Anaxsys Files 510(k) for respiR8™ Continuous Respiratory Rate Counter

SEND, England--(BUSINESS WIRE [1])--Anaxsys Ltd, the medical device company developing innovative respiratory devices, announced the filing of a 510(k) Premarket Notification with the U.S. Food and Drug Administration (FDA) for regulatory clearance for respiR8™ continuous respiratory rate counter. respiR8, which monitors respiratory rates in post-operative, trauma and emergency procedure patients, has already received a CE Mark and is available in hospitals in the U.K. and Europe.

“The filing of the 510(k) for Anaxsys is an important milestone as it will facilitate the Company’s growth strategy and make respiR8 available to one of the largest healthcare markets – the United States,” stated Dr Deryk Williams, Co-founder and Managing Director of Anaxsys. “Subject to clearance by the FDA, U.S. healthcare professionals will be able to better monitor patient respiratory rate, which has been highlighted by the medical community as the vital sign which provides the earliest indication of patient deterioration in the post-operative period yet is the least monitored. Recent studies and publications in the U.S. by eminent physicians and patient safety organisations1 are calling for routine continuous monitoring of respiratory rate in order to improve patient safety and help reduce the incidence of post-operative drug induced respiratory depression, post-operative cognitive impairment (dementia) and cardiac arrests.”

Dr Williams, added: “Studies have shown that post-operative myocardial infarctions, the most common cardiovascular complication following non-cardiac surgery, affect around 10 million patients each year with a staggering mortality rate of up to 21%2. The importance of continuous monitoring of respiratory rate is being highlighted by the medical community, now more than ever, as major public health issues such as post-operative myocardial infarctions and post-operative cognitive impairment (dementia), are being addressed.”

“By continuously monitoring respiratory rate, respiR8 can alert healthcare professionals to patient deterioration from inadequate oxygenation, which has been shown to lead to significant post-operative delirium which can result in cognitive impairment and increased mortality, or potentially life threatening respiratory depression that can result in fatal respiratory arrest. A recent publication reports that severe post-operative drug induced respiratory depression occurs in up to 29% of patients3. respiR8 can also provide early warning signs of possible myocardial infarctions as it will alert healthcare professionals to patients’ rapid breathing - a symptom which can occur up to 45 minutes before cardiac arrest.”

respiR8 is the world’s first continuous electrochemical respiratory rate counter. The device consists of a novel patented sensor that is pre-fitted into a standard oxygen mask providing a very accurate respiratory counter for doctors, nurses and

emergency healthcare professionals. The mask is connected to a small electronic monitor that captures, displays and records the patients' continuous respiratory rate. respir8 is a reliable method for this crucial monitoring procedure in the awake or sedated patient and has the potential to dramatically improve patient safety and considerably minimize post anaesthetic risks.

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[1] http://www.businesswire.com/