

Evoke Neuroscience, Inc. Announces Expanded Indications for Use with 510(k) Clearance for the eVox® System

510(k) Clearance for the eVox System, a non-invasive device that aids diagnosis of cognitive diseases

NEW YORK, NY, USA, January 2, 2018 /EINPresswire.com/ -- Evoke Neuroscience, Inc. announced today that it has received 510(k) clearance from the Food and Drug Administration (FDA) for the eVox® System – expanding the Indications for Use to include electroencephalography (EEG) and Event-related Potentials (ERP) that aid physicians in diagnosis.



The eVox® System is a medical device that gives primary and specialty care physicians the ability to assess brain function in-house via a non-invasive procedure and use results to aid in making a clinical diagnosis.

Assessing Memory Loss with EEG and ERP:

eVox acquires biomarkers based on EEG and ERP that aid doctors in:

- identifying the root cause of memory loss
- identifying MCI and memory loss sooner
- performing a differential diagnosis of depression vs. dementia

eVox Aids Physicians in Diagnosis:

Historically, most providers have relied on self-report questionnaires and effort-based computerized testing for determining a diagnosis. "There is a clear need for objective memory-related biomarkers that aid in diagnosis – and to access these biomarkers early in the course of a potential disease." said David Hagedorn, Ph.D., CEO of Evoke Neuroscience, Inc. Many causes of mild cognitive impairment (MCI) can be readily treated if caught early (Alzheimer's Foundation of America, 2016). The eVox System was developed to aid physicians in the early diagnosis of cognitive diseases such as dementia. "To understand cognitive health, and more specifically memory, it is important to isolate key biomarkers of the brain itself."

Obtaining these biomarkers with the eVox System occurs within any office setting and with minimal staff training and time. eVox is an accessible tool that helps doctors assess brain health and identify

root causes of cognitive decline symptoms, many of which are treatable. Doctors should use their professional judgment in determining when the eVox System is appropriate to aid in diagnosis.

About Evoke Neuroscience, Inc.:

Evoke Neuroscience (<u>www.evokeneuroscience.com</u>) was formed in 2009 by research scientists, clinicians, medical doctors, and business professionals dedicated to developing and delivering the most important advances in brain science. Evoke Neuroscience's goal is to improve people's health, performance, and quality of life with cognitive tools that are accessible, affordable, and easy to use. Since 2014, physicians have used the eVox® System to help guide neurofeedback treatment. The new 510k clearance expands the Indications for Use of the eVox System to include EEG and ERP to aid in diagnosis.

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