



ReWalk™ Personal Exoskeleton System Cleared by FDA for Home Use

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Revolutionary technology that allows individuals with Spinal Cord Injury, such as paraplegia, to stand & walk receives clearance for personal use in the U.S.

Marlborough, MA—June 26, 2014 — Exoskeleton leader ReWalk Robotics announced today that the U.S. Food and Drug Administration has cleared the company's ReWalk Personal System for use at home and in the community. ReWalk is a wearable robotic exoskeleton that provides powered hip and knee motion to enable individuals with Spinal Cord Injury (SCI) to stand upright and walk. ReWalk, the only exoskeleton with FDA clearance via clinical studies and extensive performance testing for personal use, is now available throughout the United States.

The FDA has issued a marketing clearance for the ReWalk, which was granted via a rigorous de novo process that involved multiple clinical studies demonstrating safety and effectiveness of the technology.

"This revolutionary product will have an immediate, life-changing impact on individuals with spinal cord injuries," said Larry Jasinski, CEO of ReWalk Robotics. "For the first time individuals with paraplegia will be able to take home this exoskeleton technology, use it every day and maximize on the physiological and psychological benefits we have observed in clinical trials," he added. "This is truly the beginning of 'ReWalking' as a daily reality in the U.S."

Derek Herrera, a Captain in the U.S. Marine Corps, is a paraplegic trained on the ReWalk Personal System, and will be one of the first Americans to own the ReWalk. "I see this as a milestone for people in my same situation who will now have access to this technology – to experience walking again, and all of the health benefits that come with ReWalking," Captain Herrera said. The Marine Special Operations Command Foundation (MARSOC Foundation) will be donating the funds for Herrera's ReWalk system; Herrera works for the Marine Special Operations Command. "It will be incredible for me to regain independence, to use the system to walk and stand on my own," he added.

ReWalk provides user-initiated mobility through the integration of a wearable brace support, a computer-based control system and motion sensors. The system allows independent, controlled walking while mimicking the natural gait patterns of the legs, similar to that of an able-bodied person. In addition to the ability to stand and walk independently, clinical studies of the ReWalk Rehabilitation system show significant health benefits to the user, on both a physiological and psychological level.

Study data of the ReWalk system indicates potential improvements in cardiovascular health, loss of fat tissue, building of lean muscle mass, and improved bowel function. Feedback from ReWalk users supports these potential benefits and others, such as better pain management, fewer medications, and potentially reduced hospitalizations.

"What makes this so exciting is the understanding that, in addition to the psychological benefits realized by ReWalking, consumers are able to improve upon the clinical benefits," said Jasinski. "Now, with FDA clearance, users will continue to experience these benefits on a daily basis at home."

ReWalk has been tested extensively in the U.S., Europe, and Israel. The ReWalk system is supported by the most published data of all exoskeleton systems in the rehabilitation market, and is used by more people worldwide than all other exoskeleton systems combined.

ReWalk was developed by Dr. Amit Goffer, an Israeli inventor who became quadriplegic after an ATV accident in 1997. It was through his own personal experience in utilizing mobility devices for people with spinal cord injury that Dr. Goffer developed the ReWalk.

The company offers two products: ReWalk Personal and the ReWalk Rehabilitation wearable robotic systems. The ReWalk Personal System, designed for everyday use by individuals at home and in their communities, is custom-fit for each user. The system is designed for daily use in a range of environments such as in the home, at work, at social events, indoors as well as outdoors, as well as on different surfaces or terrains. This revolutionary, cutting-edge technology allows users to stand, turn and walk with independent control of the system.

The ReWalk Rehabilitation system is used in the clinical rehabilitation environment, where it provides a valuable means of exercise and therapy as well as a training base for individuals to be certified, enabling them to purchase a Personal system.

"The person walks the system, the system does not walk them. The users are in control — when they want to sit, they sit, when then want to stand and walk, they do so," said ReWalk inventor Dr. Goffer.

"ReWalking is much more than walking," says Jeff Dykan, ReWalk's Chairman of the Board. "ReWalk provides paralyzed individuals with the ability to stand and walk, to look someone in the eye, to hug and be hugged. These are simple acts which many of our ReWalkers thought they would never be able to do again," he added. "When you take that into account in addition to the health benefits, it underscores just how monumental a day this is for the SCI community here in the U.S."

The ReWalk Personal System is available to consumers upon meeting requirements from a medical examination and successful completion of the required training program. The company also offers a comprehensive maintenance and warranty program for the system.

FOR MEDIA USE:

FDA official press announcement:

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm402970.htm>

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Photos and videos of the ReWalk Personal System: <https://www.flickr.com/photos/125630444@N05/>

About ReWalk Robotics:

ReWalk Robotics (formerly Argo Medical Technologies) develops, manufactures and markets wearable robotic exoskeletons for people with lower limb disabilities, such as paraplegia. ReWalk's mission is to fundamentally change the health and life experiences of individuals with spinal cord injury. Founded in 2001, ReWalk Robotics is a global company with headquarters in the US, Germany, and Israel. For more information on ReWalk Robotics and the ReWalk Systems, please visit <http://www.rewalk.com>