DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 11, 2017

Winner Sg Pte Ltd
% Diane Horwitz, Ph.D., RAC
Regulatory Consultant
Eminence Clinical Research, Inc.
1880 Office Club Pointe, Suite 1360
Colorado Springs, Colorado 80920

Re: K162328
Trade/Device Name: Winner Transfer Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: April 10, 2017
Received: April 12, 2017

Dear Dr. Horwitz:

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. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162328

Device Name
Winner Transfer Wheelchair

Indications for Use *(Describe)*
The Winner Transfer Wheelchair is a manually operated wheelchair that 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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K162328
510(k) Summary
Winner Transfer Wheelchair

1. Submission Sponsor

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Owner/Operator number: 10034069

4. Date Prepared

May 9, 2017

5. Device Identification

Trade/Proprietary Name:	Winner Transfer Wheelchair
Common/Usual Name:	Mechanical Wheelchair
Classification Name:	Mechanical Wheelchair
Classification Regulation:	890.3850
Product Code:	IOR
Device Class:	Class I
Classification Panel:	Physical Medicine

6. Legally Marketed Predicate Device(s)

Breezy Elegance Manual Folding Wheelchair, K133855, Sunrise Medical LLC

7. Device Description

The Winner Transfer Wheelchair is a manual wheelchair used by individuals for whom walking is difficult or impossible and who need assistance in transport. The Winner Transfer Wheelchair is propelled manually by the user propelling the wheels or being pushed by an assistant. The Winner Transfer Wheelchair has the standard attributes of the predicate wheelchair, such as an aluminum frame with flip away, height adjustable and retractable armrests, an adjustable upholstered tension back and flip down back, and a swing away and removable footrest.

The Winner Transfer Wheelchair has an accessory, the Kingfisher 125T Retractable Kit, which can be attached to either the left side or the right side of the Winner Transfer Wheelchair. The Retractable Kit serves to allow the rear wheel to be retracted (moved back in a linear motion), thereby opening the side distance in front of the wheel to permit easier lateral transfer. Whereas in most wheelchairs, the rear wheel is obstructing placement of a Transfer Board which is often used during lateral transfer. When the rear wheel is retracted using the Kingfisher 125T Retractable Kit, it is easier for the user to positioning the transfer board. The base wheelchair can be fitted with a left or right retractable kit.

8. Indication for Use Statement

The Winner Transfer Wheelchair is a manually operated wheelchair that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

9. Substantial Equivalence Discussion

The following table compares the Winner Transfer Wheelchair to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

K162328
510(k) Summary
Winner Transfer Wheelchair

Table 1. Comparison of Characteristics

Manufacturer	Predicate Device Breezy Elegance Manual Folding Wheelchair (K133855) Sunrise Medical	Subject Device Winner Transfer Wheelchair K162328 Winner SG G Pte Ltd/ A & I Industries	Same or Different (Reason that difference does not impact safety or effectiveness)
Product Code	IOR	IOR	Same
Regulation Number	890.3850	890.3850	Same
Regulation Name	Mechanical Wheelchair	Mechanical Wheelchair	Same
Intended Use / Indications for Use Statement	Breezy Elegance Folding Manual Wheelchairs are manually operated devices with wheels that are intended for medical purposes to provide mobility to persons restricted to a sitting position.	The Winner Transfer Wheelchair is a manually operated wheelchair that is intended for medical purposes to provide mobility to persons restricted to a sitting position.	Similar Intended Use and Indications for Use. Both devices have the same general purpose and both devices are used for subjects with similar mobility with one additional functionality.
Use Environment	Healthcare Setting or Home; inside or outside	Healthcare Setting or Home; inside or outside	Same
Patients	Individuals who cannot walk for long distances	Individuals who cannot walk for long distances	Same
Movement from Wheelchair to Bed or Other Surface	Lateral transfer using transfer board for assistance	Lateral transfer using transfer board for assistance Easier process due to Kingfisher Retractable Kit accessory	Similar but easier transfer with wheel retracted with the Subject Device
DIMENSIONS, WEIGHT AND WEIGHT LIMITATION			
Front Seat to Floor Height	17 in. (43 cm) expandable to 20 in. (51 cm)	19.7 in. (500 mm)	Similar
Front Wheel Diameters	8 in. x 1.3 in.	7.9 in. x 2 in. (200 mm x 50 mm)	Similar
Rear Wheel Diameters	24 in. x 1 in. (61 cm x 2.5 cm)	24 in. x 1 in. (61 cm x 2.5 cm)	Same
Seat Width	16 in. or 18 in. (41 cm or 46 cm)	17.7 in. (450 mm)	Similar
User Weight Limit	275 lbs. (125 kg)	275 lbs. (125 kg)	Same
Chair Weight	32 lbs. (16 kg)	39.7 lb. to 52.9 lb. (18 kg to 24 kg), including accessories (retractable wheel(s))	The retractable wheel accessory weighs 8.4 lb. (3.8 kg)
Backrest Angle	80°	75°	Similar angle; allows for comfortable seating of user
MATERIAL			
Frame Material	Aluminum	Aluminum	Same
Upholstery	Polyurethane Foam with Nylon Cover	Polyurethane Foam with Nylon Cover	Same
Hand Rims	Aluminum Tubing	Aluminum	Same

