September 25, 2018

Sichuan AST Medical Equipment Co., Ltd.
Johnson Van
Technical Sales Associate
No.58, Jin-Peng Road, C Area, Luxian Industrial Park
Luzhou City, Sichuan 646100 China

Re: K181795
Trade/Device Name: AST Model MA012 and MS019 Rehab Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: July 3, 2018
Received: July 5, 2018

Dear Johnson Van:

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 and Part 809); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for Carlos Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181795

Device Name
AST Model MA012 and MS019 Rehab Wheelchair

Indications for Use *(Describe)*
The AST Model MA012 and MS019 Rehab Wheelchairs are 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.

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

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510(k) SUMMARY

Sichuan AST medical Equipment Co., Ltd.
510(k) Premarket Notification

Submitter:

Sichuan AST Medical Equipment Co., Ltd.

No.58, Jin-Peng Road, C Area, Luxian Industrial Park, Luzhou City, Sichuan, China, 646100

Contact Person:

Johnson Van

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Date Prepared:

June 2nd, 2018

Proprietary Name:

AST Model MA012 and MS019 Rehab Wheelchair

Common name:

Manual Wheelchair

Classification name:

Mechanical Wheelchair, Class 1

Product Code:

IOR

Regulation Number:

21 CFR 890.3850

Indications for Use

The AST Model MA012 and MS019 Rehab Wheelchairs are to provide mobility to persons limited to a sitting position.

The Predicate Device:

This submission indicates the Substantial Equivalence of the AST Model MA012 and MS019 Rehab Wheelchair, with the predicate Invacare Tracer SX5 Manual Wheelchair (Heavy Duty 450lbs) mechanical wheelchair (K162621). MA012 and MS019 have the same intended uses and similar indications, technological characteristics and principles of operation with predicate device.

Device Description

The AST Model MA012 and MS019 Rehab Wheelchair are manual wheelchairs. They have adjustable armrests, and multiple axle position. The casters are 6”/7”/8" PU wheels with height adjustable forks and the rear wheels are 20”/22”/24"*1-3/8" polyurethane(MA012 and MS019). The wheelchair also has a shear reduction system: by carefully aligning the pivot points of the user, to minimize the sliding down of the user and also minimize the
shear force and pressure against the back. The armrest height can be adjusted from 8" to 12" and it is detachable.
The wheel for MA012 is quick release rear wheel. The AST MS019 Rehab Wheelchair has NO quick release rear wheel;
The upholstery of the device complies with ISO 7176-16:2012 Resistance to ignition of postural support devices.
The device can be operated indoors, or outdoors on dry, level surfaces composed of concrete, blacktop, or asphalt under normal driving conditions.

Discussions of Non-clinical Tests Performed for Determinations of Substantial equivalence are as follows:

ISO 7176-1:2014	Determination of Static Stability
ISO 7176-3:2012	Determination of effectiveness of brakes
ISO 7176-5:2008	Determination of overall dimensions, mass and maneuvering space
ISO 7176-7:1998	Method of Measurement of Seating and Wheel Dimensions
ISO 7176-8:2014	Requirements and test methods for static, impact and fatigue strengths
ISO 7176-11:2012	Test dummies
ISO 7176-13:1989	Determination of coefficient of friction of test surfaces
ISO 7176-15:1996	Requirements for Information Disclosure, Documentation and Labeling
ISO 7176-16:2012	Resistance to ignition of postural support devices
ISO 14971:2007	Medical devices -- Application of risk management to medical devices
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

The results of the testing confirm that the device meets specifications and is substantially equivalent to the predicate device.

Comparison of the Technological Characteristics:

The AST Model MA012 and MS019 Rehab Wheelchair, is substantially equivalent to the Invacare Tracer SX5 Manual Wheelchair (Heavy Duty 350lbs) mechanical wheelchair (K162621). Both products are mechanical designed for use as personal manual mobility aids. Performance characteristics and drive mechanisms are similar and all have the same intended function and use which is to provide mobility to persons limited to a sitting position. Additional, they are all constructed from the same basic materials, have the same basic operational principles or operated by others. The comparison table is as follow:

