March 2, 2023

ReWalk Robotics Ltd.
Miri Pariente
VP QA, RA & Operations
3 Hatnufa St.
POB Box-161
Yokneam, 2069203
Israel

Re: K221696
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: June 10, 2022
Received: June 10, 2022

Dear Miri Pariente:

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,

Tushar Bansal -S

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)*
K221696

Device Name
ReWalk® P6.0

Indications for Use *(Describe)*
The ReWalk® P6.0 fits to the lower limbs and part ofthe upper body and is intended to enable individuals with spinal cord injury at levels T7 to L5 to perform ambulatory functions in home and community settings with supervision of a specially certified 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 intended for indoor and outdoor use: including standing and walking on level surfaces and mild slopes and ascending and descending stairs and curbs.

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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ReWalk® P6.0
510(k) Summary
K221696

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.
   3 Hatnufa St.
   Yokneam, Israel 2069203, POB: 161
   Establishment Registration: 3007615665

2. **Submission Correspondent**
   Miri Pariente, VP QA, RA & Operations
   Phone: (+972) 58-5605090
   E-mail: miri.pariente@rewalk.com

3. **Date Prepared**
   June 09, 2022

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):	K200032

6. **Legally Marketed Reference Device**

Reference Device Manufacturer:	ReWalk Robotics Ltd.
Reference Device Trade Name:	ReWalk
Reference Device 510(k):	K160987

7. **Device Description**

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

   The ReWalk is intended to enable certified users with spinal cord injuries at levels T7 to L5 to perform ambulatory functions in in home and community setting accompanied by a certified companion. Additionally, the ReWalk Personal Exoskeleton 6.0 is intended to enable certified users with spinal cord injuries at levels T4 to T6 to perform ambulatory functions in rehabilitation centers accompanied by a certified therapist.

   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 system includes Remote control (RC) Communicator, Exoskeleton (Inc. Rigid Frames, Waistpack and Straps), Battery charger and Laptop (GUI), and off the shelf crutches. All of the ReWalk components are mandatory, suitable for indoor and outdoor usage. The device is intended for indoor and outdoor use: including standing and walking on level surfaces and mild slopes, and ascending and descending stairs and curbs for users who are at

least 18 years old.

8. Intended Use / Indication for Use

The ReWalk® P6.0 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 in home and community settings with supervision of a specially certified 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 intended for indoor and outdoor use: including standing and walking on level surfaces and mild slopes, and ascending and descending stairs and curbs.

9. Technological Characteristics

The current submission introduces the stairs ascend and descend functionality to the ReWalk P6.0 device (already cleared for sit, stand, and walk under K160987 and K200032). The ReWalk P6.0 with stairs functionality is identical to the previously cleared version of the device ("Predicate Device") (K200032) in terms of design, material, physical & electrical components, energy source, and principles of operation.

Adding the Stairs ascend and descend functionality to the ReWalk P6.0 device does not raise different questions of safety and effectiveness, as confirmed by the company's clinical and performance testing.

10. Performance Data

10.1 Performance Testing - Bench

Both the Subject Device and Predicate Device are identical in physical and electrical components and software, with Stairs functionality disabled for the cleared device and enabled for the subject device. Therefore, testing submitted under (K160987 and K200032) remain applicable to the subject device: EMC (per IEC 60601-1-2), Electrical safety (per IEC 60601-1), Biocompatibility (per ISO 10993-1), Software validation & verification (per IEC 62304), Environmental testing (per IEC 60601-11).

The Subject Device has undergone additional bench and non-clinical testing to demonstrate that the ReWalk P6.0 device with stairs ascend and descend functionality meets all design requirements and is in compliance with all applicable standards and regulations including special controls in 21 CFR 890.3480. These tests include non-clinical performance testing, and user testing. The tests are summarized at a high level in the tables below.

