May 13, 2026

Jiangsu Intco Medical Products Co.,Ltd.
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd., Pudong
Shanghai, 200120
China

Re: K253241
Trade/Device Name: Electric Wheelchair (Y207BL)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: April 15, 2026
Received: April 15, 2026

Dear Boyle 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,

Digitally signed by
ZACHARY MCKINNEY -S
Date: 2026.05.13
12:21:55 -04'00'

for 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)*
K253241

Device Name
Electric Wheelchair (Y207BL)

Indications for Use *(Describe)*
The Y207BL 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. This product is suitable for disabled people with mobility difficulties and elderly people.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K253241

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's information

Name: Jiangsu Intco Medical Products Co.,Ltd.
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Contact: Terry Gu

Designated Submission Correspondent

Mr. Boyle Wang
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Email: Info@truthful.com.cn

Date of Preparation: Apr.14, 2026

2.0 Device information

Trade name:	Electric Wheelchair
Common name:	Electric Wheelchair
Classification name:	Powered Wheelchair
Model(s):	Y207BL

3.0 Classification

Production code:	ITI
Regulation number:	21 CFR 890.3860
Classification:	Class II
Panel:	Physical Medicine

4.0 Predicate device information

510(k) Number:	K202482
Product Name:	Electric Wheelchair, Y207
Manufacturer:	Jiangsu Intco Medical Products Co.,Ltd.

5.0 Indication for Use Statement

The Y207BL 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. This product is suitable for disabled people with mobility difficulties and elderly people.

6.0 Device description

The Y207BL 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. This product is suitable for disabled people with mobility difficulties and elderly people.
The device consists of two parts: the electrical part and the wheelchair main body. The electrical part includes brushless motor, battery box, brushless split-type controller and charger. The main parts of the wheelchair include front wheels, rear wheels, frame, foldable armrest, seat and back upholstery.
The device is powered by Li-ion Battery pack (24V 12Ah, 288Wh) with 15.1 Km (9.3 miles) range, which can be recharged by an off-board battery charger that can be plugged into an AC socket outlet (100-240V, 50/60Hz) when the device is not in use.

7.0 Summary of Non-Clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 7176-1:2014 Wheelchairs - Part 1: Determination of static stability
ISO 7176-2:2017 Wheelchairs - Part 2: Determination of dynamic stability of electrically powered 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 overall dimensions, mass and manoeuvring 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 strengths
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 7176-14:2008 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 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 7176-31:2023 Wheelchairs - Part 31: Lithium-ion battery systems and chargers for powered wheelchairs — Requirements and test methods
ISO 16840-10:2021 Wheelchair seating - Part 10: Resistance to ignition of postural support devices - Requirements and test method
IEC 60601-1-2:2020 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC TS 60601-4-2:2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Software Verification and Validation Testing

Software documentation including verification & validation was provided in accordance with FDA Guidance: Content of Premarket Submissions for Device Software Functions for software.
The Software Validation is in compliance with FDA Guidance.

8.0 Summary of Clinical Testing

No clinical study implemented for the electric wheelchair.

9.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Proposed device	Predicate device	Remark
Manufacturer	Jiangsu Intco Medical Products Co.,Ltd.	Jiangsu Intco Medical Products Co.,Ltd.	Same
Product name	Electric Wheelchair, Y207BL	Electric Wheelchair, Y207	/
510(k) No.	K253241	K202482	/
Class	Class II	Class II	Same
Regulation No.	21 CFR 890.3860	21 CFR 890.3860	Same
Product code	ITI	ITI	Same
Indication for use	The Y207BL 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. This product is suitable for disabled people with mobility difficulties and elderly people.	The Y207 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. This product is suitable for disabled people with mobility difficulties and elderly people.	Same
Intended user	This product is suitable for disabled people with mobility difficulties and elderly people.	This product is suitable for disabled people with mobility difficulties and elderly people.	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
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
Main frame material	Aluminum alloy	Aluminum alloy	Same
Motor	Brushless motor, DC24V* 200W*2pcs	Brushless motor; DC24V* 200W*2pcs	Same
Battery	li-ion battery pack; rechargeable, 24 VDC 12Ah	li-ion battery pack; rechargeable, 24 VDC 20Ah	Similar. Similar in type. The difference in capacity will affect the endurance time only, which will not cause new safety and effectiveness concerns raised.
Battery charger	Off-board charger Input: 100-240V~50/60Hz 1.5A Output: 29.4V 2000mA	Off-board charger Input: 100-240V, 50/60Hz, 2.5A, Output: 24 Vdc, 6A	Similar. Output current difference will impact charging time only, which will not cause new safety and effectiveness concerns raised.
Electronic controller	Brushless split - type controller	newVSi ELECTRIC WHEELCHAIR CONTROL SYSTEM, 50A, Manufactured by PG DRIVES TECHNOLOGY LTD.	Different. 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 status displaying and abnormal condition displaying. Both of the control systems are evaluated according to standard ISO 7176-14:2022 and software validation requirement and there are no new safety and effectiveness concerns due to the difference.

