November 16, 2017

Merits Healthcare Industries (suzhou) Co., Ltd.
Guangyong Li
Manager
No.29, Fuzhou Road
Taicang City, 215411 CN

Re: K170517
Trade/Device Name: Merits Model R106/R136 Rehab Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: September 29, 2017
Received: October 19, 2017

Dear Guangyong 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 (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); 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*
K170517

Device Name
Merits Model R106/R136 Rehab Wheelchair

Indications for Use *(Describe)*
The Merits Model R106/R136 Rehab Wheelchair is to provide mobility to persons limited 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Merits Healthcare Industries. (suzhou) Co., LTD.
510(k) Premarket Notification
K170517

Submitter:

Merits Healthcare Industries. (suzhou) Co., LTD.
No.29, Fuzhou Road, Taicang City.
Jiangsu province, China.

Contact Person:

Guangyong Li
Merits Healthcare Industries. (suzhou) Co., LTD.
No.29, Fuzhou Road, Taicang City.
Jiangsu province, China.
Phone: +86-512-53510000 ext.211
Fax: +86-512-82775985

Date Prepared:

November 15, 2017

Proprietary Name:

Merits Model R106/R136 Rehab Wheelchair

Common name:

Manual Wheelchair

Classification name:

Wheelchair, Mechanical

Product Code:

IOR

Indications for Use

The Merits Model R106/R136 Rehab Wheelchair is to provide mobility to persons limited to a sitting position.

The Predicate Device:

This submission indicates the Substantial Equivalence of the Merits Model R106/R136 Rehab Wheelchair, with the predicate ORION Ⅱ(Heavy Duty 350lbs and 500lbs) mechanical wheelchair (K101277). R106/R136 has the same intended uses and similar indications, technological characteristics and principles of operation with predicate device.

Device Description

The Merits Model R106/R136 Rehab Wheelchair are manual wheelchairs. They have adjustable headrest, adjustable armrests, cozy ergonomics seat and multiple axle position. The seat and back are supported by two cylinders, so the fully back reclines can be adjusted from 9° to 57° and seat tilting angles from 4° to 34°. The casters are 7"*1" PU wheels with height adjustable forks and the rear wheels are 24"*1-3/8" polyurethane spoke wheels (R106) or 12-1/2"*2-1/4" polyurethane spoke wheels (R136). The wheelchair also has a shear reduction system: by carefully aligning the pivot points of the user and the Recline Backrest of the wheelchair, to minimize the sliding down of the user and also minimize the shear force and pressure against the back. The armrest height can be adjusted from 8" to 12". Its seat width is also adjustable: 16" /17" /18" /19" and 20" and seat depth: 18" /19" and 20".

The upholstery of the device complies with ISO 7176-16:2012 Resistance to ignition of postural support devices.

The device can be operated indoors, or outdoors on dry, level surfaces composed of concrete, blacktop, or asphalt under normal driving conditions.

Discussions of Non-clinical Tests Performed for Determinations of Substantial equivalence are as follows:

ISO 7176-1:2014	Determination of Static Stability
ISO 7176-3:2012	Determination of effectiveness of brakes
ISO 7176-5:2008	Determination of overall dimensions, mass and maneuvering space
ISO 7176-7:1998	Method of Measurement of Seating and Wheel Dimensions
ISO 7176-8:2014	Requirements and test methods for static, impact and fatigue strengths
ISO 7176-11:2012	Test dummies
ISO 7176-13:1989	Determination of coefficient of friction of test surfaces
ISO 7176-15:1996	Requirements for Information Disclosure, Documentation and Labeling
ISO 7176-16:2012	Resistance to ignition of postural support devices
ISO 14971:2007	Medical devices -- Application of risk management to medical devices
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

The results of the testing confirm that the device meets specifications and is substantially equivalent to the predicate device.

Comparison of the Technological Characteristics:

The Merits Model R106/R136 Rehab Wheelchair, is substantially equivalent to the ORION Ⅱ(Heavy Duty 350lbs and 500lbs) mechanical wheelchair (K101277). Both products are mechanical designed for use as personal manual mobility aids. Performance characteristics and drive mechanisms are similar and all have the same intended function and use which is to provide mobility to persons limited to a sitting position. Additional, they are all constructed from the same basic materials, have the same basic operational principles or operated by others. The comparison table is as follow:

