classification

Production code: ITI
Regulation number: 21 CFR 890.3860
Classification: Class II
Panel: Physical Medicine

Predicate device information

Manufacturer: JIANGSU INTCO MEDICAL PRODUCTS CO., LTD.
Trade/Device: Y207 Electric Wheelchair
510(k) number: K202482

Indication for Use Statement

The YH-E7007 Power 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. This product is suitable for disabled people with mobility difficulties and elderly people.

Device description

The subject device, Power Wheelchair, mainly powered by battery, motivated by DC motor, driven by user controlling joystick controller and adjusting speed.
The power wheelchair is a battery powered four wheeled vehicle. It consists Li-ion battery with an off-board battery charger, Push handle, Seat, Back support, Joystick controller, Control panel(including: Battery indicate, ON/OFF button, Horn, Gear indicator, Accelerated button, Deceleration button), Arm supports, Anti-tip wheel, Front wheel, Rear wheels.
The operation of the scooter: Use the On/Off button to turn on or turn off the power, The main function of the Joystick is to control the speed and direction of the wheelchair, the Joystick can control the wheelchair to travel in any direction, the operation of the Joystick movement will determine the wheelchair in that direction speed of movement. The farther the Joystick is moving from the center, the faster the wheelchair runs. When you release the Joystick, the wheelchair is automatically braked. Use the speed control button to reduce or increase the speed setting. The Electric/ manual model change lever underneath the seat will allow for the brakes to engage or disengage. When adjusted to the manual model, the assistant can easily push the wheelchair. The power wheelchair has a structure for quick assembly and disassembly that is convenient to be stored or placed in the trunk of your vehicle while traveling.
The Power Wheelchair has 8 inch front wheel and 12 inch rear tire.
The motor of power wheelchair is DC24V 250W; the battery is 24V 12AH, Li-ion battery; the charger is 24V/2A.
Max. loading can not be over than 120Kgs.
Max. distance of travel on the fully charged battery is 20km and Max. speed forward is 6km/h.
The braking time is about 2s, and the braking distance is ≤1.5m.

Summary of Non-Clinical Testing

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 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 : 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, and battery chargers
- ISO 7176-22 : 2014 Wheelchairs - Part 22: Set-up procedures
- ISO 7176-25 : 2014 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
- IEC 60601-1-2:2020 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 62133-1 Edition 1.0 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 1: Nickel systems

Biocompatibility of patient-contacting parts

Patient-contacting material are carried out biocompatibility assessment in accordance with ISO 10993-1: 2018, including:
Cytotoxicity per ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
Irritation and Skin Sensitization per ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

Software Verification and Validation Testing

Software documentation including verification & validation was provided in accordance with FDA Guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices for software with a moderate level of concern. The Software Validation is in compliance with FDA Guidance.

Summary of Clinical Testing

No clinical study implemented for the electric wheelchair.

Technological Characteristic Comparison Table

Table 1: General Comparison

Item	Proposed device	Predicate device	Remark
Product Code	ITI	ITI	Same
Regulation No.	21 CFR 890.3860	21 CFR 890.3860	Same
Class	II	II	Same
Product name	Power Wheelchair	Y207 Electric Wheelchair	-
510(k) No.	Pending	K202482	-
Models	YH-E7007	Y207	-
Intended Use	The YH-E7007 Power 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. This product is suitable for disabled people with mobility difficulties and elderly people.	The Y207 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. This product is suitable for disabled people with mobility difficulties and elderly people.	Same
Use environment	Indoor and outdoor use	Indoor and outdoor use	Same
Patient Population	This product is suitable for disabled people with mobility difficulties and elderly people.	This product 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, two Li-ion batteries, an off-board battery charger, a control panel, and an electric motor controller.	The device consists of two parts: the electrical part and the wheelchair main body. The electrical part includes motor, battery box, controller and charger. The main parts of the wheelchair include front wheels, rear wheels, frame, armrest, seat and back upholstery.	Similar
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	Same
Number of wheels	4	4	Same
Main frame material	Aluminium alloy	Aluminium alloy	Same
Motor	Brushless motor, DC24V* 250W*2pcs	Brushless motor, 24 VDC *200W * 2 pcs	Minor differences in the dimensions will not impact the safety and effectiveness of the substantial equivalence.
Battery	DC 24V 12Ah Lithium-ion, 2 pcs	Lithium-ion 20 Ah x 24 VDC	
Battery charger	Off-board charger	Off-board charger	
	Input: 100-240 VAC Output: DC 24V, 2A	Input: 100-240 VAC Output: DC 24V, 6 Amp	

Table 2: Performance Comparison

Item	Subject Device	Predicate Device	Remark
Dimensions (mm)	1080 x 610 x 960	1110 x 700 x 980	Minor differences in the dimensions will not impact the safety and effectiveness of the substantial equivalence.
Folded dimensions (mm)	810x610x410	810 x 700 x 400	Minor differences in the folded dimensions will not impact the safety and effectiveness of the substantial equivalence.
Weight, w/ Battery	61.73 lbs. /28 kg	Not publicly available	The difference will not raise any new safety and effectiveness concerns.

