May 21, 2021

Ningbo Shenyu Medical Equipment Co., Ltd.
% Vivi Shi
Technical Manager
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1309, Dongfang Building, 1500# Central Ave.
Shanghai, Shanghai 200122
China

Re: K201461
Trade/Device Name: Manual Wheelchair, Model A011
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: March 1, 2021
Received: March 5, 2021

Dear Vivi Shi:

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,

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)*
K201461

Device Name
Manual Wheelchair, Model A011

Indications for Use *(Describe)*
The A011 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) Summary – K201461

I. Submitter

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II. Device

Name of Device: Manual Wheelchair
Common Name: Manual Wheelchair
Model(s): A011

Regulatory Information
Classification Name: Mechanical Wheelchair
Regulatory Class: I
Product code: IOR
Regulation Number: 890.3850
Review Panel: Physical Medicine

III. Predicate device:

Sichuan AST Medical Equipment Co., Ltd.
AST Model MA012 and MS019 Rehab Wheelchair
510Knumber: K181795

This predicate has not been subject to a design-related recall.

IV. Device Description

A mechanical wheelchair is a chair with wheels, designed to be a replacement for walking, where it is propelled by the seated occupant turning the rear wheels by hand. There are also handles behind the seat for someone else to do the pushing. Wheelchairs are used by people for whom walking is difficult or impossible due to illness, injury, or disability.

Manual Wheelchair A011 is a mechanical wheelchair including four wheels, a Aluminum alloy frame and a textilene upholstery that is flame resistant. A011 has a physical dimension of 1100mm × 660mm ×910mm (depth × width × height) with the seat itself has a dimension of 480mm × 430mm ×510mm (depth × width × height). The device has a weight capacity of 136 kilograms, and weighs about 16 kilograms. The color is yellow and black.

Main Components:

Main frame, back upholstery, seat upholstery, handgrip, arm pad, armrest, front wheel, rear wheel, handrim, anti-tipper, crossbrace, crossbar, side panel, Legrest strap, footplate, Seat belt, brake.

Main materials:

Frame, crossbrace, crossbar, armrest, brake: Aluminum, yellow/black coating
Handgrip, side panel, handrim, footplate: PVC
Seat and back upholstery: Cover is Nylon fabrics, inside with flame resistant foam
Armrest pad: flame retardant sponge &PU

The device can be operated indoors, or outdoors on dry, level surfaces composed of concrete, blacktop, or asphalt under normal driving conditions.

The specification table is as below:

Main dimensions and structural parameters			
Overall dimension	1100mm (L) X 660mm (W) X 910mm (H)		
Folded dimension	810mm (L) X 320mm (W) X 930mm (H)		
Seat width	475mm	Horizontal angle of seat	8°
Seat depth	420 mm	Backrest angle	14°
Seat height from floor	510mm	Angle of the legrest against the seat surface	65°
Distance between armrest and seat	180 mm	Distance from footrest to seat	410mm
Distance between armrests	500 mm	Front position of armrest structure	370mm
Backrest height	370 mm	Diameter of armrest circle on rear wheels	530mm
Footrest height from floor	145mm	Horizontal position of shaft	2.5mm
Weight of the heaviest part (net weight)	13.5 Kg		
Load capacity	136Kg (300LB)		
Specification of front wheels	ø200mm		
Specification of rear wheels	ø600 mm		
Main technical performance			
Wheel landing performance	All wheels except the lifting wheels must land smoothly		
Static stability	Vertical forward tilt ≥10°, vertical backward tilt ≥10°, and lateral tilt ≥15°		
Hill-holding performance	≥8°		
Sliding offset	≤350mm		
Minimum turning radius	≤850mm		
Minimum reversing width	≤1500mm		

V. Indications for use

The A011 Manual Wheelchair is to provide mobility to persons limited to a sitting position.

