

impedi**med**

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ASX ANNOUNCEMENT

Heart Failure 510(k) Application for SOZO™ Submitted to FDA

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) for fluid monitoring of patients, including patients living with heart failure. The 510(k) submission is for a bioimpedance spectroscopy (BIS) connected platform for use on human patients. The device is designed for use in hospitals, clinics, and in patient's homes under a clinician's direction.

The SOZO™ platform is intended for the following uses:

- Monitoring patients who:
 - Live with heart failure
 - Take diuretic medication
 - Live with fluid management problems
 - Live with end-stage renal disease
 - Are recovering from coronary artery disease related event
 - Suffer from recurrent dehydration

"We are extremely pleased that we have been able to move so quickly on filing the next 510(k) submission for SOZO to the FDA. A critical requirement in obtaining our clearance is data, showing that values obtained from SOZO, are substantially equivalent to our own predicate device. We believe we have provided the necessary information in establishing equivalency," said Richard Carreon, Managing Director and CEO of ImpediMed.

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.

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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 FDA cleared and CE Marked medical devices, including SOZO[™], sold in select markets globally.

For more information, visit www.impedimed.com.

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