March 26, 2025

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

Re: K244003
Trade/Device Name: Electrically powered wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: February 3, 2025
Received: February 26, 2025

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

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)*

K244003

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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510(K) Summary

K244003

Document Prepared Date: 2025/2/26

A. Applicant

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B. Device

Trade Name: Electrically powered wheelchair

Common Name: Powered wheelchair

Models: HP330

Regulatory Information

Classification Name: Powered wheelchair Classification:
Class II.

Product code: ITI

Regulation Number: 890.3860

Review Panel: Physical Medicine

C. Predicate device

510Knumber: K240105

Device Name:Navigator, Navigator XL

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 entire wheelchair can be disassembled and assembled, making it easy to carry. The wheelchair comes equipped with an electronically controlled rising seat that allows the user 280mm/11" of seat height adjustment using the joystick.

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 lead-acid Battery 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 carbon steel. 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 136KG. Only for one person sit.

F. Comparison with predicate Device

Table 1 General Comparison

Elements of Comparison	Proposed Device	Predicate Device (K240105)	Remark
Manufacturer	Kunshan Hi-Fortune Health Products Co., Ltd	Forcemech International LLC	--
Common or Usual name	Electrically powered wheelchair	Power wheelchair	--
Model(s)	HP330	FMNVG15, FMNVX06	--
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	It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly	S.E.

	person limited to a seated position.	person limited to a seated position.	
Use condition	indoor and outdoor use	indoor and outdoor use	S.E
Number of wheels	6, including two front wheels and two rear wheels, two anti-tip wheels	4,including two front wheels and two rear Wheels	S.E
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	S.E
Movement control method	By Joystick control	By Joystick control	S.E
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	S.E
Brake system	Automatic electromagnetic brake system	Automatic electromagnetic brake system	S.E
Braking distance	≤1.5 m	≤1.5 m	S.E
Armrest	Polyurethane	Polyurethane	S.E
Max loading weight	136kg	120kg	Similar,All safety and performance have been validated with the maximum rated weight dummy.
Maximum safe operational incline degree	6°	6°	S.E
Back cushion	Polyurethane	Polyurethane	S.E
Seat cushion	Polyurethane	Polyurethane	
Main frame material	Carbon steel material	Aluminum Alloy	Similar,Different materials will not affect safety and performance of the subject device as all related stability tests are performed according to standard ISO 7176 series.

Overall Dimension (length*width*height)	950mm*660mm*950mm	Navigator FMNVG15 Model: 980*600*940mm Navigator XL FMNVX06 Model: 980*620*940mm	Minor difference on wheelchair dimension will not cause different performance. All safety and performance have been validated with the maximum rated weight dummy.
Folded Dimension (length*width*height)	740mm*600mm*410mm	590mm*370mm*787mm	
Front wheel size/type	6" PU Solid tire	8" (203mm) Non-Pneumatic tire	Different sizes and materials will not affect safety and performance of the subject device as all related stability tests are performed according to standard ISO 7176 series.
Rear wheel size/type	10"PU Solid tires	11.8" (300mm) Non-Pneumatic tire	
Max speed forward	Up to 5.4km/h（1.5m/s）	Up to 6 km/h (1.6 m/s) adjustable	Similar
Max Speed backward	Less than 2.5km/h (0.7m/s)	Less than 3 km/h (0.8 m/s)	Similar
Maximum distance of travel on the fully charged battery	12km	16km	Similar , it will not cause new safety and effectiveness concerns.
Battery	Lead-acid Battery,;rechargeable; 12V 22AH	Li-ion battery pack;rechargeable, 24 VDC 6Ah*2	Both meet the requirements of the ISO 7176-25.It will not cause new safety and effectiveness concerns.
Battery charger	Off-board charger Input:100-240VAC,50-60Hz,1.2-0.5A Output:24V,2A	off-board charger Input: 100-240V. 50/60Hz, 1.5A. Output: 24 Vdc. 2A	
Motor	Brushless DC motor; 24VDC; 250W; 2pcs	Brushless DC motor; 24VDC; 250W; 2pcs	S.E
Electronic controller	Dynamic, DLX-REM210-A, 24V	Dual Core Twin Drive controller	Both meet the requirements of the ISO 7176-14.It will not cause new safety and effectiveness concerns.
Turning Radius	825mm	1200mm	Minor difference in turning radius is caused by different size of wheelchair and may
Min obstacle climbing	25mm	40mm	Minor difference on obstacle climbing will not cause new safety and effectiveness

			concerns.

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	IEC 60601-1-2&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

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, ISO 7176-25, and FDA guidance Submission for Power Wheelchair.

The indications for use for both devices are the same. 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.

The frame materials,Turning radius, Maximum obstacle climbing and Maximum loading weight 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 7176-8,ISO 7176-10 and ISO 7176-11.

The biocompatibility of the predicate device and proposed 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

a) 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.

b) 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 proposed device and predicate device 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.