Sibel Health Announces FDA Clearance for ANNE One--A Flexible, Wireless Vital Signs Monitoring Platform

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NILES, Ill., Oct. 26, 2021 /PRNewswire/ -- Sibel Health, an award-winning medical technology company spun out of the <u>Querrey Simpson Institute for Bioelectronics</u> at Northwestern University, announced its first 510(k) clearance from the U.S. Food and Drug Administration for the ANNE® One platform. The ANNE® One platform is a wireless, flexible, and rechargeable monitoring system indicated for the measurement of multiple vital signs in the healthcare setting for clinical decision-making by medical providers for patients 18 years or older. It includes a companion mobile device pre-loaded with ANNE® View software to visualize clinical data in real time.

Prior to FDA 510(k) clearance, the ANNE® One system has been deployed extensively in thousands of patients across a wide range of geographic locations including low-resource settings with scientific publications in *Nature Medicine*, *Lancet Digital Medicine*, and *Proceedings of the National Academy of Medicine*. With U.S. government support, Sibel Health has also deployed the ANNE®One platform to assess patients with COVID-19. "It's so rewarding to see a cutting-edge technology go from scientific and technical proof of concept to FDA clearance—a hugely important milestone as we deploy ANNE® One clinically," says Ha Uk Chung PhD, cofounder and VP of Research and Development at Sibel Health. Jong Yoon Lee, cofounder and VP of Software Engineering, notes "the ability for our system to monitor a wide range of vital signs using a dual-sensor platform is very powerful and unique. The interoperability and the extendability of the system will allow us to use this approval as a foundation to expand to other novel indications and make monitoring accessible to everyone."

About Sibel Health

Sibel Health is a medical technology company spun out of the Querrey Simpson Institute for Bioelectronics at Northwestern University with the goal to deliver *Better Health Data for All*[®]. Backed by a consortium of for-profit and non-profit strategic partners, Sibel's ANNE[®] One platform offers a comprehensive physiological monitoring platform with advanced analytics for both clinical care and research applications. Sibel has received widespread recognition for its technology including being named the inaugural 2020 winner of Nature's Spinoff Prize. Sibel is headquartered in Niles, IL with an international office in Seoul, South Korea. Visit Sibel Health online at www.sibelhealth.com. Follow us on Twitter: @Sibel_Health.

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