September 16, 2022

Silver Fox Corporation Limited
% Iris Fung
Regulation Manager
Guangdong Jianda Medical Technology Co., Ltd.
906 Room, Longxiang Garden, Tianhe District
Guangzhou, 510000
China

Re: K221799
Trade/Device Name: Electric Wheelchair, Model: 9000N
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: June 13, 2022
Received: June 21, 2022

Dear Iris Fung:

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, Ph.D
Acting 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)*
K221799

Device Name
Electrical Wheelchair, Model: 9000N

Indications for Use *(Describe)*
The Electrical Wheelchair (Model: 9000N) is a motor-driven, and indoor transportation vehicle with the intended use to provide mobility to the disabled, the elderly and the infirm for short-distance travel.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1. Submitter Information

Sponsor Company Name: Silver Fox Corporation Limited
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Phone: +86-13422526650
Contact Person (including title): CHEN YAN /QA manager
E-mail: Yan.chen@silverfox.cn

Application Correspondent: Guangdong Jianda Medical Technology Co Ltd.
Address: 906 Room, Longxiang Garden, Tianhe district, Guangzhou, China
Contact Person: Ms. Iris Fung
Tile: Regulation Manager
Tel: +86- 13211147965
Email: mdc-fs@foxmail.com; jianda-lee@foxmail.com

2. Subject Device Information

Type of 510(k) submission: Traditional
Common Name: Powered Wheelchair
Trade Name: Electrical Wheelchair
Classification Name: Powered Wheelchair
Review Panel: Physical Medicine
Product Code: ITI
Regulation Number: 21 CFR 890.3860
Regulation Class: Class II

3. Predicate Device Information

Sponsor: JERRY MEDICAL INSTRUMENT (SHANGHAI) CO., LTD.
Common Name: Powered Wheelchair
Trade Name: Electric Wheelchair

510(k) number: K192739
Review Panel: Physical Medicine
Product Code: ITI
Regulation Number: 21 CFR 890.3860
Regulation Class: Class II

4. Device Description

The proposed device, Electrical wheelchair, mainly powered by battery, motivated by DC motor, driven by user controlling joystick and adjusting speed.
The electrical wheelchair consists of two foldable armrests, a backrest, a seat cushion, a foldable frame, two rear driving wheels with hub motor/electromagnetic brake assemblies, two pivoting casters, a Lithium-ion battery, a battery charger, a controller and master module. .
Wheelchair frame: Foldable for easy storage and transportation.
Controller and Master module: control the forward, backward, steering and speed adjustment of the electric wheelchair.
Battery: It was installed at the bottom of the wheelchair.
Rear wheel (Driving Wheel): equipped with motor and electric brake device.
Front wheel: Provide support to keep the wheelchair stable.
The battery of electrical wheelchair is Lithium-ion 24V, 11AH, and the charger is Input:100-240VAC,50-60Hz, 1.2-0.5A, Output:DC24V,3A
The maximum weight limitation of the user is 100kg.
This product can be quickly folded, disassembled and assembled, and is easy to place in the trunk of a car or lift upstairs.
The wheelchair is made of high-quality aluminum alloy. The weight without battery is 23kg.
This product is an indoor wheelchair that can be driven indoors or on flat roads near buildings. In principle, it cannot be cross-country. It is not recommended to drive on grass, gravel roads, slopes greater than 12°, and motor vehicle lanes.

5. Intended Use

The Electrical Wheelchair (Model: 9000N) is a motor-driven, and indoor transportation vehicle with the intended use to provide mobility to the disabled, the elderly and the infirm for short-distance travel.

6. Test Summary of Non-clinical Testing

The Electrical Wheelchair has been evaluated the safety and performance by lab bench testing according to the following standards:

- ISO 7176-1: 2014 Wheelchairs - Part 1: Determination of static stability

- ISO 7176-2: 2017 Wheelchairs - Part 2:Determination of dynamic stability of electrically powered wheelchairs
- ISO 7176-3: 2012 Wheelchairs - Part 3: Determination of effectiveness of brakes
- ISO 7176-4: 2008 Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
- ISO 7176-5: 2008 Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space
- ISO 7176-6: 2018 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs
- 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 7176-9: 2009 Wheelchairs - Part 9: Climatic tests for electric wheelchairs
- ISO 7176-10: 2008 Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
- 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 7176-14: 2008 Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods
- 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 7176-19:2008 Wheelchairs - Part 19: Wheeled mobility devices for use as seats in motor vehicles

EMC

- ISO 7176-21: 2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

Biocompatibility

The parts in contact with the user include：Joystick handle， is made of 100% Nitrile rubber; Joystick buttons are made of 100% silica gel; Upper/lower cover of Joystick are made of 100% ABS; Armrest are

made of 100% polyurethane (PU); Seat cushion, is made of 100% Ployester. All contact materials have passed biological tests and are harmless to humans.