VI. Comparison of technological characteristics with the predicate device

Table 1 General Comparison

Device	Proposed Device	Predicate Device	Results
510K Number	**NA**	**K181795**	--
Manufacturer	Ningbo Shenyu Medical Equipment Co., Ltd.	Sichuan AST Medical Equipment Co., Ltd.	--
Proprietary Name	Manual Wheelchair	AST Model MA012 and MS019 Rehab Wheelchair	--
Model	A011	MA012 and MS019	--
Classification	I	I	Same
Indications for use	The A011 Manual wheelchair is 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
Basic Design	The Aluminum Manual Wheelchair is indoor/outdoor wheelchair that has a base with four-wheeled with a seat. The device can be disassembled for transport and it is foldable easily. The device uses a standard sling type back and seat. Aluminum frame with yellow/black coating and folding backrest Flip back armrest PU pad Detachable and elevating footrest Front caster PU tires and detachable rear wheel PU tires Nylon cushion cover of back upholstery and seat upholstery.	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). Aluminum frame with liquid coated and folding backrest Flip-up and detachable armrest PU pad Detachable footrest Front casters PU tires and quick release rear wheel PU tires Nylon cushion	Similar The structure and materials of main frame of the proposed device and predicate device are same, only individual materials are different, such as back upholstery and seat upholstery, etc. The differences do not raise safety and effectiveness of the proposed device.
Material	Frame, crossbrace, crossbar, armrest, brake: Aluminum, yellow/black coating Handgrip, side panel, handrim, footplate: PVC Seat and back upholstery: Cover is Nylon fabrics, inside with flame	AST Model MA012 Rehab Wheelchair: Aluminum frame with liquid coated and folding backrest Flip-up and detachable armrest PU pad Detachable footrest Front casters PU tires and quick release rear wheel	Similar The Main Structural materials and wheels materials are same. The differences

	resistant foam Armrest pad: flame retardant sponge &PU	PU tires Nylon cushion	do not raise safety and effectiveness of the proposed device.
Components	Main frame, back upholstery, seat upholstery, handgrip, arm pad, armrest, front wheel, rear wheel, handrim, anti-tipper, crossbrace, crossbar, side panel, Legrest strap, footplate, Seat belt, brake	AST Model MA012 Rehab Wheelchair: Main frame, handle sleeve, back upholstery, seat upholstery, armrest pad, armrest, side panel, front casters, rear wheel, legrest, footplate, brake, front fork, crossbrace.	Same Although the expressions are different, the main components are same.
Control Mode	Mechanical	Mechanical	SE
Size(unfold)	1100mm (L) *660mm (W) * 910mm (H)	1173mm(L)*645mm(W)*892mm(H)	Similar The two physical dimensions are different. The difference does not affect the effectiveness and safety
Weight(Total)	16kg(35.2lbs)	38lbs	Similar The proposed device is heavier than the predicate device.
Weight Capacity	136Kg(300lbs)	Model MA012: 300lbs/136kg	Same
Seat Width	480mm	Model MA012: 16”(406mm) 18”(457mm) 20”(508mm)	Similar Different seat sizes do not raies the safety and effectiveness of the device.
Seat height	540mm	Model MA012: 19.7”(500mm)	
Seat depth	420mm	Model MA012: 16”-20”(406mm-508mm)	
Frame Type	foldable	foldable	SE
Cross-brace configuration	18”	14”, 16”, 18”, 20” or 22”	SE
Back Stype	Fixed	Model MS019: Fixed Model MA012:	Same Back style of proposed