Characteristics		**The AST Model MS019 Rehab Wheelchair(K181795)**	**The AST Model MA012 Rehab Wheelchair(K181795)**	**Invacare Tracer SX5 Manual Wheelchair mechanical wheelchair (K162621)**
Indications for Use		To provide mobility to persons limited to a sitting position.	To provide mobility to persons limited to a sitting position.	To provide mobility to persons limited to a sitting position.
Dimension	**Length**	1196mm(±1mm)	1173mm(±1mm)	828mm(±1mm)
	Width	775mm (±1mm)	645mm (±1mm)	762mm(±1mm)
	Height	894mm (±1mm)	892mm (±1mm)	889mm(±1mm)
Weight	**Total**	46 lbs	38 lbs	40 lbs
Weight Capacity		450 lbs	300 lbs	250/300 lbs
Seat width		18”/20”/22”/24”	16”/18”/20”	14”-22”
Seat height		19.8”	19.7”	17.5”-19.5”
Seat depth		18”-20”	16”-20”	18”-20”
Frame type		foldable	foldable	foldable
Cross-brace configuration		14 · , 16 · , 18 · , 20 · or 22 ·	14 · , 16 · , 18 · , 20 · or 22 ·	14 · , 16 · , 18 · , 20 · or 22 ·
Back Style		Fixed	Adjustable	Fixed
Anti-tippers		Optional	Optional	Optional
Wheel construction		Fixed	Quick release	Fixed
Tires		Front: 6”,7”,8” Rear: 20”,22”,24”	Front: 6”,7”,8” Rear: 20”,22”,24”	Front: 6”,7”,8” Rear: 20”,22”,24”
Armrest		Fixed or adjustable height; desk or full length; removable	Height Adjustable desk length armrest	Fixed or adjustable height; desk or full length; removable
Foot rest		Optional/ swing away	Optional/ swing away	Optional/ swing away
Rear Axle Position		Multiple	Multiple	Multiple
Frame Construction		Foldable frame	Foldable frame	Fixed Frame (Or foldable)
Frame Material		Steel	Auminum	Steel
Safety Feature		Manual Wheel Lock	Manual Wheel Lock	Manual Wheel Lock

The comparison of the technical details between MA012 and MS019 and its predicate device are summarized in the following:

a. Dimension: The dimensions of our device and the predicate are similar. And our device conforms to the specific ISO test and that the results are disclosed to the user appropriately, as documented in the ISO standards for disclosure. So there is no deleterious affection of safety and effectiveness about the differences from the dimensions with the predicate device.
b. Weight: Although the total weight bearing capacity of MA012 and MS019 is heavier than Invacare Tracer SX5 Manual Wheelchair (Heavy Duty 350lbs) mechanical wheelchair (K162621). The device conforms to the specific ISO test and that the results are disclosed to the user appropriately, as documented in the ISO standards for disclosure (Requirements and test methods for static, impact and fatigue strengths) test. So there is no deleterious affection of safety and effectiveness about the difference on weight bearing capacity with predicate device.
c. Both of our devices and the predicate are equipped with PU foam Seat/Backrest Pad, adjustable Headrest and Armrest. Our MA012 AND MS019 is supplied with a standard Elevating Legrest/Footrest, while the predicate device is provided it as an option. The Elevating Legrest/Footrest can provide better strain-relief for legs.
d. Multiple Rear Axle Position: Both our MA012 AND MS019 and the predicate device are provided with Multiple Rear Axle Positions to allow users to change its seat height to a best fitting position.
e. Frame Construction and material: Our MS019 and MA012 devices and the predicated device are the same foldable frames.
f. Safety Feature: Both of our devices and the predicated device are equipped with Manual Wheel Locks to prevent unexpected movement while parking.

The minor differences between MA012 and MS019 and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the MA012 and MS019 is substantially equivalent to the predicate device.

Conclusions

According to comparison table, the differences on weight capacity, adjustable back angle and dimensions do not deleteriously affect the safety and effectiveness of the device.

The non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do no raise any new questions of safety or effectiveness.

So based on the design, performance specifications and testing and intended use, The **AST** Model MA012 and MS019 Rehab Wheelchair, is substantially equivalent to the Invacare Tracer SX5 Manual Wheelchair (Heavy Duty 450lbs) mechanical wheelchair (K162621).