September 12, 2019

UPnRIDE Robotics Ltd.
℅ Yoram Levy
Qsite General Manager
Qsite
31 Haavoda St.
Binyamina, 30500 Israel

Re: K182257
Trade/Device Name: UPnRIDE
Regulation Number: 21 CFR 890.3900
Regulation Name: Standup Wheelchair
Regulatory Class: Class II
Product Code: IPL
Dated: July 15, 2019
Received: July 22, 2019

Dear Yoram Levy:

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,

Vivek Pinto, Ph.D.
Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182257

Device Name
UPnRIDE

Indications for Use *(Describe)*
The UPnRIDE™ stand-up power wheelchair is intended for medical purposes to provide mobility to persons restricted to a sitting position. The product changes people's position from Sitting to Standing and Standing to Sitting but also any position in between. The product provides indoor and outdoor mobility.

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

UPnRIDE

510(k) Number K182257

Applicant's Name: UPnRIDE Robotics Ltd.
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Yoram@qsitemed.com

Trade Name: ***UPnRIDE™***

Summary Preparation Date: **August 8, 2018**

Classification:

Classification name: Standup wheelchair
Product Code: IPL
Regulation No: 21 CFR 890.3900
Class: II
Panel: Physical Medicine

Device Description:

The ***UPnRIDE™*** device enables disabled and elderly individuals to be mobile in a sitting or standing position, indoors and outdoors.

The device design is based on the following principles:

1. Using motorized jointed braces and harnessing to safely support the user while sitting, shifting to standing, standing and returning to sitting.
2. Center of gravity (COG) is maintained substantially at the center of the device in all positions, thus maximizing stability and safety.
3. Balancing the platform which supports the user so that the user always remains vertical even on skewed surfaces.

4. Implementing an operation and safety algorithms to minimize risks and hazards to the user, even beyond the provisions of standard wheelchairs.

The product is comprised of the following modules:

1. Driving module: a motorized driving chassis that includes two front motorized wheels, two high capacity Li-Ion batteries 21.6VDC / 29.7Ah and a steel frame which is installed as a chassis for the device's components.
2. Inertial Measurement Unit ("IMU") for measuring ground slopes (pitch and roll) and user's tilt angles (pitch and roll).
3. Standing and sitting module: a motor-based lifting mechanism for shifting between standing and sitting positions.
4. Balancing module: a platform that balances the user while sitting or standing, relative to earth.
5. User interface module: a unit through which the user controls the ***UPnRIDE™***. This module has an "R-NET" controller that contains a Joystick, commanding buttons and a display for viewing indications and status and a switching box for controlling the various modes of operation.
6. Actuator drivers: five units that control the lifting motors.
7. Main Controller: a unit which reads all sensors and user inputs, performs the balancing and safety algorithms, and controls all the chairs function.

Indications for Use:

The ***UPnRIDE™*** stand-up power wheelchair is intended for medical purposes to provide mobility to persons restricted to a sitting position. The product changes people's position from Sitting to Standing and Standing to Sitting but also any position in between. The product provides indoor and outdoor mobility.

Predicate Devices:

Substantial equivalence to the following predicate and reference devices is claimed:

	Device Name	**510k No**	**Date of Clearance**
Predicate	**Levo** *comfort* II	K051387	June 10, 2005
Reference	Quickie® Q700-UP M	K172384	January 16, 2018

Comparison with Predicate Devices

Intended use and indications for use

The ***UPnRIDE***^{TM} stand-up power wheelchair is a product which changes people's position from sitting to standing and standing to sitting but also any position in between, same as the cleared **Levo** *comfort* II (K051387). Both devices are intended to allow indoor and outdoor mobility.
The proposed ***UPnRIDE***^{TM} and the two predicate devices: the **Levo** *comfort* II and the **Q700-UP M** (K172384) wheelchairs are intended for any individual who needs a power wheelchair and cannot stand up on their own.
The ***UPnRIDE***^{TM} can be used on uneven ground, same as with the **Levo** *comfort* II and the **Q700-UP M**.