		Adjustable	device is same as predicate device model MS019.
Anti-tippers	Optional	Optional	Same
Wheel construction	Quick release	Model MA012: Quick release Model MS019: Fixed	Same Wheel construction of proposed device is same as predicate device model MA012.
Tires	Front: 200mm(8'') Rear:610mm(24'')	Front: 6",7",8" Rear: 20",22",24"	SE
Armrest	Flip back armrest	Model MA012: Height Adjustable desk length armrest, Flip back Model MS019: Fixed or adjustable height; desk or full length; removable	Similar The height of armrest of proposed device can not be adjustable.
Foot rest	Optional/ swing away Optional/ swing away	Optional/ swing away Optional/ swing away	SE
Rear Axle Position	Single	Multiple	Similar The rear axle of proposed device has only one size.
Frame Construction	Foldable frame	Foldable frame	SE
Frame Material	Aluminum	Model MA012: Aluminum Model MS019: Steel	SE The frame material of proposed device is same as predicate device model MA012.
Safety Feature	Manual Wheel Lock	Manual Wheel Lock	SE
Standard	ISO7176-1 ISO7176-3 ISO7176-5	ISO7176-1 ISO7176-3 ISO7176-5	SE

	ISO7176-7 ISO7176-8 ISO7176-11 ISO7176-13 ISO7176-15 ISO7176-16 ISO10993-1 ISO10993-5 ISO10993-10	ISO7176-7 ISO7176-8 ISO7176-11 ISO7176-13 ISO7176-15 ISO7176-16 ISO10993-1 ISO10993-5 ISO10993-10	

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Test

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 10993-1 :2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- 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 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, Second edition 2008-06-01, Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space
- ISO 7176-7, First Edition 1998-05-15, 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 Test dummies
- ISO 7176-13, First edition 1989-08-01, 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 Resistance to ignition of postural support devices

Substantial Equivalence discussion:

Our device and the predicate device are almost identical in terms of all areas described in the above table (Table 1). There are some minor differences with the predicate device don't affect the safety or effectiveness of the subject device.

The following table (Table 2&3) shows similarities and differences of the performance between our device and the predicate device. Tests were conducted following the recommended procedures outlined in the respective consensus standards, and results for "Manual Wheelchair A011" met all relevant requirements in the test standards, our internal specifications, and are comparable to the predicate device.

Table 2 Performance comparison

Description	Proposed Device	Predicate device
Static stability	Meets ISO 7176-1:2014	Meets ISO 7176-1:2014
Effectiveness of brakes	Meets ISO 7176-3:2012	Meets ISO 7176-3:2012
Dimensions, mass and maneuvering space	Meets ISO 7176-5:2008	Meets ISO 7176-5:2008
Seating and wheel dimensions	Meets ISO 7176-7:1998	Meets ISO 7176-7:1998
Static, impact, and fatigue strengths	Meets ISO 7176-8:2014	Meets ISO 7176-8:2014
Information disclosure, documentation and labeling	Meets ISO 7176-15:1996	Meets ISO 7176-15:1996
Resistance to ignition	Meets ISO 7176-16:2012	Meets ISO 7176-16:2012

Table 3 Biocompatibility Comparison

Item	Proposed device	Predicate device	Result
Cytotoxicity	Under the conditions of the study, not cytotoxicity effect.	Comply with ISO 10993-5	Same
Irritation	Under the conditions of the study, not an irritant.	Comply with ISO 10993-10	Same
Sensitization	Under the conditions of the study, not a sensitizer.	Comply with ISO 10993-10	Same

Difference analysis:

The tests were performed following the general requirements outlined in ISO 7176-11:2012, ISO 7176-13:1989.

A brief discussion of the non-clinical testing data that was submitted, referenced or relied on to demonstrate that the Proposed Device is safe and effective, and whose performance meets the requirements of its user-defined acceptance criteria and intended uses:

Manual wheelchair is safe and effective, and its performances meet the requirements of the pre-defined acceptance criteria and intended use.

A brief discussion of the clinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence.

According to the non-clinical test results, the proposed devices are as safe, as effective and perform as well as the predicate device. So the proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device.

Animal Study

No clinical study is included in this submission.

Clinical Study

No clinical study is included in this submission.

VIII. Conclusion

Based on the comparison of the proposed device of A011 is determined to be Substantially Equivalent (SE) to the predicate device of AST Model MA012 and MS019 Rehab Wheelchair, in respect of safety and effectiveness.