



November 22, 2024

Sichuan AST Medical Equipment Co., Ltd
Ivy Wang
Technical Manager
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Building, 1500# Century Ave
Shanghai, Shanghai 200122
China

Re: K242722
Trade/Device Name: Manual Wheelchair (MASY23)
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: November 15, 2024
Received: November 15, 2024

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 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,

Heather L. Dean -S

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

Enclosure

Indications for Use

Submission Number (if known)

K242722

Device Name

Manual Wheelchair (MASY23)

Indications for Use (Describe)

The Manual Wheelchair is to provide mobility to persons limited to a sitting 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) #:

510(k) Summary

Prepared on: 2024-09-09

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

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Correspondent Contact Telephone	+86-58817802
Correspondent Contact	Ms. Ivy Wang
Correspondent Contact Email	haiyu.wang@sungoglobal.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Manual Wheelchair (MASY23)
Common Name	Mechanical wheelchair
Classification Name	Wheelchair, Mechanical
Regulation Number	890.3850
Product Code(s)	IOR

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K231750	MS019 Steel wheelchair	IOR

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The MASY23 manual wheelchair is a mechanical wheelchair which is a manually operated, attendant and self-propelled transport device in a health care environment such as a hospital, nursing home or extended care facility. It is intended for medical purpose to provide mobility to persons limited to a sitting position. It can be folded for transport by bring two sides together.

The MASY23 Manual Wheelchair incorporates a main frame, a seat, two adjustable footrests, two hand rims and four wheels. The wheelchair is designed with two small rear wheels and two gearing with hand rim, it can be manually moved forward and in reverse. The wheelchair can support users of up to 136 kg.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The Manual Wheelchair is to provide mobility to persons limited to a sitting position.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The proposed device has same indications for use to the predicate device.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The design and technological characteristics of the subject device is basically similar to the predicate device chosen. The difference between the predicate and subject device is the subject device add a handrim to the frame to make the occupant driving the wheelchair by himself/herself. This is similar to the traditional manual wheelchair which will not raise safety or effectiveness of the subject device. These minor differences with the predicate device don't affect the safety or effectiveness of the subject device. Moreover, the non-clinical tests and the predicate comparisons demonstrate that these differences in their technological characteristics do not raise any questions as to the safety and effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Non-clinical tests were conducted to verify that the subject device met all design specifications and provided support of the substantial equivalence determination. 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 7176-3:2012 Wheelchairs - Part 3: Determination of effectiveness of brakes
- ISO 7176-5:2008 Wheelchairs - Part 5: Determination of dimensions, mass and maneuvering 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 strength
- 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 Wheelchair seating - Part 10: Resistance to ignition of postural support devices - Requirements and test method.

Bio-Compatibility tests were conducted to verify that the subject device met the safety requirements, and the following standards were complied:

- 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

The clinical data is not applicable.

The conclusions 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 K231750.