June 16, 2021

Mobius Mobility
Joseph Sullivan
QA / RA Manager
540 Commercial St. Suite 310
Manchester, New Hampshire 03101

Re: K210920
Trade/Device Name: iBOT® Personal Mobility Device ("iBOT® PMD")
Regulation Number: 21 CFR 890.3890
Regulation Name: Stair-Climbing Wheelchair
Regulatory Class: Class II
Product Code: IMK, ITI
Dated: March 25, 2021
Received: March 29, 2021

Dear Mr. Sullivan:

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,

For 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)*
K210920

Device Name
iBOT® Personal Mobility Device (iBOT® PMD)

Indications for Use *(Describe)*
The iBOT® Personal Mobility Device ("iBOT® PMD") is intended to provide indoor and outdoor mobility to persons restricted to a sitting position who meet the requirements of the user assessment and training certification program. The device allows for the option to climb stairs. Companions who are required to provide assistance during Assisted Stair Climbing Mode must meet the requirements of the training certification program. The iBOT® Personal Mobility Device ("iBOT® PMD") Occupied Transport option is indicated for providing persons, unable to transfer from their wheelchair into a standard factory motor vehicle seat, the option for transportation while seated in their iBOT® PMD 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

This 510(k) summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR 807.92.

Date Prepared: March 22, 2021

Submitter's Information

510(k) Sponsor:	Mobius Mobility 540 North Commercial Street Suite 310 Manchester, NH 03101
Contact Person:	Joseph Sullivan QA / RA Manager Mobius Mobility Phone: (833) 346-4268 Fax: (603) 621-0789 jsullivan@mobiusmobility.com

Device Information

Common/Usual Name:	Stair-climbing wheelchair
Trade/Proprietary Name:	iBOT® Personal Mobility Device ("iBOT® PMD")
Classification Name:	Stair-climbing wheelchair
Device Classification:	890.3890
2nd Device Classification:	890.3860
Primary Product Code (stair feature):	IMK
Secondary Product Code:	ITI
Device Panel:	Physical Medicine

Predicate Device(s)

The iBOT® PMD is substantially equivalent to the Next Generation iBOT®, which was previously cleared under 510(k) #K172601.

Reference Device

Permobil F5 Corpus VS (K191874).

Device Description

The proposed device is an update to the previously cleared device Next Generation iBOT® (K172601). The device retains all the following from the original device including:

> The device is a multi-mode powered wheelchair that enables users to maneuver in confined spaces, climb curbs, stairs, and other obstacles. The device is intended to provide indoor and outdoor mobility, including stair climbing, to persons limited to a seated position who are capable of operating a powered wheelchair.
>
> The device still includes active stabilization in multiple driving modes and allows for traversing aggressive and difficult terrain and operation at an elevated seat height. This elevated seat height offers benefits in activities of daily living (e.g., accessing higher shelves) and interaction with other people at "eye level" while either stationary or moving.
>
> The proposed device still utilizes the primary components of a stair climbing power wheelchair including drive wheels, frame, sealed electronics, sensors, battery packs, motors, seating, active stability system and battery charger. It can also be produced without the stair climbing function.

In addition, the device will incorporate the following updates to the Next Generation iBOT® design:

- Allows for occupied transportation in a motor vehicle
- Incorporates the use of an alternate seating system, mounting and peripherals
- Wheel gear train changed from spur to helical
- Redesigned brake release lever mechanism
- Changes of materials / processes in support of Design for Manufacturing efforts
- Software revisions / changes
- Incorporates change of the Trade name to iBOT® PMD
- Updates contraindications to increase clarity

Indications for Use

The iBOT® Personal Mobility Device ("iBOT® PMD") is intended to provide indoor and outdoor mobility to persons restricted to a sitting position who meet the requirements of the user assessment and training certification program. The device allows for the option to climb stairs. Companions who are required to provide assistance during Assisted Stair Climbing Mode must meet the requirements of the training certification program. The iBOT® Personal Mobility Device ("iBOT® PMD") Occupied Transport option is indicated for providing persons, unable to transfer from their wheelchair into a standard factory motor vehicle seat, the option for transportation while seated in their iBOT® PMD wheelchair.

Comparison to Predicate Device and Reference Device

The proposed device has similar technological characteristics and mobility functions as compared to the predicate device. The design modifications were done to do the following:

- Add indication for use as a seat in a motor vehicle
- Take advantage of improvements in technology since the Next Generation iBOT® was originally cleared

Where appropriate, component design has been maintained from the Next Generation iBOT®. The overall system architecture and fundamental technology from the Next Generation iBOT® has been maintained.

