September 9, 2025

Shandong Guyue Healthcare Appliance Co., Ltd.
℅ Kiwi Xu
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Building, 1500# Central Ave.
Shanghai, 200122
China

Re: K251891
Trade/Device Name: Electric Wheelchair (GY-E001)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: June 20, 2025
Received: June 20, 2025

Dear Kiwi Xu:

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

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

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.	K251891

Please provide the device trade name(s).

Electric Wheelchair (GY-E001)

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)

510(k) #:

510(k) Summary

Prepared on: 2025-06-19

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Shandong Guyue Healthcare Appliance Co., Ltd.
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Correspondent Contact	Ms. Kiwi Xu
Correspondent Contact Email	weijia.xu@sungoglobal.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Electric Wheelchair (GY-E001)
Common Name	Powered wheelchair
Classification Name	Wheelchair, Powered
Regulation Number	890.3860
Product Code(s)	ITI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K240913	Electric Wheelchair	ITI

Device Description Summary

21 CFR 807.92(a)(4)

The subject device, Electric Wheelchair, mainly powered by battery, motivated by DC motor, driven by user controlling joystick controller and adjusting speed. Products for adult use.
The Electric Wheelchair is a battery powered four wheeled vehicle. It consists Lithium battery with an off-board battery charger, Push handle, Seat, Back support, Joystick controller, Control panel (including: Speed light, ON/OFF button, Horn, Joystick, Accelerated button, Deceleration button), Arm supports, Anti-tip wheel, Front wheel, Rear wheels.
The operation of the Controller: 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 Electric 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 Electric Wheelchair has 7 inch front wheel and 12 inch rear tire.
Max. distance of travel on the fully charged battery is 12.4 km and Max. speed forward is 6.48 km/h.
When the wheelchair needs to stop, release the joystick. After a set period of time, the controller disconnects the solenoid brake power supply, and the internal spring squeezes the suction plate and friction plate to lock the motor, so as to brake.
The braking time is about 2s, and the braking distance is ≤1.5m.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

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.

Technological Comparison 21 CFR 807.92(a)(6)

The design and technological characteristics of the Power Wheelchair is similar to the predicate chosen. There are minor differences between the devices including Battery, Maximum distance of travel on the fully charged battery, Turning Radius and Maximum obstacle climbing. All of the parameter with differences have been tested according to ISO 7176 series standards and the test records support it safety and effectiveness. There is no deleterious effect on safety and effectiveness due to the minor differences, Additionally, they do not influence the intended use of the device. And the same materials were used for parts in contact with user. Therefore, the proposed Wheelchair is substantially equivalent (SE) to the Electric Wheelchair.

Table 1 General Comparison

Elements of Comparison	Subject Device	Predicate Device (K240913)	Remark
Manufacturer	Shandong Guyue Healthcare Appliance Co., Ltd.	Shanghai Hubang Intelligent Rehabilitation Equipment Co., Ltd	-
Common or Usual name	Power Wheelchair	Power Wheelchair	Same
Model(s)	GY-E001	HBLD3-B, HBLD3-E	--
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.	Same
Use condition	indoor and outdoor use	indoor and outdoor use	Same
Number of wheels	4, including two front wheels and two rear Wheels	4, including two front wheels and two rear Wheels	Same
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	Same

Elements of Comparison	Subject Device	Predicate Device (K240913)	Remark
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 electronic brake system	Automatic electromagnetic brake system	Same
Braking distance	≤1.0 m	⩽1.5 m	**Analysis:** Larger braking distance and safe operational incline degree of subject bring more convenient for the use environment.
Maximum safe operational incline degree	10 °	6 °	
Armrest	PUR	ABS	**Analysis:** Difference of the materials will not raise safe and effectiveness concerns. The biocompatibility tests have been conducted to verify the safety and effectiveness of the material.
Battery charger	Off-board charger Input: 100-240V, 50/60Hz, 1.5A, Output: 24 V-29.6V, 1.8A;	Off-board charger Input: 100-240V, 50/60Hz, 1.5A, Output: 24 Vdc, 2A;	Same
Main frame material	Aluminum alloy	Aluminum Alloy	Same
Seat cushion	Nylon	Polyester fabric	**Analysis:** Minor differences in the dimensions and material will not impact the safety and effectiveness of the substantial equivalence.
Back cushion	Nylon	Polyester fabric	
Overall Dimension (length*width*height)	1100×680×870 mm	HBLD3-B model: 960×580×890 mm HBLD3-E model: 1090×640×900 mm	
Folded Dimension (length*width*height)	810×650×420 mm	HBLD3-B model: 890×600×380 mm HBLD3-E model: 730×350×950 mm	

