Brain Wave Test Device for ADHD

U.S. Food and Drug Administration

The U.S. Food and Drug Administration today allowed marketing of the first medical device based on brain function to help assess attention-deficit/hyperactivity disorder (ADHD) in children and adolescents 6 to 17 years old. When used as part of a complete medical and psychological examination, the device can help confirm an ADHD diagnosis or a clinician's decision that further diagnostic testing should focus on ADHD or other medical or behavioral conditions that produce symptoms similar to ADHD.

The device, the Neuropsychiatric EEG-Based Assessment Aid (NEBA) System, is based on electroencephalogram (EEG) technology, which records different kinds of electrical impulses (waves) given off by neurons (nerve cells) in the brain and the number of times (frequency) the impulses are given off each second.

The NEBA System is a 15- to 20-minute non-invasive test that calculates the ratio of two standard brain wave frequencies, known as theta and beta waves. The theta/beta ratio has been shown to be higher in children and adolescents with ADHD than in children without it.

"Diagnosing ADHD is a multistep process based on a complete medical and psychiatric exam," said Christy Foreman, director of the Office of Device Evaluation at the FDA's Center for Devices and Radiological Health. "The NEBA System along with other clinical information may help health care providers more accurately determine if ADHD is the cause of a behavioral problem."

ADHD is one of the most common neurobehavioral disorders in childhood. According to the American Psychiatric Association, 9 percent of U.S. adolescents have ADHD and the average age of diagnosis is 7 years old. Children with ADHD have difficulty with attention, hyperactivity, impulsivity and behavioral problems.

The FDA reviewed the NEBA System through the de novo classification process, a regulatory pathway for some low- to moderate-risk medical devices that are not substantially equivalent to an already legally marketed device.

In support of the de novo petition, the manufacturer submitted data including a clinical study that evaluated 275 children and adolescents ranging from 6 to 17 years old with attention or behavioral concerns. Clinicians evaluated all 275 patients using the NEBA System and using standard diagnostic protocols, including the Diagnostic and Statistical Manual of Mental Disorders IV Text Revision (DSM-IV-TR) criteria, behavioral questionnaires, behavioral and IQ testing, and physical exams to determine if the patient had ADHD. An independent group of ADHD experts reviewed these data and arrived at a consensus diagnosis regarding whether the research subject met clinical criteria for ADHD or another condition. The study results showed that the use of the NEBA System aided clinicians in making a more

accurate diagnosis of ADHD when used in conjunction with a clinical assessment for ADHD, compared with doing the clinical assessment alone.