Nanowear Receives FDA 510 (K) Platform Clearances to Implement Forthcoming AI-based Diagnostics

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Nanowear is the leading hospital-at-home and remote diagnostics company with an AI-enabled and FDA cleared wearable platform built with nanotechnology-enabled sensors.

Nanowear, a leading hospital-at-home and remote diagnostic platform informed by proprietary cloth nanotechnology and AI, announced that it received its third FDA 510(k) clearance and first software-only clearance as an end-to-end digital platform, illustrating unique capabilities available to enterprise customer channels across a broad spectrum of diagnostic and monitoring verticals. This clearance enables Nanowear to implement standalone AI and deep learning algorithms that will inform remote diagnoses as Software-as-a-Medical Device (SaMD). Future clearances include, but are not limited to, diagnosing or monitoring of hypertension, COPD, sleep apnea, worsening heart failure and post-surgical recovery.

“AI has the invaluable ability to assist healthcare providers and payers in tracking complex biological systems and individual risk patterns within the human body where the data is inherently high-dimensional,” said Peter Norvig, Director of Research at Google and co-author of the most popular textbook in artificial intelligence, Artificial Intelligence: A Modern Approach, used in more than 1,500 universities in 135 countries. “When time-synchronously tracking a complex system like a patient’s heart, lungs and upper vascular system, the data captured needs to match the system’s level of complexity. Nanowear’s 85+ biomarkers of high-fidelity data within a closed loop system enables unique AI and deep learning algorithms to ensure that need is met.”

Nanowear’s SimpleSense uses its proprietary cloth-based smart nanosensor technology to capture and analyze these low-noise, 85+ hospital-grade biomarkers using time-synchronous scattering methods.

“The largest bottleneck for any AI deployment is data preparation, which can take 70% - 80% of the time in any given application,” said Venk Varadan, co-founder and CEO of Nanowear. “Unlike wrist or armband device-enabled hospital-at-home platforms that do not yield high-fidelity longitudinal data, our SimpleSense platform utilizes clinical-grade biomarkers with a high SNR (signal-to-noise ratio). The time required to see results with our neural network is significantly shorter, meaning we have the profound ability to scale the capabilities of our platform immediately. SimpleSense already reduces provider workflow and patient time by approximately 60%; but the long-term value is that SimpleSense truly does get smarter with each patient.”

This FDA 510(k) clearance establishes Nanowear’s core data assets, secures existing data architecture, and unifies the digital platform through guiding principles like security, privacy, modularity, scalability, interoperability and utility. This unified digital platform integrates hospital-grade nanosensors, telehealth software and AI-driven decision support to radically transform virtual care and enable providers to triage risk profiles of the cardio, pulmonary and upper vascular systems of patients while they are in the comfort of their own home.

Read the original article on Business Wire.