January 30, 2025

Mobius Mobility
Joseph Sullivan
Director of Quality Assurance & Regulatory Affairs
540 Commercial St. Suite 310
Manchester, New Hampshire 03101

Re: K243442
Trade/Device Name: iBOT® PMD
Regulation Number: 21 CFR 890.3890
Regulation Name: Stair-Climbing Wheelchair
Regulatory Class: Class II
Product Code: IMK, ITI
Dated: November 1, 2024
Received: November 6, 2024

Dear Joseph 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tushar Bansal -S

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and Rehabilitation 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243442

Device Name
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. The device allows for the option to climb stairs. The operator(s), either the wheelchair occupant or an assistant, must meet the requirements of the training certification program. The wheelchair occupant must meet the requirements of the user assessment.

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.

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510(K) SUMMARY

This 510(k) summary for K243442 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: November 1, 2024

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
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Device Information

Common/Usual Name:	Stair-climbing wheelchair
Trade/Proprietary Name:	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 iBOT® Personal Mobility Device ("iBOT PMD"), which was previously cleared under K210920.

Device Description

The proposed device is an update to the previously cleared iBOT® PMD (K210920). 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 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.
>
> The device still allows occupied transportation while an individual is seated in the wheelchair through both a 4-point tie down system and a docking system.

In addition, the device incorporates the following updates to the iBOT® PMD design:

- Modified the device to add the Motion Concepts Modular Power Positioning Seating System (K150574) as an option / accessory which includes greater degrees of posterior tilt, power recline with shear reduction, and power elevating legrests
- Adds anterior tilt to the power positioning options available on the product
- Adds the existing power seat elevation to the Standard Mode of the device
- Updates that operator of the chair can be the occupant or an attendant to increase clarity
- Updates contraindications to increase clarity
- Adds optional seat interface brackets that include seat height and static tilt angle adjustments
- Minor redesign of front casters and changes of materials / processes in support of design for manufacturing efforts
- Software revisions / changes
- Removes the contraindication for a mechanical ventilator mount. A ventilator mount can be added to the device, when the device is modified to remove stair and balance modes.

Indications for Use

The iBOT® Personal Mobility Device ("iBOT® PMD") is intended to provide indoor and outdoor mobility, including the option to climb

stairs, to persons restricted to a sitting position. The device allows for the option to climb stairs. The operator(s), either the wheelchair occupant or an assistant, must meet the requirements of the training certification program. The wheelchair occupant must meet the requirements of the user assessment.

Comparison to Predicate Device

The proposed device has similar technological characteristics and mobility functions as compared to the predicate device. The design modifications were done to add an option of a seating system that allows for full powered tilt, recline, and/or elevating leg rests (K150574).

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

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

Table of Comparisons from Predicate Device to Proposed Device

Characteristic	Predicate Device (iBOT® PMD K210920)	Proposed (iBOT® PMD)	Assessment of difference (if applicable)
General Characteristics			
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.	The iBOT® Personal Mobility Device ("iBOT® PMD") is intended to provide indoor and outdoor mobility to persons restricted to a sitting position. The device allows for the option to climb stairs. The operator(s), either the wheelchair occupant or an assistant, must meet the requirements of the training certification program. The wheelchair occupant must meet the requirements of the user assessment.	The modifications to the indications for use were made to clarify that the trained operator in control of the device could be either the wheelchair occupant or an assistant. This does not constitute a new intended use and does not introduce issues of safety and effectiveness. An additional modification to the indications for use was to remove the occupied transport because it's an option.
Characteristic	**Predicate Device (iBOT® PMD K210920)**	**Proposed (iBOT® PMD)**	**Assessment of difference (if applicable)**
General Characteristics			
Manufacturer	Mobius Mobility, LLC	Mobius Mobility, LLC	No change
Product Code	IMK, ITI	IMK, ITI	No change

Characteristic	Predicate Device (iBOT® PMD K210920)	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) • 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	• Weigh less than 50 lb (22.5 kg) • Weigh more than 300 lb (136 kg). • Weigh more than 275 lb (125 kg) if the device has any combination of the 55 degree tilt, recline, or elevating legrest. • Have uncontrolled seizures or loss of consciousness. • Have a known serious risk for fractures due to jarring forces. • Have not successfully completed the user training program.	Weight capacity updated to reflect original seat and new additional power positioning options. Mechanical ventilator mount added to system. Wording for contraindications updated for clarity. No new issues of safety or effectiveness.
Physical Characteristics			
Drive wheel type	Pneumatic, 5 bolt pattern, split rim design – 2-inch width.	Pneumatic, 5 bolt pattern, split rim design – 2-inch or 4-inch width.	Added 4-inch width option. No new issues of safety or effectiveness.
Caster assembly	Standard caster wheel with suspension assembly	Standard caster wheel with suspension assembly	Casters redesigned since predicate. No functional change. No new issues of safety or effectiveness.
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 (iBOT® PMD K210920)	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, Docking	Standard, 4-Wheel, Balance, Stair-climbing, Remote, Docking	No change
Inertial Measurement	MEMS based sensors	MEMS based sensors	No change
Wheel gear train	Helical Gear	Helical Gear	No change
Position monitoring	Internal absolute position sensor	Internal absolute position sensor	No change
System Communication	CAN bus	CAN bus and UART	No change for iBOT. UART is used for communication to the Modular Power Positioning System. No new issues of safety or effectiveness.
Weight (including batteries)	242.5 lb.	242.5 lb. (without Modular Power Positioning System) 295.0 lb. (with Modular Power Positioning System)	Weight of the system with optional Modular Power Positioning System added. No new issues of safety or effectiveness.
Device Performance			
Driving Range	15.5 miles	14.3 miles	Updated testing done with seat changes. No new issues of safety or effectiveness.

