FDA Grants De Novo to ML-based,
Real-time Indicator of Patient Deterioration

*Fifth Eye's noninvasive tool is the first to provide continuous monitoring
of hemodynamic status using a single ECG lead*

March 2, 2021, ANN ARBOR, Mich. — Fifth Eye™, a provider of intuitive real-time clinical analytics, today announced the U.S. Food and Drug Administration (FDA) has granted De Novo classification for its Analytic for Hemodynamic Instability (AHI). AHI can continuously monitor any patient with an electrocardiogram (ECG) for hemodynamic instability — a leading cause of death for critically ill or injured patients. This clinically validated technology enables hemodynamic assessments every two minutes as opposed to every two hours or more, increasing the likelihood of timely patient rescue.

Fifth Eye's machine learning-based software device, developed in collaboration with clinicians at Michigan Medicine, gives nurses and doctors a real-time view into patients' hemodynamic status. AHI automatically provides intuitive, time-trended updates without requiring vital sign assessment, manual data input in electronic health records, or score calculation.

"The current approach to monitoring hemodynamic instability is intermittent, resource intensive, and error prone," said Jen Baird, CEO, Fifth Eye. "AHI is an easy-to-implement device that reduces nurse burden by giving a reliable heads-up about emerging signs of hemodynamic instability that can go undetected with ECG or vital signs alone, enabling proactive patient rescue."

In an FDA-reviewed clinical study, AHI's unstable classifications were highly correlated with hemodynamic instability, defined as hypotension plus tachycardia. AHI identified hemodynamic instability with 96% sensitivity and identified stable patients with 85% specificity compared to traditional vital signs-based reference standards. The results are from over 28,000 AHI outputs across 222 adult critical care patients.

"The problem of predicting unexpected patient decompensation remains critical for hospitals," said Benjamin Bassin, MD, Director, Emergency Critical Care Center, and Associate Professor in the Department of Emergency Medicine, University of Michigan. "AHI provides reliable, noninvasive, and continuous monitoring of hemodynamic decompensation by way of ECG waveform analysis — as opposed to intermittent static vital signs — to identify at-risk patients across hospital settings, including remotely. This allows for much earlier intervention and has the potential to improve confidence, quality, safety and appropriate resource allocation across the spectra of U.S. healthcare systems."

The AHI software is intended for use by healthcare professionals managing in-hospital patients 18 years or older who are receiving continuous physiological monitoring with ECG.

About Fifth Eye Inc.

Fifth Eye Inc. is an Ann Arbor, Michigan-based company that develops intuitive real-time clinical analytics based on physiologic waveforms to improve outcomes and reduce costs. Born in a hospital and taught by clinicians, Fifth Eye's licensed technology from the University of Michigan has FDA De Novo authorization for in-hospital, continuous monitoring of patient clinical trajectory. For more information, please visit www.fiftheye.com.

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