Characteristics		**The Merits Model R106 Rehab Wheelchair**	**The Merits Model R136 Rehab Wheelchair**	**ORION Ⅱ(Heavy Duty 350lbs and 500lbs) mechanical wheelchair (K101277)**
Indications for Use		To provide mobility to persons limited to a sitting position.	To provide mobility to persons limited to a sitting position.	To provide mobility to persons limited to a sitting position.
Dimension	**Length**	47.5” (±1”)	44.5(±1”)	47”
	Width	28-32” (±1”)	26”-30” (±1”)	24.5-33.5"
	Height	42” (±1”)	42” (±1”)	42"
Weight	**Total**	89 lbs	62 lbs	65 lbs
Weight Capacity		300 lbs	300 lbs	350 lbs
Seat width		16-20”	16-20”	15-24”
Seat height		19-21”	21”	16-20”
Seat depth		18-20”	18-20”	15-24”
Tires		Front: 7”/ Rear: 24”	Front: 7”/ Rear: 12-1/2”	Front: 4”,5”,6”,7”,8”/ Rear: 12”,20”,22”,24”
Headrest		Adjustable	Adjustable	Adjustable
Armrest		Height Adjustable (8”~12”)	Height Adjustable (8”~12”)	Height Adjustable (9-1/2”~14”)
Back Recline		9°~57°	9°~57°	6°~36°(Optional)
Seat Tilt		4°~34°	4°~34°	3°~48°
Elevating Legrest		Standard	Standard	Optional
Seat/Backrest Pad		Cozy Ergonomics PU Foam	Cozy Ergonomics PU Foam	Cozy Ergonomics PU Foam
Rear Axle Position		Multiple	Fixed	Multiple
Shear Reduction		Aligned Backrest Recline & User Pivot Points	Aligned Backrest Recline & User Pivot Points	None
Hand Brake (Brake Force/Dist.)		13.5N/0.5M	13.5N/0.5M	13.5N/0.5M
Frame Construction		Fixed Frame (Not foldable)	Fixed Frame (Not foldable)	Fixed Frame (Not foldable)
Frame Material		Steel	Steel	Steel
Turning Radius		30”~35.8” (76.5cm~91cm)	32”~38.1” (81.5cm~96.8cm)	28”~37” (71cm~94cm)
Safety Feature		Manual Wheel Lock	Manual Wheel Lock	Manual Wheel Lock

The comparison of the technical details between R106/R136 and its predicate device are summarized in the following:

a. Dimension: The dimensions of our device and the predicate are similar. And our device has passed ISO 7176-1:2014 (Determination of Static Stability) and ISO 7176-2:2001(Determination of Dynamic Stability of electric wheelchairs). So there is no deleterious affection of safety and effectiveness about the difference on Dimension with predicated device.
b. Weight: Although the total weight of R106/R136 is heavier than ORION Ⅱ (Heavy Duty 350lbs and 500lbs) mechanical wheelchair (K101277). The device has passed ISO 7176-8 (Requirements and test methods for static, impact and fatigue strengths) test (Please see Appendix IV: Test reports). So there is no deleterious affection of safety and effectiveness about the difference on Weight with predicate device.
c. Cozy Ergonomics Seating System: Both of our devices and the predicate are equipped with similar Cozy Ergonomics PU foam Seat/Backrest Pad, adjustable Headrest and Armrest which can offer the most comfortable seating experiences to users. Our R106/R136 is supplied with a standard Elevating Legrest, while the predicated device is provided it as an option. The Elevating Legrest can provide better strain-relief for legs.
d. Multiple Rear Axle Position: Both our R106 and the predicate device are provided with Multiple Rear Axle Positions to allow users to change its seat height to a best fitting position. But for the attendant control wheelchair, the seat height adjustment is not as important as the stability, so a Fixed Rear Axle Position is used on our R136 device to achieve the most stable position.
e. Shear Reduction: On the predicated device, the Reclined Backrest and user pivot points are not aligned resulting in a non-synchronized movement. As a result, when it reclines, the headrest and back support move up, forcing the user to slide down the chair to compensate. This leads to shear and friction forces. Our R106/R136 devices are carefully designed to align the pivot points of the user and the Recline Backrest of the wheelchair. This minimizes the sliding down of the user while reclining the backrest. And this also minimizes the shear force and pressure against the back.
f. Frame Construction and material: Both of our devices and the predicated device are the same steel, fixed frames.
g. Safety Feature: Both of our devices and the predicated device are equipped with Manual Wheel Locks to prevent unexpected movement while parking.

The minor differences between R106/R136 and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the R106/R136 is safe.

Conclusions

According to comparison table, the differences on weight capacity, adjustable back angle, adjustable armrest height and dimensions do not deleteriously affect the safety and effectiveness of the device.

The non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do no raise any new questions of safety or effectiveness.

So based on the design, performance specifications and testing and intended use, The Merits Model R106/R136 Rehab Wheelchair, is substantially equivalent to the ORION Ⅱ (Heavy Duty 350lbs and 500lbs) mechanical wheelchair (K101277).