

AIOMEGA®'s AIO Breathe® for children Receives FDA Clearance—Expanding Innovative Sleep Apnea Treatment to pediatrics

AIO Breathe® for children and adolescents with mild to moderate obstructive sleep apnea features identical design and engineering as the adult device.

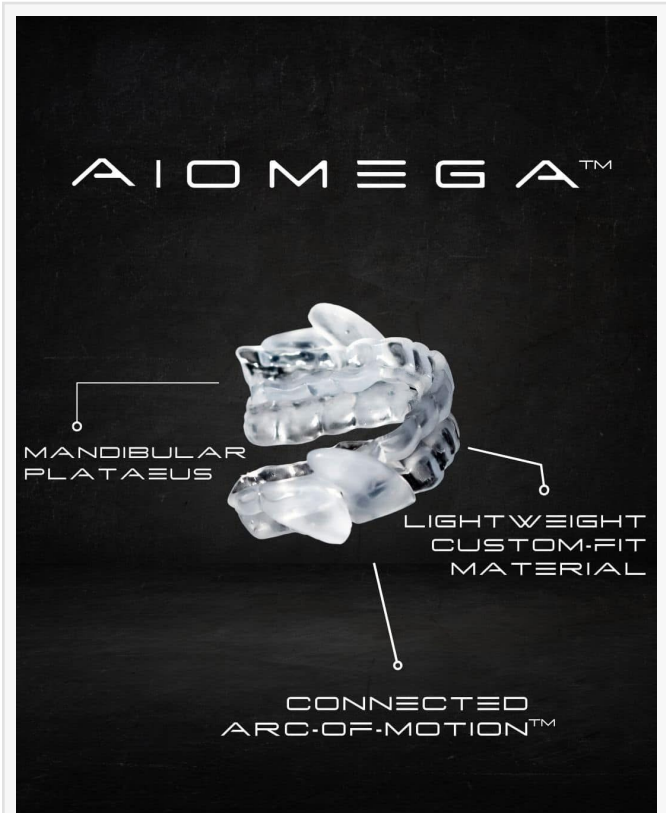
TYLER, TX, UNITED STATES, November 10, 2025 /EINPresswire.com/ -- AIOMEGA® Receives Pediatric Clearance for AIO Breathe®—Expanding Innovative Sleep Apnea Treatment to Children

AIOMEGA, a Texas biomedical company, today announced that the U.S. Food & Drug Administration (FDA) has granted clearance for the pediatric use of its flagship device, the AIO Breathe®, in children and adolescents with mild to moderate obstructive sleep apnea (OSA). The pediatric version features identical design, engineering, and therapeutic technology as the adult device—offering a seamless adaptation to the pediatric patient population.

“As a company committed to advancing airway and sleep health across the lifespan, we are thrilled to make AIO Breathe available to

pediatric patients,” said Dr. Raghavendra V. Ghuge, MD, MBA, DABSM, FAASM, the Founder and Chief Executive Officer of AIOMEGA. “[Obstructive sleep apnea in children](#) is often underrecognized yet carries profound implications—from impaired neurocognitive development and growth delays to cardiovascular and metabolic disturbances.”

Studies estimate prevalence in the general pediatric population at approximately 1%–4%. (Frontiers) In practice, the risks are even higher among children with craniofacial abnormalities, neuromuscular disorders, or obesity. (Dove Medical Press).



AIO Breathe oral appliance for treatment of adult and pediatric Obstructive Sleep Apnea

Dr. Ghuge continued, “With clearance of the pediatric version of AIO-Breathe, we are now positioned to offer a novel, non-invasive airway enhancement solution that may fill a critical gap in pediatric sleep-disordered breathing management. Our goal is to support improved sleep, growth, behavior, and cardiovascular wellness for children impacted by OSA.”

