

Nanowear receives FDA clearance for its transformative remote diagnostic monitoring device differentiated by novel cloth-based nanosensor technology (SimpleECG™)

NEW YORK, NY – December 1, 2016 – Nanowear, an early stage developer of cloth-based diagnostic monitoring nanosensor technology, today announced that it has received FDA Class II 510(k) clearance for its first product, SimpleECG™, a remote cardiac monitoring undergarment. SimpleECG™ collects continuous multi-channel ECG, heart rate and respiratory rate data from the garment and transfers it to a web-based portal for review by a physician, by way of a mobile application. The initial version of the product is iPhone-based.

This marks the company's first FDA clearance, and reflects Nanowear's strategy of differentiating itself in an otherwise crowded market for wearables, with an eye towards the future of the "Connected Self." SimpleECG™ will provide an easier and more patient-friendly means of capturing and transmitting diagnostic data via everyday garments in an effort to monitor heart behavior and prevent cardiac-related events. John Zimmerman M.D., Nanowear's Chief Medical Officer, said, "As healthcare continues to evolve and move beyond the walls of the hospital, easy-to-use and clinically validated solutions are essential to ensure patient compliance and actionable diagnostic insights for physicians and providers."

"This is a big milestone for our young company," said co-founder & CEO Venk Varadan. "The FDA's decision not only positions us for commercial opportunities in remote cardiac monitoring, but more importantly, it provides accreditation of the company's one-of-a-kind, cloth-based sensor technology as medical-grade. This is the first step and foundation of what we believe to be an extensive array of applications for our nanosensor technology – including numerous other electrical, biometric and biochemical signals that can be measured directly from the skin without conductive gels, adhesives or skin preparation. The market of applications for healthcare alone is a multi-billion-dollar opportunity, but as we look beyond to consumer, industrial, clinical research, military and public sector applications, the addressable market expands exponentially."

The company has worked in close partnership with the FDA since early 2015 to understand the unique dynamics of this device, specifically the nanosensor technology. "Our discussions were collaborative and interactive, culminating in this announcement," said Varadan.

Having spent the last two years focused solely on product development and the regulatory process, Nanowear will now focus its near-term efforts on product commercialization, strategic partnerships and continued development of complementary products and applications for chronic disease states.

About Nanowear

Nanowear is the leading developer of patented, textile-based nanosensor technology with applications in the cardiac, neurological, industrial, safety, government and sports medicine / performance diagnostics monitoring markets. The company's proprietary technology enables continuous electrophysiological, biometric and biochemical monitoring that provides medical professionals with accurate diagnostic data through a cost-effective and non-invasive wearable solution. Nanowear's core focus on innovation and next-gen technologies will continue to propel the company towards unique and groundbreaking applications for its nanosensors. The company is headquartered in New York, NY, with a research and development center in University Park, PA.

Contact Information:

For more information, please visit www.nanowearinc.com, or contact us at the following:

info@nanowearinc.com

[LinkedIn](#) | [Twitter](#)