March 14, 2022

Mobility Source Medical Technology Co., Ltd.
% Shanfeng Jiang
Regulation Control Manager
Guangzhou Junyi Information Technology Co., Ltd.
Room 304, Building A, 62 Nanyun2 Road
Huangpu District, Science City, Guangdong 510663
China

Re: K213790
Trade/Device Name: Manual wheelchair SYIV 100-LQXAL2482-407
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: December 6, 2021
Received: December 6, 2021

Dear Shanfeng Jiang:

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,

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

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)*
K213790

Device Name
Manual Wheelchair SYIV1OO-LQXAL2482-407

Indications for Use *(Describe)*
The device is intended for medical purposes to provide mobility to persons restricted 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

Date of Summary Preparation: Nov,08, 2021

1. Submitter's Identifications

Submitter's Name: Mobility Source Medical Technology Co., Ltd.
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2. Correspondent’s Identifications

Correspondent’s Name: Guangzhou Junyi Information Technology Co., Ltd.
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Contact Person: Shanfeng Jiang
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3. Name of the Device

Device Classification Name: Wheelchair, Mechanical
Product Name: Manual wheelchair SYIV100-LQXAL2482-407
Trade Name: Aluminum back folding wheelchair
Model: SYIV100-LQXAL2482-407
Classification Panel: Physical Medicine
Regulation Number: 21 CFR 890.3850
Product Code: IOR
Device Classification: Class I

4. The Predicate Devices

5. Device Description

【Operating principle】
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.

【Structure composition】
The device is mainly composed of painted frame, fireproof and breathable seat cushion, armrest, backrest, hand push tube, detachable leg, 8-inch front wheel, 24-inch rear wheel, brake group and anti-overturn device.

【Main materials】
Frame: high strength aluminum alloy 6061 - T6, external diameter of Ø 25.4 mm, wall thickness of 2.0 mm.
Armrest: high strength aluminum alloy 6061 - T6, external diameter of Ø 19 mm, wall thickness of 1.5 mm
Brake assembly: aluminum alloy
Seat and backrest: flame resistant fabrics
Tire: PU

6. Intended Use of Device

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

7. Summary of Substantial Equivalence

Table 1 Comparison to Predicate Device

	Proposed Device	**Predicate device**	**Comparison**
510k Number	K213790	K181795	------
Product Code	IOR	IOR	Same
Proprietary Name	Manual Wheelchair SYIV100-LQXAL2482 -407	AST Model MA012 and MS019 Rehab Wheelchair	------
Model	SYIV100-LQXAL2482 -407	MA012 and MS019	------
Manufacturer	Guangdong Shunde LQX Health Technology Inc.	Sichuan AST Medical Equipment Co., Ltd.	------
Indications for Use	The device is intended for medical purposes to provide mobility to persons restricted to a	The AST Model MA012 and MS019 Rehab Wheelchairs are to provide mobility to persons limited to a sitting	Same

	sitting position.	position.	
Type of Use	Over-the-counter	Over-the-counter	Same
Basic Design	1. The wheelchair adopts aluminum alloy tube frame and ergonomic design, the surface of the piano paint treatment, to achieve high strength, high load bearing, light weight, small volume, and at any time folding structure, do not take up space, easy to carry; 2. Seat depth and backrest angle can be adjusted according to human comfort. 3. Backrest height can be adjusted. 4. The armrest of the wheelchair can be lifted back, the height of the armrest can be adjusted, the front and back can slide, the footplate can rotate, and the angle can be adjusted. 5. Front and rear wheels adopt PU solid tire, fireproof and breathable seat cushion and backrest. 6. Backrest can be back folding. 7. The device can be equipped with drum brake, easy for the caregiver control and down the steep slope control flexibility and stability. 8. There is equipped	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.

		with aluminum alloy brake assembly. 9. There is Equipped with anti-overturn device.		
Materials		Frame: high strength aluminum alloy 6061 - T6, external diameter of Ø 25.4 mm, wall thickness of 2.0 mm. Armrest: high strength aluminum alloy 6061 - T6, external diameter of Ø 19 mm, wall thickness of 1.5 mm Brake assembly: aluminum alloy Seat and backrest: flame resistant fabrics Tire: PU	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 PU tires Nylon cushion	Similar The Main structural materials and wheels materials are same. The differences do not raise safety and effectiveness of the proposed device.
Components		The device is mainly composed of painted frame, fireproof and breathable seat cushion, armrest, backrest, hand push tube, detachable leg, 8-inch front wheel, 24-inch rear wheel, brake group and anti-overturn device.	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, cross-brace.	Same Although the expressions are different, the main components are same.
Control Mode		Mechanical	Mechanical	Same
Dimension	**Length**	1070mm	Model MA012: 1173mm(±1mm)	Similar The two physical dimensions are different. The difference does not affect the effectiveness and safety
	Width	625mm	Model MA012: 645mm (±1mm)	
	Height	1035mm	Model MA012: 892mm (±1mm)	

