June 3, 2026

Jiangsu Yveelt Medical Equipment Co., Ltd.
% Ivy Wang
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Bldg., 1500# Century Ave.
Shanghai, 200122
China

Re: K260373
Trade/Device Name: Electric Wheelchair (DF506)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: February 5, 2026
Received: February 5, 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.

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

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5A: 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260373

Please provide the device trade name(s).

Electric Wheelchair (DF506)

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)

510(k) Summary - K260373

I. SUBMITTER

Name: Jiangsu Yveelt Medical Equipment Co., Ltd.

Address: No. 1, Building 11, No. 230, Yunnan West Road, Xinbei District, Changzhou City, Jiangsu, 213131, China

Name of contact person: Zhang Peng

Tel: +86 15951227036

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Date prepared: 2026-02-04

II. Device

Device trade name: Electric Wheelchair

Model: DF506

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 DF506 electric wheelchair is a four wheeled personal mobile device with a complementary chair support system that is powered by two motors. The traveling speed is controlled by the motor, and the traveling direction is controlled by the passenger. 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 mainly consists: a frame (a front wheel bracket, a motor frame, a seat frame, a backrest frame), armrests, a controller, a seat cushion, a back cushion, footrest, 4 wheels, 2 rear wheel motors, 2 anti-tilt wheels, a safety belt and 1 lithium battery. The device is installed with an electromagnetic brake that will engage automatically when the wheelchair is not in use and the brake cannot be used 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	Jiangsu Yveelt Medical Equipment Co., Ltd.	SUZHOU KD Medical Appliance Co. Ltd.	/
Proprietary name, model	Electric Wheelchair DF506	Power wheelchair, PL00l	/
510(k) number	TBD	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
Type of use	OTC	OTC	Same
Number of wheels	4, including two front wheels and two rear wheels	4, including two pivoting casters and two rear drive wheels	Same

Attribute	Subject device	Predicate device	Discussion/Conclusion
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
Armrest cushion	Polyurethane (PU)	Polyurethane (PU)	Same
seat cushion/ back cushion	Nylon cloth covered PU foam	PU foam covered by nylon fabric cloth	Same
Main frame material	aluminum alloy	aluminum alloy	Same
Differences			
Overall dimensions (L*W*H)	1020*620*780mm	880*570*890 mm	Minor difference on dimension do not affect safety and effectiveness. All safety and performance have been validated with the maximum rated weight dummy.
Folded dimensions (L*W*H)	370*620*780mm	720*570*400 mm	
Ground clearance	94mm	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" / pneumatic tire	8" /PU Solid tire	better stability and safety performance. All safety and performance have been validated with the maximum rated weight dummy.
Max loading weight	100kg (220 lbs)	114kg (251 lbs)	minor difference on loading weight will not cause different performance.
Maximum distance of travel on the fully charged battery	15.4 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 6.12 km/h (3.8mph), 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	Less than 3 km/h (0.8 m/s)	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: 0.7m	Forward:1.5m	Our device has shorter braking distance than the predicate device, such differences will not affect safety and performance of the device.
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

Attribute	Subject device	Predicate device	Discussion/Conclusion
			stability under specific inclining degree have been evaluated according to standard ISO 7176 series.
Motor	Brush motor; 24VDC; 250W; 2pcs	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. In addition, although brush motor and brushless motor has some difference, while all safety and performance tests are performed, it will not affect the difference on clinical use.
Electronic controller	Brush power wheelchair controller	Brushless dual-drive rocker controller	Although different controller is used, both the control system, including the joystick controller, the electromagnetic brakes and the user interface are similar. The joystick controls the directions and speed of movement, and when the joystick is released, the powered wheelchair will slow down to stop and the brakes will automatically re-engage. The controller also provides the battery

Attribute	Subject device	Predicate device	Discussion/Conclusion
			status displaying and abnormal condition displaying. 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.
Battery	lithium battery; rechargeable, 24 VDC 12Ah	Li-ion, Rechargeable; 24 VDC 20Ah	Same rated voltage with different power capacity will not affect the safety and performance of the subject device.
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.
Turning Radius	900mm	800 mm	The minor difference in the turning radius will not raise any new safety and effectiveness concerns.
Maximum obstacle climbing	25 mm	30 mm	Minor difference in the obstacle climbing will not impact the safety and effectiveness of the subject device.
Safety comparison			
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

Attribute	Subject device	Predicate device	Discussion/Conclusion
Performance	ISO 7176 series	ISO 7176 series	Same
Labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	Same

VII. Summary of substantial equivalence discussion

The proposed device and predicate device are complying to the same ISO standards, 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, ISO 7176-25:2013, 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

- ISO 7176-22: 2014 Wheelchairs - Part 22: Set-up procedures
- ISO 7176-25:2013 Wheelchairs – Part 25: Batteries and chargers for powered wheelchairs
- 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.