June 22, 2026

GuangDong Yong Yi Rehabilitation Equipment Technology Co., Ltd.
Sally Peng
Primary Correspondent
#39, Baozhu E. Rd., Huangpu Town
Zhongshan, Guangdong 528400
China

Re: K261076
Trade/Device Name: Caregiver-assisted wheelchair (MS02);Caregiver-assisted wheelchair (MA02)
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: March 31, 2026
Received: April 1, 2026

Dear Sally Peng:

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 MARY S. KESZLER -S
Date: 2026.06.22 15:01:22 -04'00'

for Tushar Bansal, PhD
Acting Assistant Director
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261076

Please provide the device trade name(s).

Caregiver-assisted wheelchair (MS02);
Caregiver-assisted wheelchair (MA02)

Please provide your Indications for Use below.

Caregiver-assisted wheelchair (model:MS02,MA02) Caregiver-assisted wheelchair is intended for medical purpose to provide mobility to persons limited to a sitting 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 - K261076

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: March 20,2026

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	GuangDong Yong Yi Rehabilitation Equipment Technology Co., Ltd.
Address:	No.39, Baozhu East Road, Huangpu Town, Zhongshan City, Guangdong, China.
Contact person:	Sally Peng
Title:	Manager
E-mail:	sally@yongyicn.com
Tel:	0086-760-23235999

2. Device Identification

510(K) number:	
Trade/Device Name:	Caregiver-assisted wheelchair
Models:	MS02,MA02
Common name:	Manual Wheelchair
Regulation Number:	21CFR 890.3850
Regulation Name:	Mechanical wheelchair
Regulation Class:	Class 1
Panel:	Physical Medicine
Product Code:	IOR

3. Predicate Device

510(K) number:	K231750
Trade/Device Name:	MA012 Aluminum wheelchair, MS019 Steel wheelchair
Models:	MA012,MS019
Common name:	Manual Wheelchair
Regulation Number:	21CFR 890.3850
Regulation Name:	Mechanical wheelchair
Regulation Class:	Class 1
Panel:	Physical Medicine
Product Code:	IOR

4. Indication for Use

Caregiver-assisted wheelchair (model:MS02,MA02) Caregiver-assisted wheelchair is intended for medical purpose to provide mobility to persons limited to a sitting position.

5. Device Description

Caregiver-assisted wheelchair (model:MS02,MA02) are intended for medical purpose to provide mobility to persons limited to a sitting position.The Caregiver-assisted wheelchair (model:MS02,MA02) is controlled, steered and operated completely by a trained caregiver.

This caregiver-assisted wheelchair (model: MS02,MA02) is contraindicated for overloading beyond the specified maximum occupant mass of 100 kg; the wheelchair is strictly prohibited from being used as a seat in a motor vehicle.It is forbidden to use the wheelchair on gradients exceeding 10°, reverse down a gradient, or on escalators, and the wheelchair is only suitable for single occupancy with no multi-person use allowed. Standing on the footrests and overloading the footrests are prohibited; leaning or pushing down on the push handles is not permitted to avoid structural damage to the wheelchair. The wheelchair is not designed for ascending or descending staircases, and if no elevators or ramps are available, manual carrying is required with the strict prohibition of carrying the wheelchair by its push handles or any removable parts. The storage bag on the back upholstery shall not hold items exceeding 5kg to prevent the wheelchair from tipping backwards. During use and assembly, fingers and foreign objects are forbidden to be caught in wheel spokes and other moving parts; users shall not move their center of gravity out of the seating area or reach for items beyond arm's length. The wheelchair is prohibited from being used when damaged or severely worn, and long-term storage near high-temperature sources, in direct sunlight, in non-ventilated environments with corrosive harmful gases, as well as stacking and pressing the wheelchair during storage are all forbidden.

The wheelchair is designed with two 12” rear wheels, and can be moved forward and in reverse.

Wheelchair frames are made of either steel or aluminum.Frame serves as the primary structural chassis of the device, providing the foundational support, mechanical integrity, and overall dimensional form to the wheelchair assembly. It dictates the essential geometry and foldability of the device.

The back upholstery consists of a backrest made of fireproof nylon fabric and foam. Its function is to provide postural support to the user's back and pelvis, distribute pressure.

The seat upholstery consists of a cushion made of fireproof nylon fabric and foam.It is to provide seating interface for the user, contributing to pressure distribution and postural stability.

Armrest is a horizontally oriented support pad mounted laterally to the frame. It functions to support the user's forearm and elbow, aid in upper body stability and posture.

Footrests and foot plate are adjustable, cantilevered support structure extending from the lower front frame. The function is to provide a stable, ergonomic platform.

Brake is to securely immobilize the wheelchair by preventing rotation of the rear wheel, thereby stabilizing the device during stationary periods such as user transfers from wheelchair.

Castors are 8 inches in size, swiveling wheel assembly mounted at the front of the frame.The functions are to provide directional stability during straight-line travel, facilitate tight-radius turns by pivoting.

