



February 12, 2025

Kunshan Hi-Fortune Health Products Co., Ltd
% Ariel Xiang
Consultant
Shanghai Sungo Management Consulting Co. Ltd.
14th Floor, 1500# Century Avenue
Shanghai, Shanghai 200122
China

Re: K243962
Trade/Device Name: Electrically Powered Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: December 20, 2024
Received: December 23, 2024

Dear Ariel Xiang:

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

Indications for Use

Submission Number (if known)

K243962

Device Name

Electrically Powered Wheelchair

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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Kunshan Hi-Fortune Health Products Co., Ltd.
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510(K) Summary

K243962

Document Prepared Date: 2025/02/11

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B. Device

Trade Name: Electrically powered wheelchair

Common Name: Powered wheelchair

Models: HP558

Regulatory Information

Classification Name: Powered wheelchair Classification: Class II.

Product code: ITI

Regulation Number: 890.3860

Review Panel: Physical Medicine

C. Predicate device

K212503

Electrically powered wheelchair,HP458E

Kunshan Hi-Fortune Health Products Co., Ltd.

D. Indications for use of the device

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.

E. Device Description

This product consists of frame, wheels, seat, armrest, lithium battery, motor and controller with a lightweight and compact design. The whole wheelchair can be folded and it can be easily carried or rolled after folding. The seat cushion is detachable. The armrest can be flipped upside down, which is convenient for the elderly to move. Users can drive the wheelchair by themselves through the control device.

The wheelchair uses lithium batteries as its power source. The controller controls the drive left/right motor to realize the wheelchair forward, backward and turn functions.

The frame of the device is Magnesium alloy. The front wheels are driven wheels suitable for rotation, acceleration, retrograde and other actions of the wheelchair. The front wheels movement will be achieved by thrust generated from the rear wheels. The rear wheels are driving wheels to control the speed and direction. The wheels are Solid PU tires. When in use, the operator drives the motor of the rear wheel by operating the controller joystick to achieve the rear wheels movement.

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

The max loading of the device is 120KG. Only for one person sit.

F. Comparison to predicate device

a) There are three changes to the proposed device:

changes	Proposed Device	Predicate Device (K212503)
1.Change Motor	DC Brushless Motor, 24Vdc 170W;2pcs	DC Brush Motor, 24Vdc 120W;2pcs
2. Change controller	M7084	PG Drives Technology Ltd., VR2
3. Change the Main frame material size	Magnesium alloy	Aluminium alloy

b) Technical comparison

Table 1 General Comparison

Elements of Comparison	Proposed Device(K243962)	Predicate Device (K212503)	Remark
Manufacturer	Kunshan Hi-Fortune Health Products Co., Ltd	Kunshan Hi-Fortune Health Products Co., Ltd	--
Common or Usual name	Electrically powered wheelchair	Electric wheelchair	--
Model(s)	HP558	HP458E	--
Classification	Class II	Class II	Same
Classification regulation	21 CFR890.3860	21 CFR890.3860	Same
Product code	ITI	ITI	Same
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	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	Front wheels: driven wheels suitable for rotation, acceleration, retrograde Rear wheels: driving	Same

	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	wheels to control the speed and direction Anti-tip wheels: preventing the wheelchair from tipping turning over when driving on the slope. Non-adjustable	
Product structure	Consists of two foldable armrests, a backrest, a seat cushion, a foldable frame, two rear driving wheels with hub motor/electromagnetic brake assemblies, two pivoting casters, a Li-ion batteries, an off-board battery charger, a control panel, and an electric motor controller	Consists of two foldable armrests, a backrest, a seat cushion, a foldable frame, two rear driving wheels with hub motor/electromagnetic brake assemblies, two pivoting casters, a Li-ion batteries, an off-board battery charger, a control panel, and an electric motor controller	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
Armrest	PU	PU	Same
Back cushion	Terylen (polyester fabrics)	Terylene	Same

