September 12, 2024

Zhejiang Hfizer Medical Equipment CO.,LTD.
% Eva Li
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.,
Shanghai, 200122
China

Re: K242136
Trade/Device Name: Electric wheelchair (C001)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: July 22, 2024
Received: July 22, 2024

Dear Eva Li:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Rehabilitation 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)*
K242136

Device Name
Electric wheelchair (C001)

Indications for Use *(Describe)*
The Electric wheelchair is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated 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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# 510k Summary

# K242136

## I. SUBMITTER

Name: Zhejiang Hfizer Medical Equipment CO.,LTD.
Address: No.7, Yunliu Road, Baiyun Industrial Zone, Jiangnan Street, Yongkang City, Zhejiang Province, China
Telephone: +86-579-87192878
Email: 582349548@qq.com
Date prepared: June 16, 2024

## II. Device

Device trade name: Electric wheelchair
Model(s): C001
Common name: Electric wheelchair
Classification name: Powered wheelchair
Regulation class: 2
Regulation number: 21CFR 890.3860
Panel: Physical Medicine
Product code: ITI

## III. Predicate device

K231508
Power wheelchair, W5521
Zhejiang Innuovo Rehabilitation Devices Co., Ltd.

## IV. Device Description

The subject Electric wheelchair(C001) is a wheeled personal mobility device that incorporates a seat-support system for a person with a disability or a person without the full capacity to walk designed to be propelled by power from electric motors. The electronic control of speed and direction can be performed by the occupant with the help of controlling joystick. The device can be quickly folded and disassembled, which makes it convenient to be stored or placed at the trunk of vehicles while traveling.

The subject device is intended to provide mobility to a disabled or elderly limited to a seated position. It is of indoor and outdoor type, suitable for the use indoor and outdoor road like flat stone road and so on.

The subject device consists of two parts, the wheelchair main body and the electrical part. The main body includes a main foldable Carbon fiber frame, two armrests, a backrest, a seat cushion, a safety belt, two rear driving wheels(8''/ PU solid tire) and two front wheels(6"/ PU solid tire). The electrical part is composed of two motors, two brakes, a lithium battery, a controller and an off-board charger.

The device is powered by a Li-ion battery with 14.8km range, which can be recharged by an off-board battery charger that can be plugged into an AC socket when the device is not in use. The patient can activate the controller handle (joystick) to control the speed and direction of

the wheelchair. The further the joystick is pushed from its central position, the faster the wheelchair moves, when it is released, it will automatically reset and brake.
The device can convered between electric driving and manual push.

## V. Indication for use

The Electric wheelchair is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

## VI. Comparison of technological characteristics with the predicate device

| Item | Subject device | Predicate device | Comparison |
|---|---|---|---|
| Manufacturer | Zhejiang Hfizer Medical Equipment CO.,LTD. | Zhejiang Innuovo Rehabilitation Devices Co., Ltd. | NA |
| Proprietary name, model | Electric wheelchair , C002 | Power Wheelchair, W5521 | NA |
| 510(k) number | | K231508 | NA |
| Device classification name | Class II | Class II | same |
| Classification regulations | 21 CFR 890.3860 | 21 CFR 890.3860 | same |
| Product code | ITI | ITI | same |
| Indication for use | The Electric wheelchair is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position. | The Power Wheelchair is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position. | same |
| Intended user | disabled people with mobility difficulties and elderly people | disabled people with mobility difficulties and elderly people | same |
| Use condition | indoor and outdoor use | indoor and outdoor use | same |
| Number of wheels | 6, including two front wheels ,two rear wheels, two anti-tip wheels | 6, including two front wheels and two rear wheels, two anti-tip wheels | same |
| Function of wheels | Front wheels: driven wheels<br>Rear wheels: driving wheels<br>Anti-tip wheels: preventing the wheelchair from tipping turning over when driving on the slope. Non-adjustable. | Front wheels: driven wheels suitable for rotation, acceleration, retrograde<br>Rear wheels: driving wheels to control the speed and direction<br>Anti-tip wheels: preventing the wheelchair from tipping turning over when driving on the slope. Non-adjustable | same |

