January 21, 2022

Golden Motor Technology Co., Ltd.
% Raymond Luo
Regulation Manager
Shanghai Sungo Management Consulting Company Limited
13F, Eastern Mansion, No.1500 Century Ave.
Pudong New Area, Shanghai, 200120, China

Re: K191105
Trade/Device Name: e-Throne Folding Wheelchair, Model: ET-12F22
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: December 17, 2021
Received: December 27, 2021

Dear Raymond Luo:

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)*
K191105

Device Name
e-Throne Folding Wheelchair, Model: ET-12F22

Indications for Use *(Describe)*
The e-Throne Folding Wheelchair, Model : ET-12F22 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.

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510(k) Summary

K191105

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

1. **Date of the summary prepared:** 2022-01-21

2. Submitter's Information

Company Name: Golden Motor Technology Co., Ltd.
Address: Room 1401-1405, Tower 5, No.18-50 Middle Chang Wu Road, Changzhou 213164 Jiangsu, China
Phone: +86 519 81004118
Contact Person: Philip Yao
E-mail: sales@goldenmotor.com

Application Correspondent: Shanghai Sungo Management Consulting Company Limited
Address:13F, Eastern Mansion, No.1500 Century Ave., Pudong New Area, Shanghai
Contact Person: Raymond Luo
Tile: Regulation Manager
Tel:0086-21-68828050
Email: fda.sungo@gmail.com

3. Subject Device Information

Type of 510(k) submission: Traditional
Common Name: Powered wheelchair
Trade Name: e-Throne Folding Wheelchair, Model: ET-12F22
Classification Name: wheelchair, powered
Review Panel: Physical Medicine
Product Code: ITI
Regulation Number:890.3860
Regulation Class: 2

4. Predicate Device Information

Sponsor	SUZHOU KD Medical Appliance Co. Ltd.
Device Name	PL001 power wheelchair
510(k) Number	K113463
Product Code	ITI
Regulation Number	890.3860
Regulation Class	2

5. Device Description

The e-Throne Folding Wheelchair, Model: ET-12F22 is a powered wheelchair that is designed to fold when not in use so it can be more easily transported in a car trunk or similar space. It uses rechargeable lithium batteries and is controlled by a joystick and a few other simple controls which are located on the end of the armrest. The joystick assembly may be installed on either side of the chair to accommodate both right-handed and left-handed users.

The e-Throne Folding Wheelchair consists of two foldable armrests, a back rest, a seat cushion, a foldable frame, two rear drive wheels with hub motor and electromagnetic brake assemblies, two pivoting casters, a single Li-ion battery pack, an off-board battery charger, a control panel (joystick) with connect cables and an electric motor controller. The device is powered by one Li-ion battery pack (24V, 15 Ah), which can be recharged by an off-board battery charger that can be plugged into an AC socket outlet (100-240V, 50/60Hz) when the device is not in use.

6. Intended Use / Indications for Use

The e-Throne Folding Wheelchair, Model: ET-12F22 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.

7. Comparison of technological characteristics with the predicate device

Attribute	Subject device	Predicate device	Discussion/ Conclusion
Manufacturer	Golden Motor Technology Co., Ltd.	SUZHOU KD Medical Appliance Co. Ltd.	/
Proprietary name, model	e-Throne Folding Wheelchair, Model: ET-12F22	PL001 power wheelchair	/
510(k) number	K191105	K113463	/
Device classification name	Class II	Class II	Same
Classification regulations	21 CFR 890.3860	21 CFR 890.3860	Same
Product code	ITI	ITI	Same
Similarities			
Indication for use	The e-Throne Folding Wheelchair, Model : ET-12F22 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 device 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 or elderly person limited to a seated position	Same
Use condition	indoor and outdoor use	indoor and outdoor use	Same
Number of wheels	4, including two front wheels and two rear wheels	4, including two pivoting casters and two rear drive wheels	Same
Function of wheels	Front wheels: driven wheels suitable for rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed	two pivoting casters: driven wheels suitable for rotation, acceleration, retrograde two rear drive wheels: driving wheels to	Same

Attribute	Subject device	Predicate device	Discussion/ Conclusion
	and direction	control the speed and direction	
Frame design	the frame of the wheelchair is type of aluminum frame with front and rear folding structure; Up-and-down turnable handrail, front and rear adjustable armrest.	the frame of the wheelchair is type of aluminum frame with front and rear folding structure; Up-and-down turnable handrail, front and rear adjustable armrest.	Same
Folding mechanism	The wheelchair can be folded to close the back and seat parts face to face after push the two red lock buttons to the central position. fold the back and the armrest is rotated to the down direction, and then close the back and seat face to face, close the feet pedal as well. The folding is completed.	the wheelchair can be folded to close the back and seat parts face to face after push the two lock buttons to the central position. fold the back and the armrest is rotated to the down direction, and then close the back and seat face to face, close the feet pedal as well. The folding is completed	Same
Max speed forward	6 km/h, continuously adjustable	not publicly available	/
Maximum safe operational incline degree	9 °	not publicly available	/
Movement control method	By Joystick control	By Joystick control	Same
Driving system	Direct drive on the rear wheels	not publicly available	/
Brake system	Automatic intelligent electromagnetic brake system	not publicly available	/
Electronic controller	Brushless dual-drive rocker controller	not publicly available	/
Main frame material	Aluminum alloy	not publicly available	/
Armrest	PU	not publicly available	/
Seat cushion/back cushion	Nylon (Lining: PU foam)	not publicly available	/

