



September 29, 2026

Xuzhou Heabens Medical Technology Co., Ltd.
% Ivy Wang
Consultant
Shanghai Sungo Management Consulting Co., Ltd.
Rm. 1401, Dongfang Bldg., 1500# Century Ave.,
Shanghai, 200122
China

Re: K262241
Trade/Device Name: Electric Wheelchair (0080)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: June 30, 2026
Received: July 1, 2026

Dear Ivy 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

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.

K262241

?

Please provide the device trade name(s).

?

Electric Wheelchair (0080)

Please provide your Indications for Use below.

?

The 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.

Please select the types of uses (select one or both, as applicable).

☐ Prescription Use ([21 CFR 801 Subpart D](#))

☒ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☐ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

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510(k) Summary

I. SUBMITTER

Name: Xuzhou Heabens Medical Technology Co., LTD.

Address: No. 2 Industrial Concentration Zone, Liucheng Avenue, Weimiao Town, Peixian,
Xuzhou, Jiangsu, China

Name of contact person: Eric Wang

Telephone: +86 18652292378

Email: Eric.wang@heabenswheelchair.com

Date prepared: 2026-06-29

II. Device

Device trade name: Electric wheelchair

Model: 0080

Classification name: Powered wheelchair

Regulation class: 2

Regulation number: 21CFR 890.3860

Panel: Physical Medicine

Product code: ITI

III. Predicate device

K113463

Power Wheelchair, PL001

SUZHOU KD Medical Appliance Co. Ltd.

IV. Device description

The electric wheelchair, Model 0080, is an indoor/outdoor, foldable, battery-operated 2-wheel (rear-wheel drive) powered wheelchair. It consists of two parts: the electrical part and the wheelchair main body. The electric part includes brushless motor, electromagnetic brake system, controller, rechargeable Lithium-Ion battery and off-board battery charger. The main parts of the wheelchair include front wheels, rear wheels, frame, armrest, backrest and seat cushion.

The control system, including the controller handle (joystick), is equipped on the control pad that attaches to the one of the arm rests. When the joystick is released, the electromagnetic brakes will be actuated, and the electric wheelchair is slowed to a stop.

The electric wheelchair can be travelled on flat and hard road, and direction and speed of the wheelchair can be controlled by the passenger's hand with the help of the joystick. The device can be used to provide indoor and outdoor mobility at a certain distance but not allowed to be travelled on the road or highway. The electric wheelchair can be folded/ expanded manually.

V. Indication for use

The 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.

VI. Comparison of technological characteristics with the predicate device

Attribute	Subject device	Predicate device	Discussion/Conclusion
Manufacturer	Xuzhou Heabens Medical Technology Co., LTD.	SUZHOU KD Medical Appliance Co. Ltd.	/
Proprietary name, model	Electric Wheelchair, 0080	power wheelchair, PL00I	/
510(k) number	K262241	K113463	/
Device classification name	Class II	Class II	Same
Classification regulations	21 CFR 890.3860	21 CFR 890.3860	Same
Product code	ITI	ITI	Same
Similarities			
Indication for use	The 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.	They are 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
Intended user	disabled or elderly person limited to a seated position	disabled or elderly person limited to a seated position	Same
Use condition	indoor and outdoor use	indoor and outdoor use	Same

Attribute	Subject device	Predicate device	Discussion/Conclusion
Number of wheels	4, including two front wheels and two rear wheels	4, including two pivoting casters and two rear drive wheels	Same
Function of wheels	Front wheels: driven wheels suitable for rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed and direction	two pivoting casters: driven wheels suitable for rotation, acceleration, retrograde two rear drive wheels: driving wheels to control the speed and direction	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	Intelligent electromagnetic brake system	Intelligent regenerative Electromagnetic brake	Same
Main frame material	aluminum alloy, front and rear folding	aluminum alloy, front and rear folding	Same
Armrest cushion	Polyurethane	Polyurethane	Same
Differences			
Overall dimensions (LxWxH)	1100× 610 × 1000 mm	880 mm×570 mm×890 mm	larger size is designed for bearing more loading weight. All safety and performance have been validated with the maximum rated weight dummy.
Folded dimensions (LxWxH)	370 × 600× 800 mm	720 mm×570 mm×400 mm	
Ground clearance	102 mm	80 mm	Minor difference on ground clearance do not affect effectiveness and safety performance. All safety and performance have been validated with the maximum rated weight dummy.
Front wheel size/type	8" /PU Solid tire	6/PU Solid tire	larger size of driven wheel will provide