| | | | |
|---|---|---|---|
| Movement control method | By Joystick control | By Joystick control | same |
| Driving system | Direct drive on the rear wheels | Direct drive on the rear wheels | Same |
| Brake system | Automatic electromagnetic brake system | Automatic electromagnetic brake system | Same |
| Battery charger | Off-board charger<br>Input : 100-240V, 50/60Hz, 1.5A,<br>DC output: 24V 3A | Off-board charger<br>Input: 100-240V, 50/60Hz, 1.5A,<br>Output: 24 Vdc, 2A; | similar |
| back cushion | PVC | Polyester fabric | different |
| seat cushion | PVC | rubber patch cloth and Oxford fabric | different |
| Armrest | Carbon fiber | Polyurethane (PU) | different |
| Max loading weight | 120Kg | 136kg (≈300 lbs) | different |
| Max obstacle climbing | 25mm | 40 mm | different |
| Main frame material | Carbon fiber | aluminum alloy | Different |
| Total mass | 17kg | 25kg | different |
| Overall Dimension (length*width*height)(mm) | 900*570*1000 | 1040mmX600mmX1020mm | Different |
| Stowage Dimension (length*width*height)(mm) | 740*570*290 | 390mmX600mmX810mm | Different |
| Front wheel size/type | 8”/ PU Solid tire | 7.8” x 1.9”/ PU Solid tire | Different |
| Rear wheel size/type | 12”/ PU Solid tire | 11.8” x 2.2”/ PU Solid tire | Different |
| Max speed forward | Up to 5.76 km/h (1.6m/s) adjustable | Up to 5.47 km/h (1.52 m/s), adjustable | Different |
| Max Speed backward | Less than 3.24 km/h (0.9m/s) | Less than 3 km/h (0.9m/s) | Different |
| Maximum safe operational incline degree | 10° | 6° | Different |
| Braking distance | ≤1 m | ≤1 m | Same |
| Battery | li-ion battery pack; rechargeable, 24 VDC 10Ah | li-ion battery pack; rechargeable, 24 VDC 10Ah | Same |
| Maximum distance of travel on the fully charged battery | 14.8Km | 10km | Different |
| Motor | Brushless DC motor 140W24V; 2pcs | Brush DC motor; 24VDC; 200W; 2pcs | different |

| | | | |
|---|---|---|---|
| Electronic controller | MN2WSDC/3+7F&2X-X MT | Micon M7086 controller | different |
| Turning Radius | 962.5mm | 600 mm | different |

Discussion: The difference between the subject device and predicate device will not raise any effectiveness or safety issues since the subject device meet the related requirement of series standard of ISO 7176.

## VII. Summary of substantial equivalence discussion

The subject device complied with the requirements of ISO 7176-1:2014, ISO 7176-2:2001, 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 7176-11:2008, ISO7176-13:1989, ISO 7176-14:2008, ISO 7176-15:1996, ISO 16840-10: 2021, ISO7176-21:2009, ISO 7176-22:2014, ISO 7176-25:2013, IEC 60601-1-2: 2020.

The intended uses for both devices are the same.

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 are different, it meets the requirements of the ISO 7176-3:2012.

Turning radius and Maximum safe operational incline 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 7176-10:2008.

The flame retardant test of the seat cushion/backrest of the subject device is conducted according to ISO 16840-10. Therefore, both devices are assured to be under the same safety level.

The all rest different between the subject device and predicate device can proved the safety or effectiveness by the ISO 7176 series support reports.

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.

## VIII. Summary of non-clinical testing

- Performance testing-bench

The following performance data were provided to verify that the subject device met all design specifications and provided support of the substantial equivalence determination

- Software validation
- ISO 7176-1:2014 Wheelchairs - Part 1: Determination of static stability
- ISO 7176-2:2017 Wheelchairs - Part 2: Determination of dynamic stability of electric 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 dimensions, mass and

maneuvering 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 strength
- 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 16840-10: 2021 Wheelchair seating - Part 10: Resistance to ignition of postural support devices - Requirements and test method
- ISO 7176-21:2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters
- ISO 7176-22: 2014 Wheelchairs - Part 22: Set-up procedures
- ISO 7176-25:2013 Wheelchairs - Batteries and chargers for powered wheelchairs Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2014.
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

➢ **Biocompatibility of patient-contacting material**

The biocompatibility of the subject device was determined via the declaration of identical tissue-contacting materials to the predicate device, which evaluated biocompatibility according to the ISO 10993-1.

## IX. **Summary of clinical testing**

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

## X. Conclusions

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device K231508.