March 18, 2022

Merits Health Products Co., LTD.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K220529
Trade/Device Name: Merits P335 Powered Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: February 20, 2022
Received: February 24, 2022

Dear Mr. Yungvirt:

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)*
K220529

Device Name
Merits P335 Powered Wheelchair

Indications for Use *(Describe)*
The Merits P335 Powered Wheelchair is intended to provide indoor and outdoor mobility to persons limited to a seating position that are capable of operating a powered wheelchair.

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 – K220529

I. Submitter:

Merits Health Products Co., LTD.
No.18, Jingke Rd., Nantun Dist.
Taichung City 40852, Taiwan (R.O.C.)

Phone: +886-4-23594985 ext.200
Fax: +886-4-23594992

Contact Person: Martin Tseng
Date Prepared: November 26, 2021

II. Device:

Name of Device: Merits P335 Powered Wheelchair
Common or Usual Name: Powered Wheelchair
Classification Name: Powered Wheelchair (21 CFR 890.3860)
Regulatory Class: II
Product Code: ITI

III. Predicate Device:

Permobil F3 FWD Powered Wheelchair (#K143180)
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. Device Description:

The Merits P335 Powered Wheelchair is battery powered, front wheel motor driven and is controlled by the PG power wheelchair R-net 120 amp controller. The user interface is a joystick. P335 is powered by two 12 VDC 60ah batteries. The batteries are charged by 6A off-board charger connect with 3-pin Microphone Connector to charging socket on joystick. The approximate driving range on fully charged batteries is up to 30km (19mi). The chair frame is a welded steel construction and includes two front drive wheels with drive units (including motor, gear, and brake), batteries and rear pivoting casters. Depending on users' needs, the joystick motor control is mounted to the left or right armrest. When the user activates the joystick, the controller receives a signal to release the brakes. With the brakes released, the wheelchair is allowed to move in the direction the joystick is actuated. When the user releases the joystick, the chair slows to a stop and the brakes are automatically re-engaged. The solenoid electromechanical brakes allow the user stop by letting go of the joystick.
The device is equipped with a Power Seating System consists of a power tilt unit, a power recline module and an optional power elevating seat module. The tilt, reclining and elevating systems are actuated by 24V DC motorized linear actuator. The tilt system includes one motorized linear actuator caused

the seat frame to shift forward. This enhances stability since the center of gravity is kept substantially in place while the user is tilting. The recline system include one motorized linear actuator change the position of the backrest with respect to the seat pan. The optional elevating seat module use one motorized linear actuator which allows the user to elevate the seat pan for easy accessing things stored in higher places.

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

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

The Merits P335 is substantially equivalent to Permobil F3 FWD Powered Wheelchair (#K143180). Both products are battery power, motorized vehicles designed for use as personal power mobility aids. Performance characteristics and drive mechanisms are similar and all have the same intended function and use which is to provide indoor and outdoor mobility to persons limited to a seating position that are capable of operating a powered wheelchair. Additional, they are all constructed from the same basic materials, have the same basic operational principles and all use DC batteries as their source of power.

Although there are some minor differences between P335 and its predicate device. But they raise no new issues of safety or effectiveness. Performance data demonstrate that Merits P335 is safe. 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.

V. Indications for Use:

The Merits P335 Powered Wheelchair is to provide indoor and outdoor mobility to persons limited to a seating position that are capable of operating a powered wheelchair.

The Indications for Use for the Merits P335 is identical to the predicate device.

VI. Comparison of Technological Characteristics with The Predicate Device:

The Merits P335 Powered Wheelchair is substantially equivalent to the Permobil F3 Powered Wheelchair (K143180). Both products are battery power, motorized vehicles designed for use as personal power mobility aids. Performance characteristics and drive mechanisms are similar and all have the same intended function and use. The detailed comparison table is as follow:

Description	Merits P335 Power Wheelchair K220529	Permobil F3 Powered Wheelchair K143180
Manufacturer	Merits Health Products Co., LTD.	Permobil AB
Model	P335	F3
Intended Use	To provide indoor and outdoor mobility to persons limited to a seating position that are capable of operating a powered wheelchair.	To provide indoor and outdoor mobility to persons limited to a seating position that are capable of operating a powered wheelchair.