- 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

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7. Comparison to Predicate Device

Compare with predicate device, the subject device is very similar in design principle, intended use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise and new questions of safety or effectiveness.

Table1 General Comparison

Elements of Comparison	Subject Device	Predicate Device	Verdict
Product Code	ITI	ITI	Same
Regulation No.	21 CFR 890.3860	21 CFR 890.3860	Same
Class	II	II	Same
Product name	Electrical Wheelchair	Electric Wheelchair	Same
510 (k) Number	K221799	K192739	--
Models	9000N	JRWD6010, JRWD6012	--
Intended Use	The Electrical Wheelchair (Model: 9000N) is a motor-driven, and indoor transportation vehicle with the intended use to provide mobility to the disabled, the elderly and the infirm for short-distance travel.	The device is a motor-driven, and indoor transportation vehicle with the intended use to provide mobility to a disabled or an elderly person limited to a seated position.	Same
Use environment	Indoor use	Indoor use	Same
Patient Population	This electrical wheelchair is suitable for short-distance travel for the disabled and the elderly person.	The electric wheelchair is intended to provide mobility to a person with a disability or an older adult limited to a sitting position	Same
Product structure	Consists of two foldable armrests, a backrest, a seat cushion, a foldable frame, two rear driving wheels with	Consists of two foldable armrests, a backrest, a seat cushion, a foldable frame, two rear driving wheels with hub	Same

Elements of Comparison	Subject Device	Predicate Device	Verdict
	hub motor/electromagnetic brake assemblies, two pivoting casters, a Lithium-ion battery, a battery charger, a controller and master module.	motor/electromagnetic brake assemblies, two pivoting casters, a Li-ion batteries, an off-board battery charger, a control panel, and an electric motor controller.	
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	Same
Number of wheels	4	4	Same
Main frame material	Aluminium alloy	Aluminium alloy	Same
Motor	DC 24V*180W * 2pcs	DC24V* 180W*2pcs	Same
Battery	Lithium-ion 24V, 11AH,1pcs	DC 24V 20Ah Lithium-ion,1 pcs	Subject Device has a lower output current, but this will not affect the use of the product function and safety.
Battery charger	Input:AC 100-240V, 50/60Hz Output:DC24V, 3A max	High Power Technology Inc. HP0180WL2 Input: 100-240 VAC Output: DC 24V, 6 Amp	Subject Device has a lower output current, but this will not affect the use of the product function and safety.

Table2 Performance Comparison

Elements of Comparison	Subject Device	Predicate Device		Verdict
		JRWD6010	JRWD6012	
Dimensions	39.0”x24.0”x38.0”	38.1”x24.0”x37.0”	39.3”x23.6”x37.0”	Similar
Folded Dimensions	26.0”x24.0”x16.0”	Not publicly available		--
Seat Cushion size	18.0”x18.0”x3.0”	Not publicly available		--
Weight,w/ Battery	50lbs./23kg	58.4 lbs./26.5kg	58.2 lbs./26.4kg	Subject Device has a lighter weight, but this will not affect the use of the product function and safety.
Frame design	Foldable / The device consists of a foldable and non-rigid type of power wheelchair base with rear drive and 2 casters in the front and 2 anti-tippers in the rear.	Foldable / The device consists of a foldable and non-rigid type of powe wheelchair base with rear drive and 2 casters in the front and two anti- ippers in the rear.		Same
Folding mechanism	A foldable seat frames (The backrest could be folded to	A foldable seat frames (The backrest could be folded to seat)		Same

Elements of Comparison	Subject Device	Predicate Device		Verdict
		JRWD6010	JRWD6012	
	seat)			
Front wheel（inch）	8	8 (PU solid tire)		
Rear tire (inch)	8 (PU solid tire)	10 (PU solid tire)	12 (Pneumatic tire)	Smaller sizes of rear wheels, The difference will not raise any new safety and effectiveness concerns.
Cruising Range(km)	15.5	20		Subject Device has a shorter cruising range, but this will not affect the use of the product function and safety.
Obstacle climbing(mm)	25	50		Subject Device has a lower obstacle climbing, but this will not affect the use of the product function and safety.
Max. Speed (km/h)	4.5	6		Subject Device has a smaller Max. speed, but this will not affect the use of the product function and safety.
Static stability forward	18.2°	21.8°		Both of the devices are evaluated according to standard ISO 7176-1:2014, so the different static stability will not impact the safety and effectiveness.
Static stability rearward	18.0°	19°		
Static stability sideways	Left: 17.6° Right: 16.6°	19.2°		
Max. loading (kg)	220lbs(100kg)	220lbs(100kg)		Same
Maximum safe operational incline	10°	10 degrees		Same
Min. Turning radium	950mm	1820mm		The difference in the turning radius will bring more convenience when it turns.The difference will not raise any new safety and effectiveness concerns.
Minimum braking distance	≤1meter (39 inches) flat, ≤1.6meter (63 inches) at 3°slope	1m		Similar
Max Speed Forwards	2.46mph(3.96km/h)	3.75 mph (6 km/h)		Both of the devices are evaluated according to standard ISO 7176-6:2018, so the different
Max. Speed Backward	1.57mph(2.52km/h)	2.80 mph (4.5 km/h)		

