March 2, 2018

DEKA Research & Development Corp
Roger Leroux
Director of Regulatory and Clinical Affairs
340 Commercial St.
Manchester, New Hampshire 03101

Re: K172601
Trade/Device Name: Next Generation iBOT
Regulation Number: 21 CFR 890.3890
Regulation Name: Stair-Climbing Wheelchair
Regulatory Class: Class II
Product Code: IMK
Dated: January 31, 2018
Received: February 1, 2018

Dear Roger Leroux:

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)*
K172601

Device Name
Next Generation iBOT

Indications for Use *(Describe)*

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.

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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6. 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: January 25, 2018

Submitter's Information

510(k) Sponsor:	DEKA Research & Development 340 Commercial Street Manchester, NH 03101
Contact Person:	Roger Leroux Regulatory Affairs Project Manager DEKA Research & Development Corporation Phone: (603) 669-5139 Fax: (603) 624-0573 rleroux@dekaresearch.com

Device Information

Common/Usual Name:	Stair-climbing wheelchair
Trade/Proprietary Name:	Next Generation iBOT
Classification Name:	Stair-climbing wheelchair
Device Classification:	890.3890
Product Code:	IMK
Device Panel:	Physical Medicine

Predicate Device

The Next Generation iBOT (Next Gen iBOT) is substantially equivalent to the iBOT 4000 Mobility System (iBOT 4000), which was previously approved under PMA #P020033/S002. Stair-climbing wheelchairs were reclassified into Class II, effective April 14, 2014.

Device Description

The proposed 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 Next Gen iBOT 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 incorporates updates to the iBOT 4000 design to take advantage of advances in component and process technology while maintaining the same fundamental capabilities.

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.

Comparison to Predicate Device

The Next Gen iBOT has similar technological characteristics as compared to the predicate device. The proposed device offers substantially the same mobility functions as the iBOT 4000. Many of the design modifications were done to take advantage of improvements in technology since the iBOT 4000 was originally released in 2005. Where appropriate, component design has been maintained from the iBOT 4000; the overall system architecture and fundamental technology from the iBOT 4000 has been maintained. The 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 (iBOT 4000) (P020033/S002)	Proposed (Next Generation iBOT)	Assessment of difference (if applicable)
General Characteristics			
Indications for Use	The device is indicated for individuals who have mobility impairments and the use of at least one upper extremity. The device is intended to provide mobility on smooth surfaces and inclines at home, at work, and in other environments; movement across obstacles, uneven terrain, curbs, grass, gravel and other soft surfaces; mobility in a seated position at an elevated height; ascent and decent of stairs with or without assistance; and mobility and transportation.	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 Indications for Use has been modified slightly from that previously cleared in the predicate device to align with the intended use stated in the device regulation (21 CFR 890.3890) and with other powered wheelchairs. These wording changes in the intended use do not alter the therapeutic or diagnostic effect and do not affect safety and effectiveness of the device.
Manufacturer	Independence Technology	DEKA Research & Development	N/A

Characteristic	Predicate (iBOT 4000) (P020033/S002)	Proposed (Next Generation iBOT)	Assessment of difference (if applicable)
Rx/OTC designation	Rx	Rx	No change
Physical Characteristics			
Drive wheel type	Pneumatic. Single mounting point.	Pneumatic or foam-filled. 5 bolt pattern, split rim design.	The change allows for additional tire options, which is standard in the wheelchair industry. The functionality of the wheels has not changed and the change does not affect safety and effectiveness of the device.
Caster assembly	Tweel® mounted to caster arm	Standard caster wheel with suspension assembly	This change allows for increased availability of the caster wheels. The driving and suspension functions are maintained. The caster assembly functionality has not changed and does not affect the safety and effectiveness of the device.

Characteristic	Predicate (iBOT 4000) (P020033/S002)	Proposed (Next Generation iBOT)	Assessment of difference (if applicable)
Batteries	67.2 VDC 7.2Ah NiCd (2 batteries)	Four or Six Li-ion batteries, each rated 57.6 VDC, 5.1 Ah	Li-ion batteries provide lighter weight, higher specific energy, and are the current optimal battery technology. The Li-ion batteries provide similar voltage and current characteristics as the NiCd batteries. A full suite of testing for the Li-ion batteries has been conducted and demonstrates the change in battery type does not affect safety and effectiveness of the device.