Table2 Performance Comparison

Item	Subject Device	Predicate Device	Remark
Manufacturer	Jiangsu Intco Medical Products Co.,Ltd.	Jiangsu Intco Medical Products Co.,Ltd.	Same
Model	Y207BL	Y207	/
Overall length	1030mm	1110 mm	Minor differences in the dimensions will not impact the safety and effectiveness of the substantial equivalence.
Overall width	640mm	700 mm	
Folded length	640mm	810mm	
Folded width	490mm	700mm	
Folded height	790mm	400mm	
Total mass	27kg	Not publicly available	-
Front wheel	8 inch (PU solid tire)	8 inch (PU solid tire)	Same
Rear tire	12.5 inch (PU solid tire)	10 inch (pneumatic tires)	Larger sizes of rear wheels bring steadier

			pivoting function than predicate device.
Cruising Range	15.1km	20km	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.
Obstacle climbing	50mm	50mm	Same
Static stability forward	22.2°	Not publicly available	-
Static stability rearward	21°	Not publicly available	
Static stability sideways	21.1°	Not publicly available	
Max. loading	136kg	125kg	More loading weight means more convenient for the transportation
Min. Turning radium	1200mm	950mm	The devices are evaluated according to standard ISO 7176-5:2008, so the different will not impact the safety and effectiveness
Minimum braking distance	0.97m	1.0m	The devices are evaluated according to standard ISO

			7176-3:2012, so the different will not impact the safety and effectiveness
Max Speed Forwards	1.68m/s (6km/h)	1.5m/s (5.4km/h)	The devices are evaluated according to standard ISO 7176-6:2018, so the different will not impact the safety and effectiveness
Max. Speed Backward	0.43m/s (1.54km/h)	0.8m/s (2.88km/h)	The devices are evaluated according to standard ISO 7176-6:2018, so the different will not impact the safety and effectiveness

Table3 Safety Comparison

Item	Proposed Device	Predicate Device K202482	Remark
Materials contacting user	Armrest: PU; Footplates: PU Backrest/Seat: PVC Fabric Dashboard (Joystick/button): Silicone	Armrest: PU leather; Backrest/seat: sandwich mesh fabric (polyester) Normal Seat cushion/Back cushion: Oxford fabric Handle foam tube: EVA foaming (ethylene-vinyl acetate copolymer) newVSi electric wheelchair controller: Joystick knob: Santoprene 101-80; Joystick Gaiter: Silicone 3032 (50%) & 5031 (50%) Enclosure Moulding(s): ABS/PC Wonderloy PC-540 Keypad: Silicone keypad	Biocompatibility evaluation has been carried out per ISO 10993-1 and FDA guidance. There are no new safety and effectiveness concerns due to the difference.

		coatings TC-2407 & CH-6330	
Biocompatibility Of materials contacting user	Comply with ISO 10993-1, FDA Guidance, tests included: In Vitro Cytotoxicity Test (ISO 10993-5:2009) Skin Sensitization Test (ISO 10993-10:2021) Intracutaneous Reactivity Test (ISO 10993-23:2021)	Comply with ISO 10993-1, FDA Guidance, tests included: Cytotoxicity (ISO 10993-5:2009), Sensitization and Intracutaneous Reactivity (ISO 10993-10:2010)	Same

Summary of substantial equivalence discussion:

The subject Electric 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 7176-11:2012, 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 7176-31:2023, IEC 60601-1-2: 2020 and IEC TS 60601-4-2:2024

The intended uses for both devices are the same. Mainframes of two devices are folded by way of front and rear close, and frame materials all meet the Tensile Strength, Yield Load, and Elongation tests. The design principles of the controller and Driving system are the same, and both meet the requirements of the ISO 7176-14:2022. 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 7176-3:2012. Maximum obstacle climbing 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 7176-2:2017, ISO 7176-10:2008. The biocompatibility of the Predicate device and Subject device meet the requirements of the FDA guidance" Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"". Therefore, both devices are assured to be under the same safety level.

In conclusion, the technological characteristics, features, specifications, mode of operation, and intended use of the device substantially equivalent to that of the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

10.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicated device under K202482.