

impediMed

21 June 2017

ASX ANNOUNCEMENT

SOZO™ obtains CE Mark for Heart Failure Patient Monitoring

SOZO™ CE Mark covers multiple indications including fluid status monitoring for heart failure, L-Dex® for lymphoedema monitoring, hydration monitoring, and body composition

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 that CE Mark for SOZO™ has been achieved. The CE Mark for the SOZO™ platform includes fluid status monitoring for patients living with heart failure, assessment of lymphoedema using L-Dex®, hydration monitoring and body composition.

The CE Mark specifies that SOZO™ is 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
- The clinical assessment of lymphedema using L-Dex®
- Hydration monitoring
- Body composition

"Obtaining CE Mark for multiple indications for the SOZO™ platform is a pivotal regulatory and commercial milestone for ImpediMed, enabling us to now make SOZO™ commercially available to physicians and patients throughout Europe and Australia," commented Richard Carreon, Managing Director & CEO of ImpediMed.

"The SOZO™ platform is a sophisticated connected medical device that offers significant advantages over our previous BIS products. Testing time has been reduced to mere seconds versus tens of minutes, testing no longer requires an exam room, gel backed electrodes, or the need for a highly-trained clinician to administer the test. Data can be integrated straight into a patient's electronic health records and our cloud based system allows us to analysis data streams in real-time. We are already seeing this seamless integration work first hand from several of our clinical sites," added Richard Carreon.

Richard Carreon

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About ImpediMed

Founded and headquartered in Brisbane, Australia with U.S. offices in Carlsbad, Calif. and Bloomington, Minn., ImpediMed is the world leader in the development and distribution of medical devices employing bioimpedance spectroscopy (BIS) technologies for use in the non-invasive clinical assessment and monitoring of fluid status in patients. ImpediMed has the first medical device with 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 more information, visit www.impedimed.com.

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