The reference device was chosen to demonstrate substantial equivalence for the following components and features on the device:

- Occupied Transportation Options
- Power Wheelchair Seating System cleared for use in a motor vehicle

The first table below shows the similarities and differences between the predicate and proposed devices. The second table below shows the similarities and differences between the reference and proposed devices. We believe the proposed modifications from the predicate device or reference devices do not raise new questions regarding safety or effectiveness of the device.

Table of Comparisons from Predicate Device to Proposed Device

Characteristic	Predicate Device (Next Generation iBOT®) (K172601)	Proposed (iBOT® PMD)	Assessment of difference (if applicable)
General Characteristics			
Indications for Use	The Next Generation iBOT® is intended to provide indoor and outdoor mobility to persons restricted to a sitting position who meet the requirements of the user assessment and training certification program. The device is intended to climb stairs. Companions who are required to provide assistance during Assisted Stair Climbing Mode must meet the requirements of the training certification program.	The iBOT® Personal Mobility Device ("iBOT® PMD") is intended to provide indoor and outdoor mobility to persons restricted to a sitting position who meet the requirements of the user assessment and training certification program. The device allows for the option to climb stairs. Companions who are required to provide assistance during Assisted Stair Climbing Mode must meet the requirements of the training certification program. The iBOT® Personal Mobility Device ("iBOT® PMD") Occupied Transport option is indicated for providing persons, unable to transfer from their wheelchair into a standard factory motor vehicle seat, the option for transportation while seated in their iBOT® PMD wheelchair.	The modifications to the Indications for Use to make the stair-climbing functions optional and to add the (optional) Occupied Transport capability do not constitute a new intended use and do not introduce new issues of safety and effectiveness.
Manufacturer	DEKA Research & Development	Mobius Mobility, LLC	Product continues to be designed by DEKA and is now distributed by Mobius Mobility.
Product Code	IMK	IMK, ITI	No product difference, applying for additional code for non-stair climbing version

Characteristic	Predicate Device (Next Generation iBOT®) (K172601)	Proposed (iBOT® PMD)	Assessment of difference (if applicable)
General Characteristics			
Contraindications	• Weigh less than 50 lbs. (22.5 kg) or more than 300 lbs. (136kg) • Have lost consciousness or had a seizure in the past 90 days (there are some exceptions, ask your clinician for details) • Have a condition where jarring forces could cause fractures • Have not successfully completed the user training program • Need a mechanical ventilator	• Weigh less than 50 lbs. (22.5 kg) or more than 300 lbs. (136kg) • Are at risk for seizure or loss of consciousness. • Are at risk of fracture while driving over rough terrain or while experiencing jarring forces related to rapid iBOT® PMD transitions. • Have not successfully completed the user training program • Need a mechanical ventilator	Wording updated for clarity. No new risks identified.
Physical Characteristics			
Drive wheel type	Pneumatic or foam-filled. 5 bolt pattern, split rim design.	Pneumatic or foam-filled. 5 bolt pattern, split rim design.	No change
Caster assembly	Standard caster wheel with suspension assembly	Standard caster wheel with suspension assembly	No change
Batteries	Four or Six Li-ion batteries, each rated 57.6 VDC, 5.1 Ah	Four or Six Li-ion batteries, each rated 57.6 VDC, 5.1 Ah	No change

Characteristic	Predicate Device (Next Generation iBOT®) (K172601)	Proposed (iBOT® PMD)	Assessment of difference (if applicable)
Physical Characteristics			
Communication with external applications/devices	Bluetooth 4.2 Low Energy	Bluetooth 4.2 Low Energy	No change
Drive system	Rear wheel drive, 4-wheel drive, 2-wheel balancing	Rear wheel drive, 4-wheel drive, 2-wheel balancing	No change
Operating modes	Standard, 4-Wheel, Balance, Stair-climbing, Remote	Standard, 4-Wheel, Balance, Stair-climbing, Remote, Docking	One additional mode option (docking) available. Design follows structure for other modes available in the controller and does not involve additional safety risk. Confirmation done through human factors testing to ensure no new risks emerged in use.
Inertial Measurement	MEMS based sensors	MEMS based sensors	No change
Wheel gear train	Spur Gear	Helical Gear	Gear changed to reduce drive noise. No new risks identified.
Position monitoring	Internal absolute position sensor	Internal absolute position sensor	No change
System Communication	CAN bus	CAN bus	No change
Weight (including batteries)	242.5 lb.	242.5 lb.	No change
Device Performance			
Driving Range	15.5 miles	15.5 miles	No change