Elements of Comparison	Subject Device	Predicate Device (K240913)	Remark
Front wheel size/type	8"/ Solid tyre	7" x 1.75"/PU Solid tire	**Analysis:** Different sizes and type of rear wheel will not affect the safety and performance of the subject device as all related stability tests are performed according to standard ISO 7176 series.
Rear wheel size/type	12.5" x 1.75"/ Solid tyre	12" x 2.125" pneumatic tire	
Max speed forward	6.48 km/h	6-8 km/h (1.6-2.2 m/s), adjustable	**Analysis:** Slightly difference on the parameter will not affect the safety and performance of the subject device as all related stability tests are performed according to standard ISO 7176-6:2018.
Max Speed backward	Less than 3.6 km/h (1.0 m/s)	Less than 3 km/h (0.8m/s)	
Max loading weight	100 kg	100 kg	Same
Battery	24V 12Ah Lithium-ion battery	Li-ion battery pack; rechargeable, 24 V DC 5.2 Ah*2	**Analysis**: The subject device complies with ISO 7176-25: 2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs and EMC testing, these differences do not affect safety and effectiveness.
Maximum distance of travel on the fully charged battery	12.4km	20km	**Analysis:** The subject device complies with ISO 7176-4: 2008 Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range, these differences do not affect safety and effectiveness.
Motor	DC motor; 24VDC; 250W; 160 r/min	Brushless DC motor; 24VDC; 150W; 2pcs	

Elements of Comparison	Subject Device	Predicate Device (K240913)	Remark
Electronic controller	Brushless dual-drive rocker controller	Brushless dual-drive rocker controller	Same
Turning Radius	950mm	HBLD3-B model: 875 mm HBLD3-E model: 1050 mm	**Analysis:** The predicate device and subject device have different dimensions. Both comply with ISO 7176-5:2008 Wheelchairs – Part 5: Determination of dimensions, mass, and maneuverings space so these differences do not affect safety and effectiveness.
Maximum obstacle climbing	45 mm	20mm	

Table 2 Safety comparison

Item	Proposed Device	Predicate Device	Results
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5, ISO10993-10 and ISO 10993-23 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	Same
EMC	ISO7176-21 & IEC 60601-1-2	ISO7176-21 & IEC 60601-1-2	Same
Performance	ISO7176 series	ISO7176 series	Same
Label and labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	Same

Item	Proposed Device	Predicate Device	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

Item	Proposed Device	Predicate Device	Results
ISO7176-6	The dimensions, mass has been determined after the testing according to the ISO 7176-6	The dimensions, mass 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 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	Same
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/ ISO 16840-10	The performance of resistance to ignition meet the requirements of ISO 16840-10	The performance of resistance to ignition meet the requirements of ISO 16840-10	Same
ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21	Same

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 and FDA guidance Submission for Power Wheelchair.

The proposed device performs in a similar manner to the predicate device. All these tests have corresponding requirements/ control criteria following above mentioned standards. And the test results show that the subject product is substantially equivalent to the predicate device in performance.

The performance testing demonstrates that the subject device is substantially equivalent to the predicate devices regarding Static ability (tipping angle), The Dynamic stability (Safe Gradient Maximum Gradient), Brake performance, Theoretical distance range, Dimension and weight, Maximum speed, Dimension of wheel Static, impact and fatigue strengths, Climatic tests, Obstacle-climbing ability, Dummy, friction of test surfaces, Power and control systems, Documentation and labeling, Resistance to ignition, Electromagnetic Compatibility and Electrical Safety, Batteries and chargers.

The non-clinical laboratory data support the safety and performance of the subject device and demonstrate that the subject device should perform as intended in the specified use conditions.

3. Substantially Equivalency Conclusion

Based on the comparison and analysis above, the subject device is determined to be Substantially Equivalent (SE) to the predicate devices, K240913 Power Wheelchair from Shanghai Hubang Intelligent Rehabilitation Equipment Co., Ltd.