Elements of Comparison	Subject Device	Predicate Device		Verdict
		JRWD6010	JRWD6012	
				will not impact the safety and effectiveness
Controller	Silver Fox Corporation Limited	PG Drives Technology Ltd., newVSI		Different Although different controller is used, both the control system, including the joystick controller, the electromagnetic brakes are similar. The joystick controls the directions and speed of movement, and when the joystick is released, the powered wheelchair will slow down to stop and the brakes will automatically re-engage. The controller also provides the battery status displaying and abnormal condition displaying. Both of the control systems are evaluated according to standard ISO 7176-14:2008 and software validation requirement and there are no new safety and effectiveness concerns due to the difference.
Speed control method	Joystick control method	Joystick control method		Same

Table3 Safety Comparison

Elements of Comparison	Subject Device	Predicate Device	Verdict
Main materials	Frame: Aluminium alloy; Wheel, Armrest: PU; Backrest:polyeter	Frame: Aluminium alloy; Wheel, Armrest: PU; Backrest: oxford cloth	The material for the main frame is the same. Biocompatibility evaluation has been carried out per ISO 10993-1. There are no new safety and effectiveness concerns due to the difference.
Materials contacting user	Armrest: PU; Backrest，Seat cushion: polyeter Joystick handle：Nitrile rubber; Joystick buttons：silica gel; Upper/lower cover of Joystick：ABS	Armrest: PU; Backrest: oxford cloth Seat: oxford cloth newVSi electric wheelchair controller: Joystick knob: Santoprene 101-80; Joystick Gaiter: Silicone 3032 (50%) & 5031 (50%) Enclosure Moulding(s): ABS/PC Wonderloy PC-540 Keypad: Silicone keypad coatings	

Elements of Comparison	Subject Device	Predicate Device	Verdict
		TC-2407 & CH-6330	
Biocompatibility of materials contacting user	Comply with ISO 10993-1, FDA Cytotoxicity (ISO 10993-5:2009), Sensitization and Intracutaneous Reactivity (ISO 10993-10:2010)	Comply with ISO 10993-1, FDA Cytotoxicity (ISO 10993-5:2009), Sensitization and Intracutaneous Reactivity (ISO 10993-10:2010)	Same
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	Same
Level of Concern of the Software	Moderate	Moderate	Same

8. Summary of substantial equivalence discussion

The 9000N electrical wheelchair complied with the requirements of ISO 7176-1:2014, ISO 7176-2:2017, ISO 7176-3:2012, ISO 7176-4:2008, ISO 7176-5:2008, ISO 7176-6:2018, ISO 7176-7:1998, ISO 7176-8:2014, ISO 7176-9:2009, ISO 7176-10:2008, ISO 7176-11:2012, ISO 7176-13:1989, ISO 7176-14:2008, ISO 7176-15:1996, ISO 7176-16:2012, ISO 7176-19:2008, ISO 7176-21:2009, IEC 60601-1-2:2014, ISO 10993-1:2018, ISO10993-5:2009, ISO 10993-10:2010..

The intended uses for both devices are the same. Mainframes of two devices are folded by way of front and rear close, and frame materials all meet the Tensile Strength, Yield Load, and Elongation tests. The design principles of the controller and Driving system are the same, and both meet the requirements of the ISO 7176-14:2008. Software validation is carried out on both control systems. Brake system and speed control are designed in the same way as well, and both meet the requirements of the ISO 7176-3:2012. Maximum obstacle climbing, Max Speed and Static stability are slightly different while such differences will not impact the safety and effectiveness of the subject device or raise new safety and effectiveness concerns as well as both meet the requirements of the ISO 7176-2:2001,ISO 7176-6: 2018, ISO 7176-10:2008. The biocompatibility of the Predicate device and Subject device meet the requirements of the ISO 10993-5:2009 & ISO 10993-10:2010.

The flame retardant test of the seat cushion/back cushion and armrest of subject device is carried out according to the ISO 7176-16 test. Therefore, the subject device meets the flame retardancy of FDA requirements.

In conclusion, the technological characteristics, features, specifications, materials, mode of operation, and intended use of the device substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

9. Summary of Clinical Test

No animal study and clinical studies are available for our device. Clinical testing was not required to demonstrate the substantial equivalence of the electrical wheelchair to its predicate device.

10. Conclusion

The differences between 9000N electrical wheelchair and its predicate devices do not introduce a new intended use and do not raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended. From the results of nonclinical testing described, it can be concluded that 9000N electrical wheelchair is substantially equivalent to the legally marketed predicate device.

11. Summary Prepared Date

13 June 2022