Framework		Steel welded frame	Steel welded frame
Overall Dimensions	Length	39.6” (±0.6”)	40”
	Width	24.7” (±0.6”)	24"
	Height	42” (±0.6”)	38"
Seat Dimensions	Width	14~22” (±0.6”)	17~23”
	Depth	18” (±0.6”)	18"
	Height	17.5~19.5” (±0.6”) From Ground	17.5~19.5” From Ground
Weight	Total	386.1lb	386 lb
	Base	147 lb	169 lb
	Seat	122 lb	140 lb
	Footplate	40.1lb	
	Battery	38.5lb*2pcs	38.5lb*2pcs
Unit Configuration		Front Wheel Drive	Front Wheel Drive
Weight Capacity		300 lb	300 lb
Gradient		7.5°	6°
Obstacle Climbing		2.4”(60mm)	2.4”(60mm)
Turning Radius		26.6”	26.6”
Ground Clearance		3”	3”
Drive Wheel Tires		O.D.=355.6mm (14”) Foam Filled Tire I.D.=203.2mm (8”) Width=76.2mm(3”)	O.D.=355.6mm (14”) Foam Filled Tire I.D.=203.2mm (8”) Width=76.2mm(3”)
Caster Tires		225x70 mm (9”) Foam Filled Tire	210x65 mm (8”) Foam Filled Tire
Anti-Tip Wheel		100x24 mm (4”) Non-Removable	100x24 mm (4”) Non-Removable
Suspension		Front/ Rear Gas Spring	Front/ Rear Gas Spring
Max. Speed		6 mph	6 mph
Range up to		19miles	20 miles
Brake System		Electronic braking by drive motor. Magnetic parking brakes	Electronic braking by drive motor. Magnetic parking brakes
Motor		2 Pole, 24Vdc Motor	2 Pole, 24Vdc Motor
Controller		PG R-net 120A	PG R-net 120A
Battery		2*12V 60Ah Lead Acid Battery	2*12V 60Ah Lead Acid Battery
Charger		Type: Off-board charger Input: 100-240Vac, 50/60Hz, 2.5A Output: 6A /24Vdc	Type: Off-board charger Input: 100-240Vac, 50/60Hz, 3.8A Output: 8A /24Vdc
Footplate		Yes	Yes
Tilt		Yes	Yes
Recline		Yes	Yes
Elevate		Optional	Optional
Backrest Cover		Vinyl Fabric	Vinyl Fabric
Backrest Upholstery		PU Foam	PU Foam
Cushion cover		Vinyl Fabric	Vinyl Fabric
Cushion Upholstery		PU Foam	PU Foam
Armrest Type		PU Foam	PU Foam

There are some differences between P335 and its predicate device:

a. Dimension: The dimensions of the Merits P335 is equivalent in size to the Premobil F3 (K143180). Although there are some differences, the device passed ISO 7176-1 (Determination of Static Stability) and ISO 7176-2 (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. Gradient: The Merits P335 has a larger Gradient than the Permobil F3 (K143180). The device has passed ISO 7176-2 (Determination of Dynamic

Stability of electric wheelchairs) & ISO 7176-3 (Determination of Efficiency of Brake of Electric Wheelchair) test. So there is no deleterious affection of safety and effectiveness about the difference on Gradient with predicated device.

c. Rear Caster size: The Merits P335 is equipped with 2 larger 9" Casters, which give the same or better curb climbing ability than the Permobil F3 (#K143180) 8" Castors while moving backward. There is no deleterious affection of safety and effectiveness about the difference on Rear Castor size with predicated device.
d. Weight: Although the total weight of P335 is slightly heavier than Permobil F3 Powered Wheelchair (K143180). The device has passed ISO 7176-8 (Requirements and test methods for static, impact and fatigue strengths) test. So there is no deleterious affection of safety and effectiveness about the difference on Weight with predicated device.
e. Charger: The Merits P335 uses a 6A off-board charger which is smaller than the 8A off-board charger used on Permobil F3 (K143180). This will slightly increase the charging time needed for the same 60Ah batteries. But the charger has passed the ISO 7176-25 (Batteries and charger for powered wheelchairs) test. So there is no deleterious affection of safety and effectiveness about the difference on charger with predicated device.