Seat cushion	Terylene (polyester fabrics)	Terylene	Same
Main frame material	Magnesium alloy	Aluminium alloy	Different
Max loading weight	120Kg	264lbs(120Kg)	Same
Min obstacle climbing	35mm	50mm	Minor difference will not cause different performance.
Total mass	18KG	41.9lbs/19KG	Similar
Overall Dimension (length*width*height)	1100mmX600mmX940mm (43.3"×23.6"×37.0")	39.0"×24.4"×34.6"	Minor difference will not cause different performance.
Folded Dimension (length*width*height)	690mmX380mmX720mm (27.0"×15.0"×28.3")	28.3"×13.4"×28.0"	
Front wheel size/type	5.5" PU tire	6" PU tire	Similar
Rear wheel size/type	9.5" PU tires	10" PU tires	Similar
Max speed forward	5.0km/h(1.4m/s)	6km/h	Similar
Max speed backward	2.88km/h(0.8m/s)	2.88km/h	Same
Static stability	Forward:20.0° Rear ward:17.0° Sideways:19.2°	Forward:16.5° Rear ward:16.5° Sideways:17°	Minor difference on safe operational incline degree will not cause new safety and effectiveness concerns, as both the static and dynamic stability under specific inclining degree have been evaluated according to
Maximum safe operational incline	10°	6°	

cline degree			standard ISO 7176 series.
Braking distance	1.1m	1 m	Minor difference on braking distance will not cause different performance. Shorter distance for braking will be more safety.
Maximum distance of travel on the fully charged battery	12.6km	15km	Minor difference will not cause different performance.
Min.Turning Radius	900mm	1000mm	Minor difference in turning radius is caused by different size of wheelchair ,it will not cause different performance.
Battery	li-ion battery pack;rechargeable, 25.2VDC, 10.4Ah,2pcs	li-ion battery pack;rechargeable, 25.2VDC, 10.4Ah,2pcs	Same
Battery charger	High Power TechnologyInc. HP0060W(L2) Input: 100-240 VAC Output: DC 24V, 2 Amp	High Power TechnologyInc. HP0060W(L2) Input: 100-240 VAC Output: DC 24V, 2 Amp	Same
Motor	DC Brushless Motor, 24Vdc 170W;2pcs	DC Brush Motor, 24Vdc 120W;2pcs	Analysis,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 is carried out on both control systems.
controller	M7084	PG Drives Technology Ltd., VR2	

Table 2 safety comparison

Item	Proposed Device	Predicate Device	Results
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5、ISO10993-10 and ISO10993-23 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	SE
EMC	ISO7176-21& IEC 60601-1-2	ISO7176-21	SE
Performance	ISO7176 series	ISO7176 series	SE

Label and labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	SE
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G. 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, ISO7176-22,ISO 7176-25, IEC 60601-1-2 and FDA guidance Submission for Power Wheelchair.

The indications for use, design, structure, composition, principle of operation and energy source of proposed device and predicate device are identical. The dimensions and performance parameters are similar. The main differences are motor ,controller and main frame appearance and materials.

The design principles of the controller and Driving system are the same, and both meet the requirements of the ISO 7176-14. Software validation is carried out on both control systems. Brake system and speed control are designed in the same way as well, and both meet the requirements of the ISO 7176-3. Turning radius, Maximum obstacle climbing and Maximum safe operational incline are slightly different while such differences will not impact the safety and effectiveness of the subject device or raise new safety and effectiveness concerns as well as both meet the requirements of the ISO 7176-2 and ISO 7176-10.

The main frame is not in contact with human tissue, and the material difference does not cause a security risk. The materials in contact with human tissue are identical for both proposed device and predicate device. The biocompatibility of the proposed device and predicate device meet the requirements of the ISO 10993-5:2009 & ISO 10993-10:2021 & ISO 10993-23: 2021.

The flame-retardant test of the seat cushion/ backrest of both subject device and predicate device is carried out according to the ISO 16840-10 test. Therefore, both devices are assured to be under the same safety level.

In conclusion, 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.

H. Product Performance

2.1 Product Material Safety

To ensure the safety of the wheelchair material, the bio-compatibility testing was done to the products. The testing was conducted according to the following standards:

ISO10993-5 Biological evaluations of medical devices -- Part 5: Tests for In Vitro

cytotoxicity

ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for skin sensitization

ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation

From the test result, we can find the material are safety and can meet the requirements.

2.2 Performance of the products

The following performance data were provided to verify that the subject device met all design specifications and provided support of the substantial equivalence determination.

Risk Analysis developed in accordance with ISO 14971: 2019.

Software validation

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: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range

ISO 7176-5:2008 Wheelchairs - Part 5: Determination of dimensions, mass and maneuvering 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 strength

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 7176-14:2022 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 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

ISO 7176-22: 2014 Wheelchairs-Part 22: Set-up proceduresd

ISO 7176-25: 2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs.

Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2020

I. Conclusion

The subject device and the predicate products have the same technological characteristics, features, specifications, materials, mode of operation, and intended use of the device. To ensure all the key characteristic of the products can meet the requirements, the testing was done and all the results indicate the positive conclusion.

Based on the analysis above, we confirm these two products are substantially equivalent.