



ONWARD Receives FDA Breakthrough Device Designation for ARC-IM for Blood Pressure and Trunk Control in Spinal Cord Injury

18 Jun 2021

Third Breakthrough Device Designation Awarded to the Company for Innovative Technologies

June 17, 2021 08:30 AM Eastern Daylight Time

EINDHOVEN, Netherlands & LAUSANNE, Switzerland--([BUSINESS WIRE](#))--ONWARD today announced the Company has received Breakthrough Device Designation status from the U.S. Food and Drug Administration (FDA) for their ARC-IM platform for blood pressure and trunk control in people with spinal cord injury. This is the third such Breakthrough Device Designation awarded to ONWARD, following previous awards for ARC-EX for upper extremity function and ARC-IM for mobility.

ARC-IM consists of an implantable pulse generator and lead that is placed near the spinal cord. The system is operated via a tablet programmer and smartwatch. The STIMO study demonstrated the ability of this technology to enable long-paralyzed people to stand and walk again with little or no assistance and a recently published *Nature* [paper](#) showed the potential for this same therapy to normalize blood pressure in people with spinal cord injury.

"Blood pressure and trunk control are two of the many challenges people with spinal cord injury must manage in order to navigate their daily lives," said Dave Marver, Chief Executive Officer of ONWARD. "We are excited about this award and thankful to the FDA for recognizing the potential of our technology to improve the quality of life for those with spinal cord injury."

Breakthrough Device Designation is an FDA program designed to help patients and their physicians receive timely access to technologies that have the potential to provide more effective treatment or diagnosis for debilitating conditions of great unmet need, such as spinal cord injury. As part of this designation, the FDA will provide ONWARD with priority review and the opportunity to interact with FDA's experts throughout the premarket review phase as the technology moves toward eventual commercialization.

About ONWARD

ONWARD ([@onwdempowered](#)) is a medical technology company creating innovative therapies to restore movement, independence, and health in people with spinal cord injury. ONWARD's work builds on more than a decade of basic science and preclinical research conducted at the world's leading neuroscience laboratories. ONWARD's ARC Therapy, which can be delivered by implantable (ARC-IM) or external (ARC-EX) systems, is designed to deliver targeted, programmed stimulation of the spinal cord to restore movement and other functions in people with spinal cord injury, ultimately improving their quality of life. ONWARD has received three Breakthrough Device Designations from the FDA encompassing both ARC-IM and ARC-EX. The company's first FDA pivotal trial, called Up-LIFT, commenced in January 2021 with plans to enroll 65 subjects at up to 15 centers worldwide.

ONWARD is headquartered at the High Tech Campus in Eindhoven, the Netherlands and the EPFL Innovation Park in Lausanne, Switzerland, with a growing U.S. presence in Boston, Massachusetts, USA. For additional information about the company, please visit [ONWD.com](#) and follow us on [Twitter](#) and [LinkedIn](#).



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