March 12, 2025

ReWalk Robotics Ltd. DBA Lifeward
Pariente Miri
VP of QA, RA and Operations
3 Hatnufa St., P.O Box 161
Yokneam Ilit, 2069203
Israel

Re: K241822
Trade/Device Name: ReWalk® 7 Personal Exoskeleton (50-20-0005)
Regulation Number: 21 CFR 890.3480
Regulation Name: Powered Lower Extremity Exoskeleton
Regulatory Class: Class II
Product Code: PHL
Dated: June 23, 2024
Received: June 24, 2024

Dear Pariente Miri:

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
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241822

Device Name

ReWalk® 7 Personal Exoskeleton (50-20-0005)

Indications for Use *(Describe)*

The ReWalk® 7 Personal Exoskeleton 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 7 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.

510(k) #: K241822

510(k) Summary

Prepared on: 2025-02-13

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Lifeward LTD.
Applicant Address	3 Hatnufa St., P.O Box 161 Yokneam Ilit 2069203 Israel
Applicant Contact Telephone	+972-58-5605090
Applicant Contact	Mrs. Pariente Miri
Applicant Contact Email	miri.pariente@golifeward.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ReWalk® 7 Personal Exoskeleton (50-20-0005)
Common Name	Powered lower extremity exoskeleton
Classification Name	Powered Exoskeleton
Regulation Number	890.3480
Product Code(s)	PHL

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221696	ReWalk® P6.0	PHL
K200032	ReWalk® P6.0	PHL
K160987	ReWalk® P6.0	PHL

Device Description Summary

21 CFR 807.92(a)(4)

The ReWalk® 7 Personal Exoskeleton is a wearable, battery-powered prescription device intended for use by certified individuals at least 18 years old with lower limb disability to perform routine ambulatory functions at home and in the community.
Control of the exoskeleton is achieved through a user-worn wireless, web connected wrist control unit (WCU), a wireless crutch-mounted control unit (CCU), and specific body movements as measured through a tilt sensor. The powered device movements are performed by a set of gears and motors at the knee and the hip joints.
The ReWalk 7 Personal Exoskeleton includes the exoskeleton (incl. rigid frames, waist pack, and straps), battery power supply, crutches with integrated powered crutch control add-on unit (CCU), and the Wrist Control Unit (WCU). The wireless, web connected therapist handheld device (THD) is used by certified therapists for device configuration and control.
All ReWalk 7 Personal Exoskeleton components are suitable for indoor and outdoor use.
The ReWalk use includes standing, walking on level surfaces, mild slopes, ascending and descending stairs and curbs.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The ReWalk® 7 Personal Exoskeleton 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 7 is intended for indoor and outdoor use: including standing and walking on

level surfaces and mild slopes, and ascending and descending stairs and curbs.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indication for use of the subject device and the predicate are identical.

Technological Comparison 21 CFR 807.92(a)(6)

This traditional 510(k) submission introduces the ReWalk 7 personal exoskeleton, an enhanced version of its predicate device, the ReWalk P6.0 (K221696). The ReWalk 7 is identical to the predicate device in terms of intended use, contraindications, indications for use, indications, environment of use, intended users nad basic principles of operations.
Importantly, the exoskeleton's structure remains unchanged.

The enhancement and refinements focus on device safety, improving user interfaces, and device connectivity:

1. Battery Spec Change: Implementation of off-the-shelf smart rechargeable Li-ion battery following the predicate Recall number-1553-2021, RES# 8781. To accommodate the battery change, the internal structure of the Waist Pack including the Main processing board (MPB) was changed and its overall weight increased due to the battery replacement following the recall. An analysis confirmed that this weight increase is negligible and does not alter the center of mass.

2. Off-the-shelf Wrist Control Unit (WCU), which remains the primary device controller, replaces the proprietary Remote Control (RC). Additionally, an optional Crutch Control Unit (CCU) mounted on the existing right crutch was added, enabling users to control ReWalk exoskeleton modes (SIT, STAND, WALK SLOW, WALK FAST, ASCEND/DESCEND) without releasing their grip from the crutch.

3. System Modes of Operation - The system modes of operation have been updated in two ways: The existing Walk gait configuration has been split into two modes: Walk Fast and Walk Slow. This change does not affect the speed range of the cleared device, and the gait settings are still preconfigured by a certified therapist. The new pseudo modes in ReWalk 7 introduce a pseudo-STAND mode for ascending and descending stairs and curbs.

Both changes are supported by an icon in the WCU for user convenience.
4. Therapist Means for Control: Introduction of an off-the-shelf cloud-connected Therapist Handheld Device (THD), instead of the laptop. Introduction of laptop only for maintenance activities executed by certified ReWalk technicians.

5. Device Connectivity: Introduction of a cloud server application for device utilization tracking and maintenance transition to device proprietary wireless communication and improved cybersecurity.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

To evaluate the performance and safety of the ReWalk 7, tests and analysis were executed according to accepted scientific methods, FDA applicable recognized consensus standards, guidance documents, and regulations including special controls in 21 CFR 890.3480.

The subject device operation and technical characteristics were tested and evaluated according to below applicable recognized standards:

• 60601-1 Edition 3.2 2020-08 consolidated version, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US.

• IEC60601-1-2 Edition 4.1 2020-09 consolidated version Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

• IEC TR 60601-4-2 Edition 1.0 2016-05, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

• IEC 60601-1-11 Edition 2.1 2020-07 consolidated version O Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

• IEC 62133-2 Edition1.0 2017-02, 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 - Part 2: Lithium systems

• IEC 60601-1-6 Edition 3.2 2020-07 consolidated version - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

• IEC 62366-1 Edition 1.1 2020-06 consolidated version , Medical devices - Part 1: Application of usability engineering to medical devices.

• IEC 62304 Edition 1.1 2015-06 consolidated version Medical device software - Software life cycle processes.

• ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

• ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

• ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

• AAMI TIR69:2017/(R2020), Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems.

• ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices
• AAMI TIR57:2016, Principles for medical device security - Risk management.

• IEC 80601-2-78 Edition 1.0 2019-07, Medical electrical equipment - Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation assessment compensation or alleviation

• ASTM D4332-22 Standard Practice for Performance Testing of Shipping Containers and Systems

• ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems

Clinical tests were not required as the device's intended use/ indication for use, indications and contraindications are identical to predicate device.

To evaluate the performance and safety of the ReWalk 7, tests and analysis were executed according to accepted scientific methods, FDA applicable recognized consensus standards, guidance documents, and regulations including special controls in 21 CFR 890.3480, demonstrated that ReWalk 7 performs safely and effectively according to its intended use.
The substantial equivalence analysis demonstrated that ReWalk 7 and its predicate have an identical intended use, indication for use, indications , contraindication and basic principles of operations. The devices have similar technological characteristics such communication methods and operation modes.
Accepted scientific methods exist to evaluate the performance and safety of the ReWalk 7 compared to its Predicate Device, the ReWalk 7 Personal Exoskeleton device is substantially equivalent to the previously cleared ReWalk P6.0 device (K221696). ReWalk 7 Exoskeleton device demonstrated that it is as safe and effective as its Predicate.
Thus, it can be concluded that the safety and effectiveness of ReWalk 7 is the same as the predicate ReWalk P6.0 and does not raise different questions of safety and effectiveness .