ResApp announces FDA 510(k) submission for SleepCheckRx

- **ResApp has submitted a 510(k) premarket notification to the US FDA for SleepCheckRx**
- **SleepCheckRx is a smartphone-only solution that uses clinically accurate algorithms to assess a patient's risk of obstructive sleep apnoea by analysing breathing and snoring sounds during sleep**
- **42 million American adults suffer from sleep disordered breathing, with 75% of cases undiagnosed**

Brisbane, Australia, 11 October 2021 – ResApp Health Limited (ASX:RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, today announced that it has submitted a 510(k) premarket notification[i] to the US Food and Drug Administration (FDA) for SleepCheckRx, a prescription-only, software-as-a-medical-device (SaMD) smartphone application for at-home sleep apnoea screening. The targeted time period for review of a 510(k) application by the FDA is 90 days.

SleepCheckRx is ResApp's easy to use smartphone application that uses clinically accurate algorithms to assess a patient's risk of obstructive sleep apnoea (OSA) by analysing breathing and snoring sounds during sleep. It requires no accessories or hardware other than a smartphone to make an assessment.

In a 308 patient, prospective clinical study, the SleepCheckRx algorithms were tested against an American Academy of Sleep Medicine (AASM) Type II sleep study (full, but unattended polysomnography) performed simultaneously in the patient's home (ref ASX announcement 30 September 2019). In the study, the algorithms identified patients with mild (AHI[ii] ≥ 5), moderate (AHI ≥ 15), and severe (AHI ≥ 30) OSA with a sensitivity of 85%, 83% and 83%, respectively. The algorithms had a specificity of 73%, 80% and 90%, respectively.

SleepCheckRx would be made available to patients via a prescription from their healthcare provider. Patients will be provided a specific code allowing them to download SleepCheckRx from the App Store, with their results uploaded to a healthcare provider portal.

FDA clearance would unlock a substantial market opportunity for ResApp. It is estimated that 42 million American adults suffer from sleep disordered breathing (SDB)[iii] and three in ten men and almost one in five women have sleep apnoea[iv]. It is further estimated that 75% of SDB cases remain undiagnosed[v].

CEO and Managing Director, Dr Tony Keating said: *"This marks another important milestone for our sleep apnoea product line. Last year, we obtained TGA approval and CE Mark certification for our direct-to-consumer SleepCheck app which is now available in over 36 countries. This SleepCheckRx 510(k)*

submission is the first step in the review process with the FDA and we look forward to working with the FDA through the review to obtain clearance for SleepCheckRx.

Sleep apnoea is a serious sleep disorder and research tells us that most people in the US with sleep apnoea don't know they have it. With SleepCheckRx, physicians will have the opportunity to screen their patients conveniently and quickly for sleep apnoea, helping their patients take the first step in getting treatment."

About ResApp Health Limited

ResApp Health Limited (ASX: RAP) is a leading digital health company developing smartphone applications for the diagnosis and management of the respiratory disease. ResApp's machine learning algorithms use sound to diagnose and measure the severity of respiratory conditions without the need for additional accessories or hardware. ResApp's regulatory-approved and clinically validated products include ResAppDx, a smartphone-based acute respiratory disease diagnostic test for use in telehealth, emergency department and primary care settings; and SleepCheck, a smartphone application which allows consumers to self-assess their risk of sleep apnoea. Both products are CE Marked in Europe and TGA approved in Australia. For more information, please visit www.resapphealth.com.au.

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This ASX announcement was approved and authorised for release by the board of directors of ResApp Health.

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[i] https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k
[ii] Apnoea hypopnoea index (AHI) is the number of apnoeas or hypopnoeas per hour of sleep.
[iii] Young et al. New Engl J Med 1993
[iv] Peppard et al. Am J Epidemiol 2013
[v] Young et al. Sleep 2008