July 2, 2025

Vive Health LLC
℅ Kiwi Xu
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Building, 1500# Central Ave.
Shanghai, 200122
China

Re: K250729
Trade/Device Name: Power Wheelchair (MOB1107)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: May 22, 2025
Received: May 23, 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

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.

510(k) Number *(if known)*
K250729

Device Name
Power Wheelchair (MOB1107)

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.

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510k Summary

Submitter:

Name: Vive Health LLC

Address:8955 Fontana Del Sol Way, Naples, FL 34109, US

Contact: Guy Savioli

Email: guy.savioli@igbrands.com

Prepared on: July 1, 2025

Device:

510(k) number: K250729

Device Trade Name： Power Wheelchair

Model: MOB1107

Classification name: Powered wheelchair

Regulation class: 2

Regulation number: 21CFR 890.3860

Panel: Physical Medicine

Product code: ITI

Predicate device:

510(k) number: K242791

Device Trade Name: Electric Wheelchair

Model: KR8807

Zhejiang Kairui Medical Device Co., Ltd.

Device description:

The subject device, Power Wheelchair, mainly powered by battery, motivated by DC motor, driven by user controlling joystick controller and adjusting speed. Products for adult use.
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: 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 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 7 inch front wheel and 12 inch rear tire.
Max. distance of travel on the fully charged battery is 7.5 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.

Indication 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.

1. Product Parameters

Table 1 General Comparison

Elements of Comparison	Subject Device (K250729)	Predicate Device (K242791)	Remark
Manufacturer	Vive Health LLC	Zhejiang Kairui Medical Device Co., Ltd.	-
Common or Usual name	Power Wheelchair	Power Wheelchair	Same
Model(s)	MOB1107	KR-8807	--
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 (K250729)	Predicate Device (K242791)	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 electronic brake system	Same
Braking distance	⩽0.9 m	⩽0.9 m	Same
Maximum safe operational incline degree	10 °	10 °	Same
Armrest	PU	PU	Same
Battery charger	Off-board charger Input: 100-240V, 50/60Hz, 1.5A, Output: 24 Vdc, 2A;	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	Polyester fiber	Polyester fiber	Same
Back cushion	Polyester fiber	Polyester fiber	Same
Overall Dimension (length*width*height)	1000×620×900 mm	1010×620×900 mm	**Analysis:** Minor differences in the dimensions will not impact the safety and effectiveness of the substantial equivalence.
Folded Dimension (length*width*height)	790×360×730 mm	780×350×730 mm	
Front wheel size/type	7" x 1.3"/PU Solid tire	7" x 1.3"/PU Solid tire	Same
Rear wheel size/type	12" x 1.8"/PU Solid tire	12" x 1.8"/PU Solid tire	Same
Max speed forward	6.5 km/h(1.8 m/s)	6.5 km/h(1.8 m/s)	Same
Max Speed backward	Less than 3.24 km/h (0.9m/s)	Less than 3.24 km/h (0.9m/s)	Same

Elements of Comparison	Subject Device (K250729)	Predicate Device (K242791)	Remark
Max loading weight	120 kg	120 kg	Same
Battery	Lithium-ion battery; DC 25.2V 6Ah×1	Lithium-ion battery; 25.9V 11.6Ah×1	**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.
Maximum distance of travel on the fully charged battery	7.5 km	15 km	
Motor	DC motor; 24VDC; 180W; 2200RPM	DC motor; 24VDC; 180W; 2200RPM	Same
Electronic controller	Brushless dual-drive rocker controller	Brushless dual-drive rocker controller	Same
Turning Radius	887.5 mm	900 mm	**Analysis:** The predicate device and subject device have different dimensions. Both comply with ISO 7176- 5:2008 and ISO 7176-10:2008, so these differences do not affect safety and effectiveness.
Maximum obstacle climbing	25 mm	40mm	

Table 2 Safety comparison

Item	Subject Device	Predicate Device	Results
Biocompatibility	All directly tissue-contacting materials are identical to the Predicate Device, with Right-of-Reference from the predicate manufacturer.	All directly tissue-contacting materials are in compliance with ISO10993-5 and ISO10993-10 requirements.	Same
Electromagnetic Compatibility (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 requirements	Conforms to FDA Regulatory requirements	Same

Item	Subject 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

Item	Subject Device	Predicate Device	Results
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 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

Item	Subject Device	Predicate Device	Results
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
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
ISO 7176-22	The ISO 7176-series performance testing used set-up procedures according to ISO 7176-22	The ISO 7176-series performance testing used set-up procedures according to ISO 7176-22	Same
ISO 7176-25	The performance of batteries and chargers for powered wheelchairs meet the requirements of ISO 7176-25	The performance of batteries and chargers for powered wheelchairs meet the requirements of ISO 7176-25	Same

Substantial Equivalence Discussion

The proposed (subject) 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, ISO 7176-22, ISO 7176-25, and 1995 FDA Guidance on 510(k) Submissions for Mechanical and Powered Wheelchairs. The subject device also provided electromagnetic compatibility (EMC) testing according to IEC 60601-1-2 and Enhanced-level software documentation (including verification and validation testing) in accordance with FDA's 2023 Guidance on the "Content of Premarket Submissions for Device Software Functions."

The proposed device performs in a similar manner to the predicate device. All these tests have corresponding requirements/ acceptance criteria following above mentioned standards. And the test results show that the subject device is within acceptable performance specifications and thus 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. Summary of clinical testing:

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

4. Substantially Equivalency Conclusion

Based on the comparison and analysis above, the subject device is determined to be Substantially Equivalent (SE) to the predicate devices, K242791 Power Wheelchair from Zhejiang Kairui Medical Device Co., Ltd.