Characteristic	Predicate (iBOT 4000) (P020033/S002)	Proposed (Next Generation iBOT)	Assessment of difference (if applicable)
Communication with external applications/devices	Infrared	Bluetooth 4.2 Low Energy	Bluetooth has become the widely available wireless technology. The change to Bluetooth communication allows for use of Bluetooth encryption and improved communication with mobile devices (i.e. laptop). The change to Bluetooth does not affect the safety and effectiveness of the device.
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	No change

Characteristic	Predicate (iBOT 4000) (P020033/S002)	Proposed (Next Generation iBOT)	Assessment of difference (if applicable)
Inertial Measurement	Tilt bulbs and early solid state gyros	MEMS based sensors	MEMS sensors have become widely available technology to measure the same physical phenomenon as the predicate-providing the body position information to the controls software. The update allows improved alignment to improve reliability of the measurement. The change does not affect the safety and effectiveness of the device.
Position monitoring	External homing sensor	Internal absolute position sensor	The change allows for improved reliability in the homing of the device, by moving it inside. The change does not affect the safety and effectiveness of the device.

Characteristic	Predicate (iBOT 4000) (P020033/S002)	Proposed (Next Generation iBOT)	Assessment of difference (if applicable)
System Communication	RS485	CAN bus	The change to CAN Bus supports current electronic hardware and communication with other power wheelchair options. The change does not affect safety and effectiveness of the device.
Weight (including batteries)	280 lb.	242.5 lb.	The weight is comparable to the predicate device.
Device Performance			
Driving Range	15.5 miles	15.5 miles (with 4 batteries)	No change
Dynamic stability	5 degrees (standard) 10 degrees (4 wheel) 5 degrees (balance)	10 degrees (standard) 12 degrees (4 wheel) 8 degrees (balance)	The change represents equivalent or increased dynamic stability when compared to the predicate device.

Characteristic	Predicate (iBOT 4000) (P020033/S002)	Proposed (Next Generation iBOT)	Assessment of difference (if applicable)
Max Speed Settings by Mode	Standard: 6.8 mph 4-Wheel: 4.8 mph Balance: 3.2 mph	Standard: 6.7 mph 4-Wheel: 5.2 mph Balance: 3.3 mph	Maximum speed is comparable to the predicate device.
Maximum user weight capacity	250 lb.	300 lb.	Update allows additional users. All testing performed with expanded weight range.
Obstacle Climbing	5 in. (in 4 wheel mode)	5 in. (in 4 wheel mode)	No change
Turning Radius	29.5 in. – 38.6 in. (dependent on mode)	24.5 in. – 33.8 in. (dependent on mode)	Turning radius is comparable to the predicate device
User Interface Features			
Seating	Gen 3 seat	Gen 3 seat	No change

Characteristic	Predicate (iBOT 4000) (P020033/S002)	Proposed (Next Generation iBOT)	Assessment of difference (if applicable)
User controller, joystick, screen, buttons, etc.	User controller with integrated joystick, display, buttons, and toggle switches. User assist confirmation button on the back of the seat. Power off request button located on the power base.	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.	The functions that the user controller allows and the number and type of user input devices are nearly identical. Changes simplify user tasks, improve visibility, and improve screen flow. The changes do not affect the safety and effectiveness of the device.

Performance Data

The following performance testing was conducted to demonstrate that the proposed device complies with the 21 CFR 890.3890, 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 in particular 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 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
3. ISO 7176-1:2014 Wheelchairs – Part 1: Determination of Static Stability
4. ISO 7176-2:2001 Wheelchairs – Part 2: Determination of Dynamic Stability of Electric Wheelchairs
5. ISO 7176-3:2012 Wheelchairs – Part 3: Determination of Effectiveness of Brakes
6. ISO 7176-4:2008 Wheelchairs – Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
7. ISO 7176-5:2008 Wheelchairs – Part 5: Determination of dimensions, mass and maneuvering space
8. ISO 7176-6:2001 Wheelchairs – Part 6: Determination of Maximum Speed, Acceleration & Retardation for Electric Wheelchairs

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: 1999 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 7176-21:2009 Wheelchairs – Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers

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

18. ISO 7176-25:2013 Wheelchairs - Part 25: Requirements and test methods for batteries and their chargers for electrically powered wheelchairs and motorized scooters

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

20. RESNA WC-1:2009, Section 7 – Wheelchairs – Method of measurement of seating and wheel dimensions

21. UL 2054:2004 Household and Commercial Batteries

22. UN 38.3 United Nations, New York & Geneva, Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Subsection 38. 3

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 (and particularly the user interaction with the device) which have changed from the iBOT 4000. There have been no changes to the intended use environment, 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 iBOT 4000 Mobility System predicate device. DEKA finds the Next Generation iBOT to be substantially equivalent to the predicate device.