Net weight	38.3 lbs/17.4kg	Model MA012: 17.2kg/38lbs	Similar The proposed device is heavier than the predicate device.
Weight capacity	300lbs/136kg	Model MA012: 300lbs/136kg	Same
Seat width	446mm(17.6'')	Model MA012: 16"(406mm) 18"(457mm) 20"(508mm)	Similar Defferent seat sizes do not raies the safety and effectiveness of the device.
Seat height	518mm(20.4'')	Model MA012: 19.7"(500mm)	
Seat depth	495mm(19.5'')	Model MA012: 16"-20" (406mm-508mm)	
Frame type	foldable	foldable	Same
Cross-brace configuration	18"	14", 16", 18", 20" or 22"	Same Cross-brace sizes of predicate device include with that of proposed device.
Back style	Fixed	Model MS019: Fixed Model MA012: Adjustable	Same
Anti-tippers	Optional	Optional	Same
Wheel construction	Quick release	Quick release	Same Wheel construction of propose device is same as predicate device model SIVFH2A102.
Tires	Front:200mm (8") Rear: 600mm(24")	Front: 6",7",8" Rear: 20",22",24"	Same The tires

			sizes of proposed device are included to those of predicate device.
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 armest of proposed device can not be adjustable.
Foot rest	Optional/ swing away	Optional/ swing away	Same
Rear Axle Position	Single	Multiple	Similar The rear axle of proposed device has only one size.
Frame Material	high strength aluminum alloy	Model MA012: Aluminum Model MS019: Steel	Same The frame material of proposed device is same as predicate device model MA012.
Safety Feature	Manual Wheel Lock	Manual Wheel Lock	Same
Standard	ISO7176-1 ISO7176-3 ISO7176-5 ISO7176-7 ISO7176-8 ISO7176-11 ISO7176-13 ISO7176-15 ISO7176-16 ISO7176-22 ISO10993-1 ISO10993-5	ISO7176-1 ISO7176-3 ISO7176-5 ISO7176-7 ISO7176-8 ISO7176-11 ISO7176-13 ISO7176-15 ISO7176-16 ISO7176-22 ISO10993-1 ISO10993-5	Same

	ISO10993-10	ISO10993-10	

8. 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*) 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 SYIV100-LQXAL2482-407" met all relevant requirements in the test standards, our internal specifications, and are comparable to the predicate device.

Table 2: Comparison of Performance Testing

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

The tests were performed following the general requirements outlined in ISO 7176-11:2012, ISO 7176-13:1989, ISO 7176-22:2014.

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:

"Mechanical Wheelchair SIVFH2A102" meets performance requirements per ISO 7176-1:2014, ISO 7176-3: 2012, ISO 7176-5:2008, ISO 7176-7:1998, ISO 7176-8:2014, ISO 7176-11:2012, 7176-13: 1989, ISO 7176-15: 1996, ISO 7176-16:2012 and ISO 7176-22:2014. It 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.

9. Non-Clinical Tests Performed:

The following testing was performed on the "Mechanical Wheelchair SYIV100-LQXAL2482-407" in accordance with the requirements of the design control regulations and established quality assurance procedures.

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 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 strengths

ISO 7176-11:2012 Wheelchairs – Part 11: Test dummies

ISO 7176-13:1989 Wheelchairs – Part 13: Determination of friction of test surface

ISO 7176-15:1996 Wheelchairs – Part 15: Requirements for information disclosure, documentation and labeling

ISO 7176-16:2012 Wheelchairs – Part 16: Resistance to ignition of postural support devices

ISO 7176-22:2014 Wheelchairs – Part 22: Set-up procedures

Biocompatibility:

ISO 10993-1:2009 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 delayed-type hypersensitivity

10. Usability Study:

The 15 participants read the User Manual before initial use of the device. They can understand the questions and answer them. The 15 participants can operate the device referring to the User Manual.

Based on the verification & validation testing records provided, we concluded that the Manual Wheelchair, Model SYIV100-LQXAL2482-407 is considered to meet the usability requirement as defined in the verification & validation test report.

These non-clinical tests demonstrate that the labeling for the Manual Wheelchair, Model SYIV100-LQXAL2482-407, manufactured by Guangdong Shunde LQX Health Technology Inc. and also distributed by US-Distributors is comprehensive, was well understood by a variety of "patients", and provided sufficient information for safe and proper use of the device.

11. Conclusion:

Based on the comparison of the proposed device of SYIV100-LQXAL2482-407 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.