Characteristic	Predicate Device (Next Generation iBOT®) (K172601)	Proposed (iBOT® PMD)	Assessment of difference (if applicable)
Device Performance			
Dynamic stability	10 degrees (standard) 12 degrees (4 wheel) 8 degrees (balance)	10 degrees (standard) 12 degrees (4 wheel) 8 degrees (balance)	No change
Max Speed Settings by Mode	Standard: 6.7 mph 4-Wheel: 5.2 mph Balance: 3.3 mph	Standard: 6.7 mph 4-Wheel: 5.1 mph Balance: 3.5 mph Docking: 0.6 mph	Docking mode added.
Maximum user weight capacity	300 lb.	300 lb.	No change
Obstacle Climbing	5 in. (in 4 wheel mode)	5 in. (in 4 wheel mode)	No change
Turning Radius	24.5 in. – 33.8 in. (dependent on mode)	24.5 in. – 33.8 in. (dependent on mode)	No change
User Interface Features			
Seating	Gen 3 Seat	Maxx Rehab Seat	Equivalent in: • Safety features • General design • Standards met • Seat angles • Movement, including angles and heights They differ in: • Modularity • Seat Interface • Peripherals • Stair Assist Handle • Available seat sizes

Table of Comparisons from Predicate Device to Proposed Device

Characteristic	Predicate Device (Next Generation iBOT®) (K172601)	Proposed (iBOT® PMD)	Assessment of difference (if applicable)
User Interface Features			
User controller, joystick, screen, buttons, etc.	User controller with integrated joystick, display, buttons, speed setting reduction wheel, and optional toggle switches. The user controller incorporates user assist confirmation. Power off request button located on the powerbase.	User controller with integrated joystick, display, buttons, speed setting reduction wheel, and optional toggle switches. The user controller incorporates user assist confirmation. Power off request button located on the powerbase.	No change
Transportation	Unoccupied Transport Option	Unoccupied Transport Option Occupied Transport Options	Equivalent in: • Both have 4 tie down loops to secure device in vehicle Differences: • Testing done to allow tie down loops to be used while device is occupied in vehicle • Interface to docking system added to allow alternate method of securing occupied device in vehicle • Occupied Transport version complies with ISO 7176-19. Risks specific to the occupied transport option were identified via FMEA. All risk mitigations were successfully verified/validated with no impact to safety or effectiveness of the device.

Table of Comparisons from Reference Device to Proposed Device

Characteristic	Reference (Permobil F5 Corpus VS) (K191874)	Proposed (iBOT® PMD)
General Characteristics		
Indications for Use	The F5 Corpus VS powered wheelchair is to provide indoor and outdoor mobility, including stand-up feature, to persons limited to a seating position that are capable of operating a powered wheelchair.	The iBOT® Personal Mobility Device ("iBOT® PMD") is intended to provide indoor and outdoor mobility to persons restricted to a sitting position who meet the requirements of the user assessment and training certification program. The device allows for the option to climb stairs. Companions who are required to provide assistance during Assisted Stair Climbing Mode must meet the requirements of the training certification program. The iBOT® Personal Mobility Device ("iBOT® PMD") Occupied Transport option is intended to provide persons, unable to transfer from their wheelchair into a standard factory motor vehicle seat, the option for transportation while seated in their iBOT® PMD wheelchair.
Product Code	IPL, ITI	IMK, ITI
Physical Characteristics		
Drive wheel type	Pneumatic or foam-filled.	Pneumatic or foam-filled.
Caster assembly	Standard caster wheel with suspension assembly	Standard caster wheel with suspension assembly
Batteries	2 x 12V 73 Ah gel Group M24	Four or Six Li-ion batteries, each rated 57.6 VDC, 5.1 Ah
Communication with external applications/devices	Bluetooth	Bluetooth
Drive system	Front wheel drive, standing	Rear wheel drive, 4-wheel drive, 2-wheel balancing

Characteristic	Reference (Permobil F5 Corpus VS) (K191874)	Proposed (iBOT® PMD)
Operating modes	Standard, Stand-Up	Standard, 4-Wheel, Balance, Stair-climbing, Remote, Docking
Position monitoring	Internal position sensors	Internal absolute position sensor
System Communication	CAN bus	CAN bus
Weight (including batteries)	421 lb.	242.5 lb.
Device Performance		
Driving Range	Up to 16 miles	15.5 miles
Max Speed Settings	Up to 7.5 mph	Up to 6.7 mph
Maximum user weight capacity	300 lb.	300 lb.
Obstacle Climbing	3 in.	5 in. (in 4-wheel mode)
Turning Radius	30”	24.5 in. – 33.8 in. (dependent on mode)
User Interface Features		
Seating	Corpus	Maxx Rehab Seat
User controller, joystick, screen, buttons, etc.	User controller with integrated joystick, display, buttons, speed setting reduction wheel, and optional toggle switches.	User controller with integrated joystick, display, buttons, speed setting reduction wheel, and optional toggle switches.
Transportation	Unoccupied Transport Option Occupied Transport Options • 4 Point Tie-Down Docking	Unoccupied Transport Option Occupied Transport Options • 4 Point Tie-Down Docking

