

## **ANALYTICA RECEIVES US FOOD AND DRUG ADMINISTRATION 510K CLEARANCE FOR PERICOACH**

BRISBANE, AUSTRALIA (March 19, 2015) – Analytica today announced it has received 510(k) clearance from the U.S. Food and Drug Administration for the PeriCoach, the first in-home pelvic floor muscle training system that includes a device, web portal and smartphone app designed to help women regularly follow a pelvic floor strengthening program and allow their clinicians to remotely follow their progress. Pelvic floor strengthening is the first-line recommended treatment for conditions including urinary incontinence and some sexual dysfunction issues. PeriCoach will be marketed in the U.S. by prescription.

PeriCoach already has CE Mark and is currently available in Australia and New Zealand where it is marketed directly to women and clinicians.

It is estimated that 50% of women will experience urinary incontinence at some point in their lives. The real number of women affected however, is likely much higher as women experiencing symptoms of urinary incontinence often do not report the issue to their physicians out of embarrassment or an incorrect assumption that leaking is a normal part of aging. Further, when pelvic floor muscle training is recommended, up to 50% of women are unsuccessful when they are given verbal or written direction alone.

Geoff Daly, CEO of Analytica, reports the company is very pleased to launch PeriCoach in the U.S. as it addresses a significant unmet need and a long-neglected women's health issue.

“Over the last year, we have been listening closely to everything women and clinicians have told us about the significant medical, lifestyle and economic challenges of addressing bladder leaking. There is a great desire to both prescribe and follow a regular pelvic floor muscle training program but nothing currently available to provide women the ease, motivation and the direction to follow a regimen or clinicians the ability to regularly monitor patient progress,” Daly explained. “The PeriCoach addresses all of these issues: motivation, management and monitoring.”

Analytica plans to launch PeriCoach in the U.S. in the coming months where it will compete with incontinence pads, which report sales of \$5 billion annually. The company is also finalizing plans for a spring introduction of PeriCoach in the UK.

“These are significant accomplishments for the team at Analytica and exemplify our commitment to deliver innovative, effective and affordable solutions for medical issues that can benefit from personal technology.

## REFERENCES

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2944440/>

Bump RC, Hurt WG, Fantl JA, Wyman JF. Assessment of Kegel pelvic muscle exercise performance after brief verbal instruction. Am J Obstet Gynecol. 1991;165:322-329.

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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.*

*For more information about Analytica, visit [www.AnalyticaMedical.com](http://www.AnalyticaMedical.com)*

*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. 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. The product is pending USFDA 510(k) clearance in the USA.*

*For more information about the PeriCoach System, visit: [www.PeriCoach.com](http://www.PeriCoach.com)*