The minor differences between P335 and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the P335 is safe.

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.

VII. Performance Data

The following Non-clinical Tests have been Performed in support of the substantial equivalence determination:

STD No.	Title of Standard	FDA Rec. No.
ISO 7176-1:2014	Determination of Static Stability	16-195
ISO 7176-2:2017	Determination of Dynamic Stability of electric wheelchairs	16-202
ISO 7176-3:2012	Determination of effectiveness of brakes	16-192
ISO 7176-4:2008	Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range	16-162
ISO 7176-5:2008	Determination of overall dimensions, mass and maneuvering space	16-163
ISO 7176-6:2018	Determination of maximum speed, acceleration and deceleration of electric wheelchairs	16-204
ISO 7176-7:1998	Method of Measurement of Seating and Wheel Dimensions	16-196
ISO 7176-8:2014	Requirements and test methods for static, impact and fatigue strengths	16-197
ISO 7176-9:2009	Climatic tests for wheelchairs	16-167
ISO 7176-10:2008	Determination of obstacle-climbing ability of electrically power wheelchairs	16-164
ISO 7176-11:2012	Test dummies	16-190
ISO 7176-13:1989	Determination of coefficient of friction of test surfaces	16-25
ISO 7176-14:2008	Power and control systems for electrically powered wheelchairs and scooter- Requirements and test methods.	16-165
ISO 7176-15:1996	Requirements for Information Disclosure, Documentation and Labeling	16-27
ISO 7176-16:2012	Resistance to ignition of postural support devices	16-191
ISO 7176-21:2009	Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers.	16-166
ISO 7176-25:2013	Batteries and charger for powered wheelchairs	16-194
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2-258
IEC60601-1-2:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-36

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

Biocompatibility Evaluation

A Biocompatibility Evaluation has been performed according to the ISO 10993-1:2018. As the skin contact components listed below are identical to those used on our premarket devices in formulation, processing sterilization and geometry, and no other chemical have been added (e.g. plasticizers, fillers, color additives, cleaning agents, mold release agents). There is no need for any more Biocompatibility tests.

	Merits P335	**Merits P322**	**Merits Model R Series**	**Same or Different**
K Number	**K220529**	**K122357**	**K113577**	N/A
Product Code	ITI	ITI	ITI	Same
Seat Cushion: Supplier:	Vinyl Fabric ROODINSEAT Corp.	Vinyl Fabric ROODINSEAT Corp.	Vinyl Fabric ROODINSEAT Corp.	Same
Backrest Cushion: Supplier:	Vinyl Fabric ROODINSEAT Corp.	Vinyl Fabric ROODINSEAT Corp.	Vinyl Fabric ROODINSEAT Corp.	Same
Armrest Pad Material: Supplier:	PU Foam WELL YI CO., LTD.	PU Foam WELL YI CO., LTD.	PU Foam WELL YI CO., LTD.	Same
Footrest Pad Material: Supplier:	PU Foam WELL YI CO., LTD.	PU Foam WELL YI CO., LTD.	PU Foam WELL YI CO., LTD.	Same

VIII. Conclusions

According to comparison table, the differences on function of elevate, recline and dimension of width do not deleteriously affect the safety and effectiveness of the device.

So based on the design, performance specifications and testing and intended use, the Merits P335 Powered Wheelchair is substantially equivalent to Permobil F3 FWD Powered Wheelchair (#K143180).