Table 1: Bench testing

Test name	Test description	Result
Stairs usage mechanical loading test	Device has sufficient mechanical integrity for safe and effective use under worst-case conditions	PASS
Walking Speed verification	Measure the maximal walking speed of ReWalk P6.0 device with its maximal configuration (as the maximal speed depends on device configuration).	PASS

Table 2: User testing

Test name	Test description	Result
Stairs Validation	Device performs as intended when used by certified users for ascending and descending stairs and curbs in a variety of environments	PASS
Curbs Validation		PASS
Outdoor Validation		PASS

10.2 Performance Testing - Clinical

ReWalk P6.0 Active Users Field Survey Study- Stairs Usage

Use of the stairs functionality is supported by clinical data collected by the Company in the ReWalk Users Field Survey Study-Stairs Usage, which contains real world evidence collected through a survey of actual users in Europe (where ReWalk P6.0 device with stairs functionality has been commercially available on the European market since 2015). The safety and efficacy of ReWalk P6.0 device with stairs ascend and descend functionality, both indoor and outdoor use in home and community setting has been studied and monitored over a period of six (6) years.
In addition, and unrelated to the survey, for the past seven (7) years, data regarding device malfunctions, injuries, and complaints had also been monitored using ReWalk's Customer Relation Management (CRM) database.

Study subgroup analysis/ demographic characteristics

A total of 47 users have been evaluated. 87% of subjects were males and 13% females. All study subjects were at least 6 months after injury, who had a device with stairs functionality to ascend and descend stairs.
Note that information regarding users' race and ethnicity was not allowed to be collected due to local legislation laws in Europe.

Safety and effectiveness

Between 2015 to May 2022, only three (3) Stairs-related adverse events (AE) were recorded in ReWalk's Customer Relationship Management system, covering all ReWalk users in Europe. It was concluded that the AEs were not device-related, but rather associated with erroneous mode selection , not-following the device Instructions for Use and short handle at the top step. No device deficiencies/malfunctions related to stairs usage were recorded.

Study summary and conclusion

The study recruited 85 subjects, of which a total of 47 users used the device to climb stairs (ascending/ descending) indoor and outdoor use in home and community setting. Average age was 46 years; 87% of the stairs-mode users were male. On average the stairs-mode was used by the study participants for 26 months (ranging from 1 month to 5 years). Total number of stairs taken by the stairs-mode users in the study, ranged from 9 to 2,371 stairs per-user, with the mean value of 383 stairs (which is approximately equal to 22 floors, assuming 17 stairs per floor). This yields cumulatively 18,038 stairs in total for all study users over the entire duration of use.
The study has successfully demonstrated that the ReWalk P6.0 device is safe and effective in enabling individuals with spinal cord injury to ascend and descend stairs, both indoor and outdoor, in home and community settings. The use of the ReWalk P6.0 device is safe when it is

used according to its instructions for use under the supervision of a specially certified companion.

10.3 Performance Testing – Human Factor Study
ReWalk P6.0 with Stairs Enabled Human Factors Engineering Study

ReWalk Users and companions human factors engineering study have been conducted under IRB Approved protocol, according to principles of Good Clinical Practice (GCP). The study objective was to evaluate patients' ability to safely and effectively interact with ReWalk P6.0 device with stairs feature user interface components, while assisted by their companion (in which advanced functions of ascending and descending stairs and curbs are introduced).
The study was conducted in a representative real world use environment, included actual use test scenarios using the ReWalk P6.0 device with stairs enabled and comprehension questions about critical information regarding the use of the device focusing on the ascending/descending function.
The study consists of 11 ReWalk patients subjects and 11 companion's subjects who performed actual use scenarios using a working device with the Stairs feature enabled. The training during the usability testing was designed to provide realistic training environment that users would encounter in real world situations. The content and the method of delivery were identical to the training performed at the clinic.

Study Summary and Conclusion

Despite the significant limitations and constraints imposed by the unique user characteristics, the study results demonstrate that after a short and partial training session, participants were largely able to learn and execute the sequence of steps required for stair use. In 99% of the times participants successfully completed the test tasks without any observed use difficulties, and the vast majority of participants were able to correctly answer the knowledge questions evaluated in scenarios. No adverse events were reported.

The study concluded that the ReWalk P6.0 stairs and curbs ascend and descend functions can be used safely by the intended user population in the intended use environments.

11. Conclusion

The Subject Device with stairs functionality and its Predicate Device have similar intended use, same indications, contraindications, principles of operation, and technological characteristics. The difference in the intended use does not present different questions of safety or effectiveness than the Predicate Device. Accepted scientific methods exist to evaluate the performance of the Subject Device compared to its Predicate Device. Clinical and performance data have demonstrated that the Subject Device is as safe and effective as its Predicate.
Thus, the ReWalk P6.0 device with stairs functionality is substantially equivalent to the previously cleared ReWalk P6.0 device (K200032).