May 26, 2020

ReWalk Robotics Ltd.
Ofir Koren
General Manager, VP R&D, and Regulatory Affairs
3 Hetnufa St., POB 161
Yokneam, 2069203 Israel

Re: K200032
Trade/Device Name: ReWalk P6.0
Regulation Number: 21 CFR 890.3480
Regulation Name: Powered Lower Extremity Exoskeleton
Regulatory Class: Class II
Product Code: PHL
Dated: February 25, 2020
Received: February 26, 2020

Dear Ofir Koren:

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
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200032

Device Name
ReWalk™ P6.0

Indications for Use *(Describe)*
The ReWalk™ orthotically fits to the lower limbs and part of the upper body and is intended to enable individuals with spinal cord injury at levels T7 to L5 to perform ambulatory functions with supervision of a specially trained companion in accordance with the user assessment and training certification program. The device is also intended to enable individuals with spinal cord injury at levels T4 to T6 to perform ambulatory functions in rehabilitation institutions in accordance with the user assessment and training certification program. The ReWalk™ is not intended for sports or stair climbing.

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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This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92

1. **Submission Sponsor**

ReWalk Robotics Ltd.
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Yokneam, Israel
2069203, POB: 161
Establishment Registration: 3007615665

2. **Submission Correspondent**

Ofir Koren, General Manager, VP R&D and Regulatory Affairs

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3. **Date Prepared:**

May 25, 2020

4. **Device Identification**

Name of Device:	ReWalk™ P6.0
Classification Name:	Powered Exoskeleton
Regulation:	21 CFR §890.3480
Regulatory Class:	Class II
Product Classification Code:	PHL
Classification panel**:**	Neurology

5. **Legally Marketed Predicate Device**

Predicate Manufacturer:	ReWalk Robotics Ltd.
Predicate Trade Name:	ReWalk™ P6.0
Predicate 510(k):	K160987

6. **Device Description**

The ReWalk™ P6.0 is a prescription device which enables individuals with spinal cord injuries to perform ambulatory functions and composed of an external, powered, motorized frame fits to the lower limbs and part of the upper body.

Control of the device is achieved through a wrist-worn user-operated wireless remote controller (RC), tilt sensor and specific body movements. The gait movements are performed by a set of gears and motors at the knee and the hip joints. The ReWalk™ P6.0 system includes Remote control (RC) Communicator, Exoskeleton (Inc. Rigid Frames, Waistpack and Straps), Battery charger and Laptop (GUI).

7. Intended Use / Indication for Use

The ReWalk™ P6.0 orthotically fits to the lower limbs and part of the upper body and is intended to enable individuals with spinal cord injury at levels T7 to L5 to perform ambulatory functions with supervision of a specially trained companion in accordance with the user assessment and training certification program. The device is also intended to enable individuals with spinal cord injury at levels T4 to T6 to perform ambulatory functions in rehabilitation institutions in accordance with the user assessment and training certification program. The ReWalk™ is not intended for sports or stair climbing.

8. Substantial Equivalence Discussion

The following table compares the ReWalk™ P6.0 to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance. The comparison of the devices in Table 1 below provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new or different questions of safety or effectiveness based on the similarities to the predicate device.

Table 1: (Substantial Equivalence Discussion)

Characteristic	The ReWalk™ P6.0 (K200032) by ReWalk Robotics	The ReWalk™ P6.0 (K160987) by ReWalk Robotics
510(k) number	K200032	K160987
Product Code	PHL	Same
Regulation Name	Powered Exoskeleton	Same
Regulation No.	890.3480	Same
Indication for Use	The ReWalk™ P6.0 orthotically fits to the lower limbs and part of the upper body and is intended to enable individuals with spinal cord injury at levels T7 to L5 to perform ambulatory functions with supervision of a specially trained companion in accordance with the user assessment and training certification program. The device is also intended to enable individuals with spinal cord injury at levels T4 to T6 to perform ambulatory functions in rehabilitation institutions in accordance with the user assessment and training certification program. The ReWalk™ P6.0 is not intended for sports or stair climbing.	Same
Indications	Before using the device, confirm that the following prerequisites are met by the user: • Hands and shoulders can support crutches or a walker • Healthy bone density, meaning sufficient bone density according to the judgement of the prescribing physician after clinical examination of the patient – including radiological proof if needed. • Skeleton does not suffer from any fractures • Able to stand using a device such as Easy Stand • In general good health • Height is between 160 cm and 190 cm (5' 3" - 6' 2") • Weight does not exceed 100 kg (220 lbs.)	Before using the device, confirm that the following prerequisites are met by the user: • Hands and shoulders can support crutches or a walker • Healthy bone density • Skeleton does not suffer from any fractures • Able to stand using a device such as Easy Stand • In general good health • Height is between 160 cm and 190 cm (5' 3" - 6' 2") • Weight does not exceed 100 kg (220 lbs.)