About AIO-Breathe (Pediatric Version)

The pediatric version of AIO-Breathe maintains the same patented AAVOAT (Adaptive Antero-Vertical Open Airway Therapy) design that gives the adult

version clearance and is optimized in size for children. Key features include:

- Non-invasive oral airway-enhancement device engineered to reduce airway collapsibility during sleep

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As a company committed to advancing airway and sleep health across the lifespan, we are thrilled to make AIO-Breathe available to pediatric patients”

Raghavendra V Ghuge, MD



Mission Statement: Bring affordable innovative technology to health and fitness that fulfills unmet need while reducing complications.

- FDA-cleared indication for children (ages 6 to 11) and adolescents (ages 12 to 17) with mild to moderate obstructive sleep apnea
- Seamless compatibility with existing clinical workflows (already in use for adults)
- Backed by AIOMEGA's mission to integrate sleep-medicine innovation into everyday health and performance.

Clinical and Market Implications

[Pediatric OSA is associated with a spectrum of adverse conditions](#), including impaired cognitive performance, behavioral dysfunction, growth faltering, and elevated cardiovascular risk. (MDPI) Historically, treatment options have centered on surgery (e.g., adenotonsillectomy) and positive airway pressure modalities such as CPAP; yet a significant portion of children either fail first-line therapy, are non-adherent, or remain untreated. With FDA clearance for pediatric use, AIO-Breathe provides sleep medicine specialists, otolaryngologists, pediatric pulmonologists, and dentists a new therapeutic option for children with obstructive sleep apnea.

About AIOMEGA

Founded by Dr. Raghavendra V. Ghuge, a board-certified physician in sleep medicine, AIOMEGA is a biotech company dedicated to the health and well-being of every person on the

planet by engineering and patenting solutions for true MEGA airway performance in sleep and sport. The company's product portfolio includes AIO□Breathe®, AIO Breathe Comfort®, AIO□Breathe MB®, AIO Breathe MB Comfort® for Obstructive Sleep Apnea, and AIO□Swift®, AIO□Grit®, AIO□Brut®, and AIO□Revive® for improving athletic performance and concussion protection.

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The AIOMEGA name and design, and AIO□Breathe are trademarks of AIOMEGA LLC.

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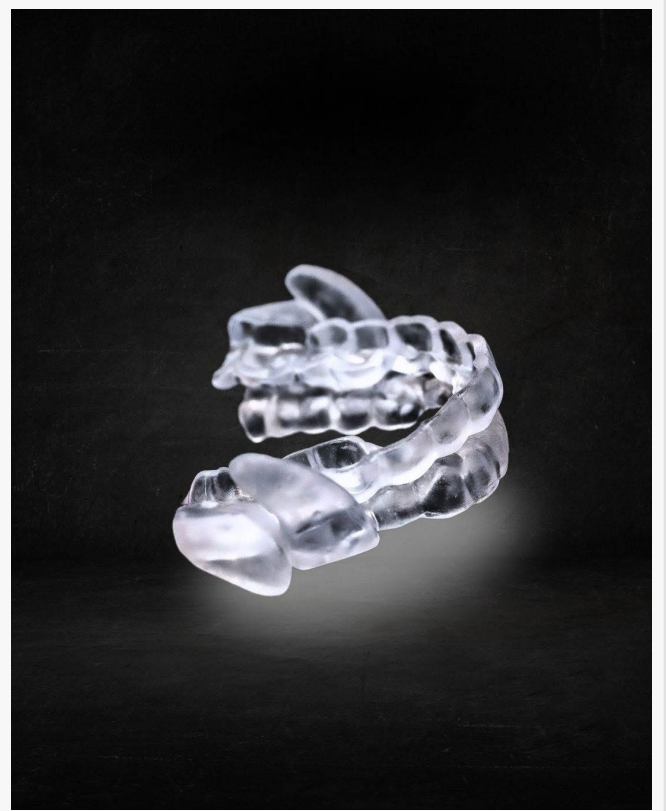
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AIO Breathe oral appliance for Obstructive Sleep Apnea in children and teenagers

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