August 15, 2023

Sichuan AST Medical Equipment Co., Ltd.
℅ Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K231750
Trade/Device Name: MA012 Aluminum wheelchair, MS019 steel wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: June 15, 2023
Received: June 15, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231750

Device Name
MA012 Aluminum wheelchair, MS019 steel wheelchair

Indications for Use *(Describe)*
MA012 Aluminum wheelchair and MS019 steel wheelchair are intended for medical purpose 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) Summary

K231750

I. Applicant

Name: Sichuan AST Medical Equipment Co., Ltd.

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Date prepared: 2023-08-11

II. Submission Correspondent

Ms. Ivy Wang

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III. Device

Device trade name: MA012 Aluminum wheelchair, MS019 Steel wheelchair

Common name: Manual Wheelchair

Regulatory Information:

Classification name: Mechanical Wheelchair

Regulation class: 1

Regulation number: 21CFR 890.3850

Panel: Physical Medicine

Product code: IOR

IV. Predicate device

Primary - K181795

AST Model MA012 and MS019 Rehab Wheelchair

Sichuan AST Medical Equipment Co., Ltd

V. Device description

MA012 Aluminum wheelchair and MS019 Steel wheelchair are mechanical wheelchairs which is a manually operated, attendant 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. The wheelchair is controlled, steered and operated completely by a trained caregiver.

The wheelchair incorporates a main frame, a seat, two adjustable footrests and four wheels. There are two models of the wheelchair, MA012 and MS019. The MA012 Aluminum wheelchair has an aluminum frame, fixed armrest and a foldable back, while the MS019 Steel wheelchair has a steel frame, fixed back and a detachable, flip-back armrest. The wheelchair can support users of up to115 kg.

VI. Indication for use

MA012 Aluminum wheelchair and MS019 steel wheelchair are intended for medical purpose to provide mobility to persons limited to a sitting position.

VII. Non-Clinical Test Conclusion

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 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- 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 7176-16: 2012 Second edition 2012-12-01 Wheelchairs - Part 16: Resistance to ignition of postural support devices

VIII. Comparison with the predicate device

Table 1 General Comparison

Attribute	Subject device	Predicate device	Results
Manufacturer	Sichuan AST Medical Equipment Co., Ltd.	Sichuan AST Medical Equipment Co., Ltd.	/
Proprietary name, model	MA012 Aluminum wheelchair, MS019 Steel wheelchair	AST Model MA012 and MS019 Rehab Wheelchair	/
510(k) number	K231750	K181795	/
Device classification name	Class I	Class I	Same
Classification regulations	21 CFR 890. 3850	21 CFR 890. 3850	Same
Product code	IOR	IOR	Same
Indication for use	MA012 Aluminum wheelchair and MS019 steel wheelchair are intended for medical purpose to provide mobility to persons limited to a sitting position.	The AST Model MA012 and MS019 Rehab Wheelchairs are to provide mobility to persons limited to a sitting position.	Same
Dimension (Length x Width x Height)	Model MA012: 950x610x970mm Model MS019: 916x574x896mm	Model MA012: 1173x645x892mm (±1mm) Model MS019: 1196x775x894mm (±1mm)	Similar The two physical dimensions are different. The difference does

Attribute	Subject device	Predicate device	Results
			not affect effectiveness and safety.
Total weight	Model MA012: 11.5kg/25 lbs Model MS019: 18.7kg/ 41 lbs	Model MA012: 17.2kg/38 lbs Model MS019: 20kg/ 46 lbs	Similar Different weight of the device do not raise the safety and effectiveness of the device.
Weight Capacity	115 kg/250lbs	Model MS019: 200 kg/450 lbs, Model MA012: 136kg/ 300 lbs	Similar Difference on loading weight will not cause different performance. Lower weight provide less pressure to the chair and easy for the transportation.
Seat depth	Model MA012: 390mm Model MS019: 420mm	Model MA012: 16”-20” (406mm-508mm) Model MS019: 18”-20” (457mm-508mm)	Similar Different seat size do not raise the safety and effectiveness of the device.
Seat width	Model MA012: 420mm Model MS019: 450mm	Model MA012: 16” (406mm); 18” (457mm); 20” (508mm) Model MS019: 18” (457mm); 20” (508mm); 22” (558mm); 24” (609mm)	
Seat height	Model MA012: 520mm Model MS019: 596mm	Model MA012: 19.7” (500mm) Model MS019: 19.8” (503mm)	
Frame type	Foldable	Foldable	Same
Frame material	Model MA012: Aluminum Model MS019: Steel	Model MA012: Aluminum Model MS019: Steel	Same
Back style	Model MS019: Fixed Model MA012: foldable	Model MS019: Fixed Model MA012: Adjustable	Similar The slight difference on back style do not raise the safety and effectiveness of the device.
Armrest	Flip back armrest	Model MA012: Height Adjustable desk length armrest, Flip back	Similar The height of

Attribute	Subject device	Predicate device	Results
		Model MS019: Fixed or adjustable height; desk or full length; removable	armrest of proposed device can not be adjustable.
Footrest	Optional/ swing away	Optional/ swing away	Same
Rear Axle Position	Single	Multiple	Similar The rear axle of proposed device has only one size.
Tires	Front: 200mm (8") Rear: 315mm (12.5")	Front: 6",7",8" Rear: 20",22",24"	Similar Minor difference on dimension of driven wheel will not cause different performance.

Substantial equivalence Analysis:

The design and technological characteristics of the subject device is basically similar to the predicate device chosen. There are some 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.

Table 2 Safety comparison

Attribute	Subject device	Predicate device	Results
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5, ISO10993-10, ISO 10993-23 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	S.E.
Performance	ISO7176 series	ISO7176 series	S.E.
Label and labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	S.E.

Table 3 Safety comparison

Attribute	Subject device	Predicate device	Results
ISO7176-1	The Static stability has been determined after the testing according to the ISO 7176-1, and test results meet its design specification.	The Static stability has been determined after the testing according to the ISO 7176-1, and test results meet its design specification.	S.E.

Attribute	Subject device	Predicate device	Results
ISO7176-3	The effectiveness of brakes has been determined after the testing according to the ISO 7176-3, and test results meet its design specification.	The effectiveness of brakes has been determined after the testing according to the ISO 7176-3, and test results meet its design specification.	S.E.
ISO7176-5	The dimensions, mass has been determined after the testing according to the ISO 7176-5.	The dimensions, mass has been determined after the testing according to the ISO 7176-5.	S.E.
ISO7176-7	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7	S.E.
ISO7176-8	All test results meet the requirements in Clause 4 of ISO 7176-8	All test results meet the requirements in Clause 4 of ISO 7176-8	S.E.
ISO7176-11	The test dummies used in the testing of ISO 7176 series are meet the requirements of ISO 7176-11.	The test dummies used in the testing of ISO 7176 series are meet the requirements of ISO 7176-11.	S.E.
ISO7176-13	The coefficient of friction of test surfaces has been determined, which could be used in other 7176 series tests involved	The coefficient of friction of test surfaces has been determined, which could be used in other 7176 series tests involved	S.E.
ISO7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	S.E.
ISO 7176-16	The performance of resistance to ignition meets the requirements of ISO 7176-16.	The performance of resistance to ignition meets the requirements of ISO 7176-16.	S.E.

IX. Summary of clinical testing

No clinical study is included in this submission.

X. Conclusions

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well the legally marketed predicate device K181795.