Attribute	Subject device	Predicate device	Discussion/Conclusion
Rear wheel size/type	12.5"×2.2" /PU Solid tire	8" x 2.4"/PU Solid tire	similar safety and performance. All safety and performance have been validated with the maximum rated weight dummy.
Battery	Lithium battery; rechargeable, 24 VDC 6.4Ah*2pcs	Li-ion, Rechargeable; 24 VDC 20Ah*1pcs	Same rated voltage with different power capacity will not affect the safety and performance of the subject device.
Maximum distance of travel on the fully charged battery	12 km	20 km	Minor difference on travel distance will not cause different performance. This difference will not raise any new safety and effectiveness concerns.
Max speed forward	Up to 5.76 km/h (3.58 mph), continuously adjustable	Up to 6 km/h (3.75 mph), variable	minor difference on max. forwarding speed will not cause different performance.
Max Speed backward	0.7 m/s (2.52km/h)	2.4 mph (3.84 km/h)	minor difference on max. backward speed will not cause different performance. lower speed will be more safety.
Minimum braking distance from maximum speed	Forward: 0.9 m	Forward:1.5 m (59")	subject device has shorter braking distance than the predicate device, such differences will not affect safety and performance of the device.
Max loading weight	150kg (330 lbs)	114 kg (251 lbs)	minor difference on loading weight will not cause different performance. more

Attribute	Subject device	Predicate device	Discussion/Conclusion
			loading weight provides more convenient and stable performance for the transportation.
Maximum safe operational incline degree	10 °	9 °	minor difference on safe operational incline degree will not cause new safety and effectiveness concerns. Both the static and dynamic stability under specific inclining degree have been evaluated according to standard ISO 7176 series.
Battery charger	Off-board charger Input: 100-240V, 50/60Hz, 1.5A Output: 24 Vdc, 2A	Off-board, Automatic Type Input: 110-220 V / 50-60 Hz, Output: 24 Vdc, 2A;	More wide range of input voltage in the device which will not cause new safety and effectiveness concerns raised.
Motor	Brushless DC motor; 24 VDC; 250 W; 2 pcs	Brushless DC motor; 24 VDC; 180 W; 2 pcs	minor difference on motor power will not cause different performance. larger power will provide more driving force, no safety and effectiveness concerns raised.
Electronic controller	brushless power wheelchair controller	Brushless dual-drive rocker controller	Both of the control systems are evaluated according to standard ISO 7176-14 and software validation requirement and there are no new safety and effectiveness concerns due to the difference.
Turning	1000 mm (39.3")	31.5" (800 mm)	The minor difference

Attribute	Subject device	Predicate device	Discussion/Conclusion
Radius			in the turning radius will not raise any new safety and effectiveness concerns.
Maximum obstacle climbing	25 mm	1.2" (30 mm)	Minor difference in the obstacle climbing will not impact the safety and effectiveness of the subject device.
seat cushion	Polyethylene terephthalate	PU foam covered by nylon fabric cloth	different material used for parts in contact with user, which such differences will not impact the safety and effectiveness of the subject device as biocompatibility meet the requirements of ISO 10993 series.
back cushion	Polyethylene terephthalate + Polyamides	PU foam covered by nylon fabric cloth	

Safety comparison

Attribute	Subject device	Predicate device	Discussion/Conclusion
Biocompatibility	All user directly contacting materials are compliance with ISO 10993-1	All user directly contacting materials are compliance with ISO 10993-1	Same
EMC	ISO 7176-21 & IEC60601-1-2	ISO 7176-21 & IEC60601-1-2	Same
Performance	ISO 7176 series ISO 16840-10	ISO 7176 series ISO 16840-10	Same
Labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	Same

VII. Summary of substantial equivalence discussion

The power wheelchair complied with the requirements of ISO 7176-1:2014, ISO 7176-2:2017, ISO 7176-3:2012, ISO 7176-4:2008, ISO 7176-5:2008, ISO 7176-6:2018, ISO 7176-7:1998, ISO 7176-8:2014, ISO 7176-9:2009, ISO 7176-10:2008, ISO 7176-11:2008, ISO 7176-13:1989, ISO 7176-14:2022, ISO 7176-15:1996, ISO 16840-10:2021, ISO 7176-21:2009, ISO 7176-22:2014, IEC 60601-1-2: 2020 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, The Dynamic stability, 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 biocompatibility of the Predicate device and Subject device meet the requirements of the ISO 10993 requirements.

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.

VIII. Summary of non-clinical testing

➤ Performance testing-bench

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 - Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2020.

➤ **Biocompatibility of patient-contacting material**

The biocompatibility of the subject device was determined due to the low-biocompatibility-risk materials policy in Attachment G of FDA's 2023 Guidance on "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" was invoked for eligible tissue-contacting materials.

IX. 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.

X. Conclusions

The conclusion drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device K113463.