# FDA approves marketing of first device to treat ADHD

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(HealthDay)—Marketing has been approved for the first medical device

to treat attention-deficit/hyperactivity disorder (ADHD), the U.S. Food and Drug Administration announced Friday.

The Monarch external Trigeminal Nerve Stimulation (eTNS) System is available by prescription only for patients aged 7 to 12 years old who are not currently taking prescription medication for ADHD. The FDA indicates that the Monarch eTNS System should be used in the home under caregiver supervision. The device, which is about the size of a cell phone, according to the FDA, generates a low-level electrical pulse to the trigeminal nerve from a wire to a small patch placed above the patient's eyebrows. The patient should feel a tingling sensation.

Clinical trials have shown it may take up to four weeks to see results, and patients should consult with caregivers after four weeks to assess the treatment's effectiveness. In a clinical trial of 62 patients with moderate-to-severe ADHD, those who used the Monarch eTNS System nightly for four weeks had a statistically significant improvement in their ADHD symptoms compared with those who received placebo. Their average ADHD Rating Scale score decreased from 34.1 to 23.4 points compared with a decrease from 33.7 to 27.5 points for those who received placebo.

Commonly reported side effects with the Monarch eTNS System include drowsiness, increased appetite, trouble sleeping, teeth clenching, headache, and fatigue. The device is contraindicated in children younger than 7, patients with active implantable pacemakers or neurostimulators, and patients with body-worn devices like insulin pumps.

Marketing authorization was granted to NeuroSigma.

**More information:** More Information