Characteristic	Predicate Device (iBOT® PMD K210920)	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: 5.1 mph Balance: 3.5 mph Docking: 0.6 mph	Standard: 6.8 mph 4-Wheel: 5.1 mph Balance: 3.5 mph Docking: 0.6 mph	No change in electronics that impact speed. No new issues of safety or effectiveness.
Maximum user weight capacity	300 lb. with Maxx Rehab Seat	300 lb. without Modular Maxx Rehab Seat 275 lb. with Modular Ultra Low Maxx Seat with power positioning options.	Maximum weight capacity reduced for devices with seating systems that include any combination of 55-degree tilt, recline, or elevating leg rests.
Obstacle Climbing	5 in. (in 4-wheel mode)	6 in. (in 4-wheel mode)	Increased obstacle height. No new issues of safety or effectiveness.
Turning Radius	24.5 in. – 33.8 in. (dependent on mode)	24.5 in. – 37 in. (dependent on mode)	Due to length of the seating system.
User Interface Features			
Seating	Maxx Rehab Seat	Maxx Rehab Seat Ultra Low Maxx Rehab Seat with power positioning options.	Added seating options that allow for full tilt, recline, and/or elevating leg rests. Risks specific to the power positioning options were identified via FMEA. All risk mitigations were successfully verified / validated with no impact to safety or effectiveness of the device.
Power Seat Elevation	Available in 4-Wheel, Balance and Stair modes. Seat elevation height maximum of 17”.	Available in 4-Wheel, Balance, Stair and Standard modes. Seat elevation height maximum of 17”.	Added existing functionality in the powerbase to Standard mode.

			Risks specific to adding elevate to Standard mode were identified via FMEA. All risk mitigations were successfully verified / validated with no impact to safety or effectiveness of the device.

Characteristic	Predicate Device (iBOT® PMD K210920)	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.	Color Joystick (also named user controller) with integrated joystick, display, buttons, speed setting reduction wheel, and optional toggle switches. The color joystick incorporates user assist confirmation. Power off request button located on the powerbase.	Updated terminology. No change to design or function.
Transportation	Unoccupied Transport Option Occupied Transport Options	Unoccupied Transport Option Occupied Transport Options	No change

Performance Data

The following performance testing was conducted to demonstrate that the proposed device complies with 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

A summary of the testing performed is provided below.

Performance Testing

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

1. IEC 62133-2:2021 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. ANSI 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. ANSI RESNA WC-1:2019 Section 16 Resistance to Ignition of Postural Support Devices

17. ISO 7176-19: 2022 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 7176-30:2018 Wheelchairs for changing occupant posture

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

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

25. ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in Vitro Cytotoxicity

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

27. UL 2054:2021 Household and Commercial Batteries

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

29. EN 1021-1:2014 Furniture: Assessment of ignitability of upholstered furniture. Ignition source smouldering cigarette.

30. EN 1021-2:2014 Furniture: Ignition source match flame equivalent.

31. California Technical Bulletin 117-2013 – Requirements, Test Procedure and Apparatus for Testing the Smolder Resistance of Materials Used in Upholstered Furniture.

32. AIM 7351731 Rev. 3.00 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 to the Enhanced Documentation Level is included and conducted according to the FDA's *Guidance for the Content of Premarket Submissions for Device Software Functions*.

Cybersecurity risks were assessed, and documentation is included based on the FDA's *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions* and *Select Updates for the Premarket Cybersecurity Guidance: Section 524B of the FD&C Act.*

Usability Testing

The fundamental functions and movements of the proposed device are equivalent to those on the predicate device and the Modular Power Positioning System (K150574). The user interaction with these functions (based on joystick, toggle, and button interactions) is also equivalent to the predicate and K150574. The usability testing information was submitted within K210920 and K150574.

Biocompatibility

Bio-Compatibility was evaluated for all surface materials where prolonged skin contact may occur and demonstrated to be Biocompatible. Cytotoxicity testing per ISO 10993 Part 5, Sensitization testing per ISO 10993 Part 10 and Irritation testing per ISO 10993 Part 10 and 23 were performed on all skin contacting surface materials. Skin contacting materials were cleared in K210920 and K150574.

Conclusion

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