



27 December 2017

**ASX ANNOUNCEMENT**

**U.S. FDA 510(k) Clearance Issued for CHF Monitoring with SOZO™**

**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 US FDA of a 510(k) clearance to market SOZO™ for fluid monitoring of patients in the United States living with chronic heart failure (CHF).

"We are delighted to receive this additional FDA clearance for the SOZO platform in the US," said Richard Carreon, Managing Director and CEO of ImpediMed. "SOZO is a connected platform which provides a simple, yet accurate, method for monitoring fluid levels in heart failure patients under the direction of a physician in the clinic or home environments".

"This achieves yet another important regulatory milestone in our journey of providing a new model of care for monitoring cancer and heart failure patients across the entire continuum of care."

SOZO utilises ImpediMed's bioimpedance spectroscopy (BIS) technology to perform a full scan of 256 frequencies to provide both detailed and accurate information on the fluid status of patients. Studies have shown detectable differences in whole-body extracellular fluid using ImpediMed's BIS devices as low as 0.1 litres.

The SOZO Fluid Status Monitor is intended for adult patients living with heart failure. This device is intended for use, under the direction of a physician, for the noninvasive monitoring of patients with fluid management problems suffering from heart failure. Data from the device should be considered in conjunction with other clinical data.

**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

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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<sup>®</sup> device. In addition, ImpediMed produces a family of FDA cleared and CE Marked medical devices, including SOZO<sup>™</sup>, sold in select markets globally.

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