Characteristic	The ReWalk™ P6.0 (K200032) by ReWalk Robotics	The ReWalk™ P6.0 (K160987) by ReWalk Robotics
Contraindications	People with the following conditions should not use the ReWalk™: • History of severe neurological injuries other than SCI (MS, CP, ALS, TBI etc.) • Severe concurrent medical diseases: infections, circulatory, heart or lung, pressure sores • Severe spasticity (Modified Ashworth 4) • Unstable spine or unhealed limbs or pelvic fractures • Heterotopic ossification that impair joint mobility. • Significant contractures (plantar flexion > 0°, knee > 10°, hip flexion >0°) • Psychiatric or cognitive situations that may interfere with proper operation of the device • Pregnancy Warning: Crutches are required when using ReWalk™	Same
Patient Population	Individuals with spinal cord injury at levels T7 to L5 and levels T4 to T6	Same
Device construction and materials	The ReWalk™ P6.0 device is composed of rigid supporting framework and textile strapping providing body weight support to the patient	Same
SW	Release 4.2 Two minor software feature modifications for sit-to-stand transition, and additional new software feature for stand-to-sit transition.	Release 4.1
Body Coverage	Worn over legs and around hips and lower torso	Same
Size of Components	Modular small, medium, large paretic leg component, control unit integrated into adjustable waist belt	Same
Mobility Aid	Off- the- shelf forearm crutches	Same
Ability of User Mobility	Sit, Stand and Walk	Same
Walking Speed	2.3 km/Hr. (1.43 MPH)	Same
Patient height/weight	160 to 190 cm (63 inches to 75 inches) 100 kg max. (220 lbs.')	Same

Characteristic	The ReWalk™ P6.0 (K200032) by ReWalk Robotics	The ReWalk™ P6.0 (K160987) by ReWalk Robotics
Range of Motion	Hip: 34 degrees extension; 104 degrees flexion Knee: 110 degrees flexion; 2 degrees extension	Same
Use environment	Healthcare facility environment including hospital rehabilitation centers. Home environment: any environment outside a professional healthcare facility. The ReWalk™ is not intended for sports or stair climbing.	Same
Type of surface	Use the device on paved surfaces or on dry, even surfaces.	Same
Device weight	Total: 30 kg (66 lbs.)	Same
Maximum Speed	2.3 km/Hr. (1.43 MPH)	Same
Training and Certification Program (Clinical Use)	A thorough training program providing certification is required for clinicians before using ReWalk™ P6.0 with patients	Same
User/companion training	A training program providing certification is required for User & Companion before using ReWalk™ P6.0	Same
Expected Useable Life	5 years with proper servicing	Same
Operating Temperature	+5°C to +40°C (+41°F to + 104°F)	Same
Operating Humidity	15 % to 90%, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa	Same
Electrical Safety Testing	IEC 60601-1/ IEC 60601-11	Same
Electromagnetic Compatibility Testing	IEC 60601-1-2	Same
Laptop	Laptop is used for controlling and configuring through USB communication	Same
Alignment (between user and device)	Alignment of hip, knee and ankle joints with strap mechanism attached to device frame	Same
Assistance method	Motors/gears moving rigid supporting framework to power knee and hip movement	Same
System modes	Sit, Stand and Walk	Same
Battery specifications	Two rechargeable batteries: Main (Li-Ion) with capacity of 10.4 AH and Auxiliary (Li-Polymer) 2 AH	Same
Battery Life Cycle	Life Cycle > ~300 for standard charge/discharge cycles	Same
Battery charge time	Minimum 4 hours	Same
Failsafe feature	When battery is fully depleted or a power loss occurs, the Graceful Collapse feature is activated supporting the user's weight while slowly lowering the user to a seat or the ground.	Same

9. Conclusions

The subject ReWalk™ P6.0 and the ReWalk™ P6.0 (K160987) – the predicate device have the same intended use and indications for use. In addition, both have same technological characteristics, and use very similar principles of operation. The only differences between the ReWalk™ and its predicate are two (2) minor software modifications for sit-to-stand transition, and the addition of one (1) new software feature for stand-to-sit transition. These minor differences do not present any new or different questions of safety or effectiveness as confirmed by completed testing also discussed in further detail below. Thus, the subject ReWalk™ P6.0 is substantially equivalent to the ReWalk™ P6.0 (K160987).

10. Conclusion on SE based on Technical Comparison & Performance Data

The subject device is designed to fulfill the requirements of the following recognized standards:

- IEC 60601-1-11:2015 (2nd Ed) /ANSI AAMI HA60601-1-11:2011
- IEC 60601-1-2 Edition 4.0 2014-02
- ANSI AAMI ES 60601-1:2005/(R)2012 And A1:2012,
- ISO 14971 Second edition 2007-03-01 Medical devices - Application of risk management to medical devices
- IEC 62304 Edition 1.1 2015-06 - Software life cycle processes

Review of non-clinical performance testing as well as comparison of the device classification, indication for use, operating principles, technological characteristics demonstrate that the subject device is substantially equivalent to the predicate. Any differences between the subject and the predicate device do not raise new questions of safety or effectiveness.

11. Summary

Utilizing FDA's Substantial Equivalence Decision Tree we conclude the following:

- The subject device has the same Intended use and Indications for use as the predicate
- The subject device the same technological characteristics as the predicate device
- The different characteristics do not raise new or different types of safety or effectiveness questions
- Acceptable scientific methods exist for assessing the new characteristics
- Performance data are available to assess the effects of the new characteristics
- Performance data (along with descriptive characteristics) demonstrate substantial equivalence.