Intelomed Receives FDA 510(k) Clearance of CVInsight Medical Device

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WEXFORD, Pa., Sept. 20, 2012 /PRNewswire/ -- Intelomed, Inc., a developer of non-invasive medical devices and technology for monitoring fluid adaptation for patients well or poorly perfused, announced today that it has received FDA 510(k) clearance on its CVInsight medical device.

CVInsight processes a pulse wave through proprietary algorithms to measure and display vital information such as functional oxygen saturation of arterial hemoglobin (Sp02) and pulse rate of adult and pediatric patients.

Intelomed's CEO, Frank Amoruso, commented: "We are very excited about the introduction of CVInsight. We believe it will have a meaningful impact on the ability to monitor a patient's vital signs and cardiovascular health, thereby having an extremely positive effect on the quality of patient care."

CVInsight will provide clinicians and other caregivers with a utility for recording trends of pulse rate, SpO2, and the percentage of change in pulse rate and pulse strength derived from data recorded with a pulse oximeter. A clinician may use this data as an indication of a clinical event based upon their experience and training. Intelomed's Chief Researcher and inventor of CVInsight, Jan Berkow, said; "CVInsight will provide physicians with a non-invasive tool that gives a critical 'insight' into a patient's declining cardiovascular stability - much earlier than some current medical standards by trending of such values. With this early indication, the clinician may be able to determine what action to take well in advance, rather than reacting to recognition measures after the event has occurred. One major challenge facing trauma surgeons and clinicians is the ability to non-invasively measure the circulatory system's blood volume adequacy in real-time. I believe this could be a very significant step in patient care, especially in the areas of hemodialysis, cardiology, and trauma
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