Frame design	Foldable/ The device consists of a foldable and non-rigid type of power wheelchair base with rear drive and 2 casters in the front and two anti-tippers in the rear.	Foldable/ The device consists of two parts: the electrical part and the wheelchair main body. The electrical part includes motor, battery box, controller and charger. The main parts of the wheelchair include front wheels, rear wheels, frame, armrest, seat and back upholstery.	Same
Folding mechanism	A foldable seat frames (The backrest could be folded to seat)	Not publicly available	The folding mechanism of the predicate device is not publicly available. No impact on safety and effectiveness.
Front wheel(inch)	8 (Solid tires)	8 (PU solid tire)	Same
Rear tire (inch)	12 (Pneumatic tire)	10 (PU solid tire)	Larger sizes of front wheels bring steadier pivoting function than predicate device.
Cruising Range(km)	20	20	Same
Obstacle climbing(mm)	25	50	The smaller height in the obstacle climbing will not impact the safety and effectiveness of the subject device.
Static stability forward	27.1°	Not publicly available	Both of the devices are evaluated according to standard ISO 7176-1:2014, so the different static stability will not impact the safety and effectiveness
Static stability rearward	19.9°		
Static stability sideways	20.5°		
Max. loading (kg)	264.5lbs(120kg)	275lbs (125kg)	Less loading weight means more convenient for the transportation
Maximum safe operational incline	9 degrees	8 degrees	Larger safe operational incline of subject bring more convenient for the use environment

Min. Turning radium	975mm	950mm	The little difference in the turning radius will bring more convenience when it turns. The difference will not raise any new safety and effectiveness concerns.
Minimum braking distance	1.5m	1.5m	Same
Max Speed Forwards	1.7m/s (6 km/h)	1.5m/s (5.4 km/h)	The devices are evaluated according to standard ISO 7176-6:2018, so the different will not impact the safety and effectiveness
Max. Speed Backward	1.0m/s (3.6 km/h)	0.8m/s (2.88 km/h)	The devices are evaluated according to standard ISO 7176-6:2018, so the different will not impact the safety and effectiveness
Controller	Zhejiang Shiyou Driving Technology Co., Ltd. SYC-JCM21L	PG Drives Technology Ltd., newVSI	Different Although different controller is used, both the control system, including the joystick controller, the electromagnetic brakes and the user interface are similar. The joystick controls the directions and speed of movement, and when the joystick is released, the powered wheelchair will slow down to stop and the brakes will automatically re-engage. The controller also provides the battery status displaying and abnormal condition displaying. Both of the control systems are evaluated according to standard ISO 7176-14:2008 and software validation requirement and there are no new safety and effectiveness concerns due to the difference.

Speed control method	Joystick control method	Joystick control method	Same

Table 3: Safety Comparison

Item	Proposed Device	Predicate Device	Remark
Materials contacting user	Armrest: PU; Backrest/Seat/Seat belt: Polyester Controller Housing:ABS Joystick: Silicone rubber	Armrest: PU; Backrest/seat: sandwich mesh fabric (polyester) newVSi electric wheelchair controller: Joystick knob: Santoprene 101-80; Joystick Gaiter: Silicone 3032 (50%) & 5031 (50%) Enclosure Moulding(s): ABS/PC Wonderloy PC-540 Keypad: Silicone keypad coatings TC-2407 & CH-6330	Biocompatibility evaluation has been carried out per ISO 10993-1. There are no new safety and effectiveness concerns due to the difference.
Biocompatibility of materials contacting user	Comply with ISO 10993-1, FDA Guidance	Comply with ISO 10993-1, FDA Guidance, Tests included Cytotoxicity (ISO 10993-5:2009), Sensitization and Intracutaneous Reactivity (ISO 10993-10:2010)	Same

Summary of substantial equivalence discussion:

The technological characteristics, features, specifications, materials, 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 devices do not raise new issues of safety or effectiveness.

Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicated device in K202482 and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.