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ResApp Health receives US FDA clearance for at-home sleep test

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SleepCheckRx is an easy to use, at-home sleep test that screens adults for the risk of moderate to severe obstructive sleep apnoea

Australian firm ResApp Health, a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, has announced that SleepCheckRx has received 510(k) clearance as a prescription-only software-as-a-medical device from the US Food and Drug Administration (FDA). Gaining FDA clearance enables ResApp to commercially market the test in the United States.

SleepCheckRx is an easy to use, at-home sleep test that screens adults for the risk of moderate to severe obstructive sleep apnoea by analysing breathing and snore sounds recorded on an Apple iPhone. It requires no accessories or hardware other than an iPhone to make an assessment. ResApp plans to solicit 510(k) clearance for Android devices in the future.

Sleep apnoea is the most common sleep breathing disorder and affects more than three in every ten men and nearly two in every ten women. Obstructive sleep apnoea is when air stops flowing to the lungs during sleep. The prevalence of sleep apnoea is increasing due to an ageing population and increasing rates of obesity. Studies have shown that up to 80% of people with sleep apnoea are undiagnosed and untreated[2]

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