

# impedimed

14 August 2017

## ASX ANNOUNCEMENT

### U.S. FDA 510(k) Clearance Issued for SOZO™ with L-Dex®

**Brisbane, Australia and Carlsbad, Calif.** - ImpediMed Limited (ASX: IPD) a global provider of medical technology to non-invasively measure, monitor and manage fluid status and body composition, is pleased to announce the issuance by the U.S. FDA of a 510(k) clearance to market SOZO™ to aid in the clinical assessment of unilateral lymphoedema in the United States.

"We are delighted to receive this FDA clearance for SOZO in the U.S." said Richard Carreon, Managing Director and CEO of ImpediMed. "SOZO makes it far simpler for cancer patients to be monitored for lymphoedema via their L-Dex score and significantly streamlines the patient flow within the cancer clinic."

"This clearance puts us ahead of schedule for our planned market launch of SOZO in the United States, and also allows us to now expedite our regulatory strategy for additional SOZO indications including fluid status monitoring for patients living with heart failure."

**Richard Carreon**  
**Managing Director & CEO**

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**About ImpediMed**

Founded and headquartered in Brisbane, Australia with U.S. offices in Carlsbad, Calif. and Bloomington, Minn., and a European office in Thessaloniki, Greece, ImpediMed is the world leader in the design and manufacture of medical devices employing bioimpedance spectroscopy (BIS) technologies for use in the non-invasive clinical assessment and monitoring of tissue composition and fluid status.

ImpediMed was the first company to receive FDA clearance in the U.S. to aid healthcare professionals to clinically assess unilateral lymphoedema of the arm and leg in women and the leg in men, for its L-Dex® device. In addition, ImpediMed produces a family of CE Marked medical devices, including SOZO™, sold in select markets globally.

For more information, visit [www.impedimed.com](http://www.impedimed.com).

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