Attribute	Subject device	Predicate device	Discussion/ Conclusion
Differences			
Front wheel size/type	8" x 2"/PU Solid tire	not publicly available	/
Rear wheel size/type	12.5″x 2.4″/PU Solid tire	not publicly available	/
Max Speed backward	0.8m/s (2.88km/h)	not publicly available	/
Max loading weight	100 kg (220 lbs)	not publicly available	/
Battery charger	Off-board charger Input: 100-240V, 50/60Hz, Output: DC 24, 2A;	Off-board, Automatic Type Input: 110-220 V / 50-60 Hz, Output: 24 Vdc, 2A;	More wide range of input voltage in the device which will not cause new safety and effectiveness concerns raised.
Motor	brushless motor; 24VDC; 250W; 2pcs	not publicly available	/
Minimum braking distance from maximum speed	Forward: 0.75 m	not publicly available	/
Battery	Li-ion; rechargeable, 24 VDC 15Ah	Li-ion, Rechargeable; 12 VDC 10Ah	same battery type, different power will not affect the effectiveness and safety of the device as both batteries are in conformity with IEC 62133-2.
Maximum distance of travel on the fully charged battery	22 km	20 km	longer distance of travel on the subject device
Turning Radius	650 mm	not publicly available	/
Maximum obstacle climbing	50 mm	not publicly available	/

8. Summary of substantial equivalence discussion

The e-Throne Folding Wheelchair, Model: ET-12F22 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 7176-6:2001, ISO 7176-7:1998, ISO 7176-8:2014, ISO 7176-9:2009, ISO 7176-10:2008, ISO 7176-11:2008, ISO 7176-13:1989, ISO 7176-14:2008, ISO 7176-15:1996, ISO 7176-16:2012, ISO 7176-21:2009, ISO 7176-22:2014, ISO 7176-25:2013, IEC 60601-1:2005+A1:2012, 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 the same way as well. 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 are different from each other 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. 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 both subject device and predicate device is carried out according to the ISO 7176-16 test. Therefore, both devices are assured to be under the same safety level.

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.

9. Summary of non-clinical testing (Performance testing-bench)

The device has been evaluated the safety and performance by lab bench testing or other non-clinical way as follows:

Risk Management

Risk analysis and management was implemented in accordance with ISO 14971:2007.

Biocompatibility

The biocompatibility evaluation for the e-Throne Folding Wheelchair, Model: ET-12F22 was carried out in accordance with lS0 10993-1: 2018, including cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2010) and irritation (ISO 10993-10:2010).

Electrical safety and electromagnetic compatibility (EMC)

Electrical Safety Testing was conducted on the e-Throne Folding Wheelchair, Model: ET-12F22 in accordance with IEC 60601-1:2005 (3rd Edition).

Electromagnetic Compatibility Testing was conducted on the e-Throne Folding Wheelchair, Model: ET-12F22 in accordance with IEC 60601-1-2:2014 and ISO 7176-21:2009.

Li-ion battery pack used on the e-Throne Folding Wheelchair, Model: ET-12F22 was conducted in accordance with IEC 62133-2:2017.

Performance Testing

Performance Testing was conducted on the e-Throne Folding Wheelchair, Model: ET-12F22 in accordance with 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 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 7176-16: 2012 Wheelchairs -- Part 16: Resistance to ignition of postural support devices
- ISO 7176-25: 2013 Wheelchairs - Batteries and chargers for powered wheelchairs

Software Verification and Validation Testing

Software Verification Testing was performed to evaluate the functionality of the design, materials, and operational principles of the subject device. This includes the following: Software verification testing was conducted on the subject device as recommended by the FDA's guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Level of Concern: The software for this device was considered as a moderate hazard.

Animal Study

Animal testing was not required for this submission.

Clinical Testing

Clinical testing was not required to demonstrate substantial equivalence to the predicate device.

10. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of e-Throne Folding Wheelchair, Model: ET-12F22 is substantially equivalent to the predicate devices quoted above. The differences between the subject device 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 the subject device e-Throne Folding Wheelchair, Model: ET-12F22 is substantially equivalent to the legally marketed predicate device.