

# impediMed

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## ASX ANNOUNCEMENT

### **ImpediMed Submits FDA 510(k) Application for SOZO™ for Lymphoedema**

**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 submission of a premarket notification 510(k) application for SOZO™ to the US Food and Drug Administration (FDA) to aid in the clinical assessment of lymphoedema.

The submission uses the company's current medical device, the L-Dex® U400, as a predicate. The L-Dex U400 obtained its most recent FDA clearance in June of 2013.

"We are extremely pleased that we have been able to move so quickly from a CE Mark for SOZO to an FDA submission. A critical requirement in obtaining our clearance is data, showing that the L-Dex values obtained from SOZO, are substantially equivalent to our own U400 device, currently cleared and used in the US to aid in the clinical assessment of lymphoedema. We believe we have provided the necessary information in establishing equivalency," said Richard Carreon, Managing Director and CEO of ImpediMed.

"This submission puts us well on track for the market launch of SOZO in the United States, which is expected in the 4th quarter of CY 2017."

**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

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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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