

ANALYTICA LTD | ABN 12 006 464 866

19th March 2015

ASX ANNOUNCEMENT

PERICOACH SYSTEM RECIEVES 510(K) CLEARANCE IN USA

Analytica (ASX: ALT) is pleased to announce that the US Food and Drug Administration has assessed the 510(k) Premarket Notification submission for the PeriCoach system and has issued a Substantial Equivalence letter.

This clearance allows the PeriCoach system to be marketed and sold in the United States and its territories.

The 510(k) submission was sent to the USFDA on the 17th December 2014.

Analytica CEO Geoff Daly said "The rapid clearance is testament to the quality of the submission and the hard work and professionalism of Analytica's Product Development and Regulatory Affairs team. 510(k) clearance allows us to supply the PeriCoach in the world's biggest medical device market, and we can now pursue distribution agreements and enact our early adopter programme. Combined with our CE marking we now have the regulatory foundation to sell the PeriCoach globally."

For more information about the 510(k) process, visit:

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/

For more information about the PeriCoach System, visit: www.PeriCoach.com

For more information about Analytica, visit <u>www.AnalyticaMedical.com</u>



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About Analytica Limited

Analytica's lead product is the PeriCoach® System – an e-health treatment system for women who suffer Stress Urinary Incontinence. This affects 1 in 3 women worldwide and is mostly caused by trauma to the pelvic floor muscles as a result of pregnancy, childbirth and menopause.

PeriCoach comprises a device, web portal and smartphone app. The device evaluates activity in pelvic floor muscles. This information is transmitted to a smartphone app and can be loaded to PeriCloud where physicians can monitor patient progress via web portal. This novel system enables physicians to remotely determine if a woman is performing her pelvic floor exercises and if these are improving her condition.

PeriCoach has regulatory clearance in Australia, and has CE mark clearance. The product has 510(k) clearance in the USA. Product launches are anticipated in Europe and the US in 2015. The US market for incontinence pads is \$5 billion pa. It is projected that by 2030, 5.6 million women in Australia will suffer urinary incontinence.