The ***UPnRIDE***^{TM} is classified as a standup wheelchair, under the regulation code IPL (regulation number 890.3900), same as the **Levo** *comfort* II (K051387) and the **Q700-UP M** (K172384). The devices are Class II devices.

Technical Comparison

Both the ***UPnRIDE™***, the **Levo** *Comfort II* and the **Q700-UP M** devices contain two main modules. The first one is a driving module that includes a steel frame, two drive motors and batteries as a source of energy. The second is a sitting-standing module, which enables the user adjust the chair according to the user's demand. The components of the sitting-standing adjustment module of the ***UPnRIDE™*** device are similar to the cleared reference device- **Q700-UP M** powered wheelchair and includes several motors, that allow the user to transfer from a sitting to a standing position and vice versa, to amend the positions of the leg support, back support and chair's horizontal and vertical locations while sitting and standing, like the **Q700-UP M**.

Both ***UPnRIDE™*** and the predicate devices include a controller which contains a joystick and command buttons designed by PG Drives Technology. In addition, both ***UPnRIDE™*** device and **Q700-UP M** contain the same braking system which is based on PG Drives Technology**.**

UPnRIDE™ includes additional module - Balancing module. ***UPnRIDE™*** proprietary balancing system enables the user to be mobile on almost any urban environment with increased safety. Using two linear actuators, the system balances the platform which supports the user so that the user always remains vertical even on skewed surfaces. The balancing operation was validated by multitude performance tests and a usability study to ensure its efficiency and to prevent any safety concerns.

Both ***UPnRIDE™*** and the predicate devices have similar characteristics such as user weighing up, maximum curb height and distance range.

Performance Standards

UPnRIDE™ complies with the following voluntary standards:

1. **ISO 7176-1:1999 -** Wheelchairs — Part 1: Determination of static stability.

2. **ISO 7176-2:2001 -** Wheelchairs — Part 2: Determination of dynamic stability of electric wheelchairs.
3. **ISO 7176-3:2012 -** Wheelchairs — Part 3: Determination of effectiveness of brakes
4. **ISO 7176-4:2008 -** Wheelchairs — Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range.
5. **ISO 7176-5:2008 -** Determination of dimensions, mass and maneuvering space.
6. **ISO 7176-6:2001 -** Wheelchairs — Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs.
7. **ISO 7176-8:2014 -** Wheelchairs — Part 8: Requirements and test methods for static, impact and fatigue strengths- clauses 8-9 (static, impact strength).
8. **ISO 7176-9:2009 -** Wheelchairs — Part 9: Climatic tests for electric wheelchairs
9. **ISO 7176-10:2008 -** Wheelchairs — Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
10. **ISO 7176-11:2012 -Wheelchairs** — Part 11: Test dummies
11. **ISO 7176-13:2008 -** Determination of coefficient of friction of test surfaces
12. **ISO 7176-14 :2008 -** Wheelchairs — Part 14: Power and control systems for electrically powered wheelchairs and scooters — Requirements and test methods
13. **ISO 7176-15 -:1996 -** Wheelchairs — Part 15: Requirements for information disclosure, documentation and labelling.
14. **ISO 7176-16 :2012** Resistance to ignition of upholstered parts - Requirements and test methods.
15. **ISO 7176-21-:2009** Wheelchairs — Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers.
16. **ISO 7176-25:2013 -** Requirements and test methods for batteries and battery chargers intended for use with electrically powered wheelchairs
17. **ANSI/RESNA WC-1: 2009, Section 20 -** American National Standard for Wheelchairs – Volume 1: Requirements and Test Methods for Wheelchairs

Summary of Clinical Performance Data:

No Clinical Testing is required for this submission

Substantial equivalence conclusion

The performance tests and the clinical study that were conducted show that the ***UPnRIDE™*** is substantially equivalent to the listed predicate devices without raising any new safety and effectiveness questions.