Performance Data

The following performance testing was conducted to demonstrate that the proposed device complies with the 21 CFR 890.3890, 21 CFR 890.3860, special controls and recognized standards. This testing demonstrates substantial equivalence to the predicate device through:

- evaluation to current versions of the standards used in testing of the predicate device; with modification for updates in battery technology,
- software testing per the current version of FDA guidance on software testing, and
- usability testing focused on changes in the user interface when compared with the predicate device.

A summary of the testing performed is provided below.

Bench Testing

The proposed device has been demonstrated to comply with the following standards:

1. IEC 62133:2012 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
2. ISO 7176-1:2014 Wheelchairs – Part 1: Determination of Static Stability
3. ISO 7176-2:2017 Wheelchairs – Part 2: Determination of Dynamic Stability of Electrically Powered Wheelchairs
4. ISO 7176-3:2012 Wheelchairs – Part 3: Determination of Effectiveness of Brakes
5. ISO 7176-4:2008 Wheelchairs – Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
6. ISO 7176-5:2008 Wheelchairs – Part 5: Determination of dimensions, mass and maneuvering space
7. ISO 7176-6:2018 Wheelchairs – Part 6: Determination of Maximum Speed, Acceleration & Retardation for Electric Wheelchairs
8. RESNA WC-1:2019, Section 7 – Wheelchairs – Method of measurement of seating and wheel dimensions
9. ISO 7176-8:2014 Wheelchairs – Part 8: Requirements & Test Methods for Static, Impact & Fatigue Strengths

10. ISO 7176-9:2009 Wheelchairs – Part 9: Climatic tests for electric wheelchairs

11. ISO 7176-10:2008 Wheelchairs – Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs

12. ISO 7176-11: 2012 Wheelchairs — Part 11: Test dummies

13. ISO 7176-13: 1989 Wheelchairs – Part 13: Determination of coefficient of friction of test surfaces

14. ISO 7176-14 2008 Wheelchairs – Part 14: Power & Control Systems for Electric Wheelchairs-Requirements & Test Methods

15. ISO 7176-15:1996 Wheelchairs – Part 15: Requirements For Information Disclosure, Documentation And Labeling

16. ISO 7176-16:2012 Wheelchairs – Part 16: Resistance to Ignition of Postural Support Devices

17. ISO 7176-19: 2008 Wheelchairs- Part 19: Wheeled Mobility Devices for Use as Seats in Motor Vehicles

18. ISO 7176-21:2009 Wheelchairs – Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers

19. ISO 7176-22:2014 Wheelchairs-Part 22: Set Up Procedures

20. ISO 7176-25:2013 Wheelchairs - Part 25: Batteries and Chargers for Powered Wheelchairs

21. ISO 7176-28:2012 Wheelchairs – Part 28: Requirements And Test Methods For Stair-Climbing Devices

22. ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

23. ISO 10993-3:2014 Biological evaluation of medical devices – Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity

24. ISO 10993-5:2014 Biological evaluation of medical devices – Part 5: Tests for in Vitro Cytotoxicity

25. ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for Irritation and Skin Sensitization

26. UL 2054:2004 Household and Commercial Batteries

27. UN 38.3 United Nations, New York & Geneva, Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Subsection 38.3

28. AIM 7351731 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers

Software Testing

Software development and validation was conducted according to IEC 62304 and the FDA guidance document *General Principles of Software Validation – Final Guidance for Industry and FDA Staff*.

Software documentation is included according to the FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* for Major level of concern for the software embedded in the Next Generation iBOT® stair-climbing wheelchair.

Cybersecurity risks were assessed and documentation is included based on the FDA's *Guidance of Premarket Submissions for Management of Cybersecurity in Medical Device*.

Usability Testing

A usability evaluation was conducted on the elements of the device (selection of docking mode and use of pin and loop interfaces for occupied transportation) which have changed from the predicate device (Next Generation iBOT® #K172601). There have been no changes to the intended use environment, other modes of operation or drive architecture.

Conclusion

The performance data included in this premarket notification demonstrate that the proposed device is as safe and effective as the Next Generation iBOT® predicate device. Mobius Mobility finds the iBOT® PMD to be substantially equivalent to the predicate device.