The wheelchair can support users of up to100 kg.

6. Compared to Predicate Device

Compared to the predicate devices, the subject device has the same intended use, similar product design, similar performance, same safety as the predicate device, the summarized comparison information is listed in the following table

SE Comparisons	**Subject Device** Manual Wheelchair (Model: MS02,MA02)	**Predicate Device** MA012 Aluminum wheelchair, MS019 Steel wheelchair (Model: MA012,MS019:)	**Similarities/ Differences**
510(K) number	/	K231750	/
Indication for Use	MS02/MA02 Caregiver-assisted wheelchair is intended for medical purpose to provide mobility to persons limited to a sitting position.	MA012 Aluminum wheelchair and MS019 steel wheelchair are intended for medical purpose to provide mobility to persons limited to a sitting position.	Same
Product code	IOR	IOR	Same
Class	I	I	Same
Regulation Number	21 CFR 890. 3850	21 CFR 890.3850	Same
Common name	Mechanical Wheelchair	Mechanical Wheelchair	Same
Type of Use	Over the Counter (OTC Only)	Over the Counter (OTC Only)	Same
Device Length	916mm	MA012: 950mm MS019: 916mm	Different See Note 1
Device Width	574mm	MA012:610mm MS019:574mm	Different See Note 1
Device Height	896mm	MA012:970mm MS019:896mm	Different See Note 1
Total weight	MS02: 18.9kg/42 lbs MA02: 14kg/ 31lbs	MA012: 11.5kg/25 lbs MS019: 18.7kg/ 41 lbs	Different See Note 1
Weight Capacity	100kg/220lbs	115 kg/250lbs	Different See Note 1
Seat depth	420 mm	MA012: 390mm MS019: 420mm	Different See Note 2
Seat width	450 mm	MA012: 420mm MS019: 450mm	Different See Note 2

Seat surface height at front edge	596mm	MA012: 520mm MS019: 596mm	Different See Note 2
Frame type	Foldable	Foldable	Same
Frame material	Model MA02: Aluminum Model MS02: Steel	Model MA012: Aluminum Model MS019: Steel	Same
Armrest	Flip back armrest	Flip back armrest	Same
Footrest	Optional/ swing away	Optional/ swing away	Same
Tires	Front: 200mm (8”) Rear: 300mm (12”)	Front: 200mm (8”) Rear: 315mm (12.5”)	Different See Note 2
Non clinical testing			
Performance	wheelchair conforms to the ISO 7176 standards	wheelchair conforms to the ISO 7176 standards	Same
Flammability Testing	wheelchair conforms to the ISO 16840-10 standards	wheelchair conforms to the ISO 7176-16 standards	Different See Note 3
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5:2009, ISO10993-10:2021, ISO 10993-23:2021 requirements.	All user directly contacting materials are compliance with ISO10993-5, ISO10993-10, ISO 10993-23 requirements.	Different See Note 4

Substantial equivalence Analysis:

Note 1: The predicate device and subject device have different dimension. Both of them comply with ISO 7176-5:2008 Wheelchairs – Part 5: Determination of dimensions, mass, and maneuverings space, these differences do not affect safety and effectiveness.

Note 2: Both of the subject device and the predicate device comply with ISO 7176-7:1998 Wheelchairs - Part 7: Measurement of seating and wheel dimensions, these differences do not affect safety and effectiveness.

Note 3: The FDA no longer recognizes ISO 7176-16; its recognition has been superseded by ISO 16840-10, and the relevant transition period has long since ended. Both the subject device and the predicate device passed the FDA-approved ignition resistance test at that time.

Note 4: Both of the subject device and the predicate device evaluated biocompatibility according to ISO 10993 series standards. Although standard version updated, test methods for the subject device and the predicate device are same.

The subject device and predicate device are substantially equivalent in the areas of technological characteristics such as basic design, features, method of operation, general function and intended use. The subject device device does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices.

7. Performance Testing Summary

The subject device Caregiver-assisted wheelchair(Model:MS02,MA02) comply with:

Clinical test:

Clinical testing is not required.

Non-clinical data

Safety and performance

Safety and performance

ISO 7176-1:2014 Wheelchairs - Part 1: Determination of static stability
ISO 7176-3:2012 Wheelchairs - Part 3: Determination of effectiveness of brakes
ISO 7176-5:2008 Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space
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 7176-11:2012 Wheelchairs - Part 11: Test dummies
ISO 7176-13:1989 Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces
ISO 7176-15:1996 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
ISO 16840-10:2021+A1:2024 Wheelchair seating - Part 10: Resistance
to ignition of postural support devices - Requirements and test method, heat source: heating cartridge.

Biocompatibility

ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
ISO 10993-10:2021 Biological Evaluation of Medical Devices - Part 10: Tests for Skin Sensitization
ISO 10993-23:2021 Biological Evaluation of Medical Devices - Part 23: Tests for Irritation

8. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device Caregiver-assisted wheelchair(Model:MS02,MA02) is as safe, as effective, and performs as well the legally marketed predicate device K231750.