Manufacturer	Predicate Device Breezy Elegance Manual Folding Wheelchair (K133855) Sunrise Medical	Subject Device Winner Transfer Wheelchair K162328 Winner SG G Pte Ltd/ A & I Industries	Same or Different (Reason that difference does not impact safety or effectiveness)
FEATURES			
Foldable	Yes	Yes	Same
Legrests and Footplates	Adjustable and removable.	Adjustable and removable.	Same
Retractable Rear Wheels	Non-retractable	Yes	Difference does not raise safety or effectiveness concerns based on the ISO testing: 7176-1, 7176-8

10. Non-Clinical Performance Data

Mechanical Wheelchairs (21 CFR 890.3850, Product Code IOR) have the following applicable guidance document on which this submission was based:

- Guidance Document for the Preparation of Premarket Notification [510k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles, July 26, 1995.

Recognized consensus standards for Product Code IOR, Mechanical Wheelchairs, have been used in the design and testing of the device.

The Winner Transfer Wheelchair with the Kingfisher 125T accessory were tested to and comply with the following listed recognized consensus standards.

- ISO 7176-1:2014 – Determination of Static Stability
- ISO 7176-3:2012 – Determination of Effectiveness of Brakes
- ISO 7176-5:2008 – Determination of Dimensions, mass and maneuvering space
- ISO 7176-7:1998 – Measurement of Seating and Wheel Dimensions
- ISO 7176-11:2012 – Test Dummies
- BS EN 12183:2014 – Manual Wheelchairs – Requirements and Test Method, with Normative References to the following to demonstrate individual aspects of safety, effectiveness, and substantial equivalence of the Winner Transfer Wheelchair:
  - EN 1021-2: 2006, Furniture — Assessment of the ignitability of upholstered furniture — Part 2: Ignition source match flame equivalent and ISO 8191-2.
  - ISO 7176-8: 1998, Wheelchairs — Part 8: Requirements and test methods for static, impact and fatigue strengths
  - ISO 7176-13: 1989, Wheelchairs — Part 13: Determination of coefficient of friction of test surfaces
  - ISO 7176-15: 1996, Wheelchairs — Part 15: Requirements for information disclosure, documentation and labelling
  - ISO7176-16: 2012 – (Annex A) Resistance to ignition of postural support devices
  - ISO 7176-22: 2000, Wheelchairs — Part 22: Set-up procedures

As part of demonstrating safety and effectiveness of Winner Transfer Wheelchair and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Winner SG Pte Ltd completed performance tests per the International Standards above. The Winner Transfer Wheelchair meets all the requirements for overall design and confirms that the output meets the design inputs and specifications. The Winner Transfer Wheelchair passed all testing stated above as shown by the acceptable results obtained.

11. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

12. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Technological improvements may add new features, however base technological characteristics should be equivalent and no new questions should be raised regarding its safety and effectiveness.

The Winner Transfer Wheelchair device shares the same base indications for use, device operation, overall technical and functional capabilities as the predicate device, and both the Winner Transfer Wheelchair with the Kingfisher 125T Retractable Kit as well as the predicate device meet product specifications and international performance standards. The addition of the Kingfisher 125T Retractable kit does not present any new issues around safety during wheelchair use, as the wheels are not retracted while the wheelchair is being driven. The Winner Transfer Wheelchair is identical in design and function to the predicate device for the all basic expected modes of operation and use and only differs with the addition of the retractable wheel. As all items are identical with only the added convenience functionality it is concluded that the Winner Transfer Wheelchair is substantially equivalent to the predicate device.