Dr. Edward T. Sall at Advanced ENT Physicians and Surgeons of CNY is looking for volunteers with severe Obstructive Sleep Apnea (OSA) to participate in a clinical research study.

The purpose of the study is to evaluate the safety and effectiveness of the ProSomnus® EVO™ Sleep and Snore Device in individuals with severe Obstructive Sleep Apnea (OSA).

If you choose to participate, you would be asked to attend multiple study visits over a 12- to 14-month period and complete several two-night sleep studies in your home. In appreciation for your time, you would be provided with a custom ProSomnus EVO Sleep and Snore Device at no charge.

To be eligible for this study, you must meet the following criteria:

- Aged 18-80 years
- Diagnosed with uncomplicated severe OSA
- Body mass index < 45 kg/m2
- Neck circumference < 50 cm
- Absence of severe oxyhemoglobin desaturation during sleep, indicated by mean nocturnal SpO2 > 87% (low oxygen level in blood)
- Mandibular (jaw) range of motion > 5 mm in protrusive direction
- Adequate dentition, as determined by the study dentist

You would not be eligible for the study if you meet any of the following criteria:

- Inability to breathe through the nose comfortably
- Presence of > 25% central sleep apnea
- Presence of positional Obstructive Sleep Apnea
- History of surgery intended to alter anatomy for the correction of Obstructive Sleep Apnea
- Presence of hypoglossal (tongue) nerve stimulation device
- Use of CPAP or use of Oral Appliance Therapy within the two weeks prior to the screening home sleep test
- History of Oral Appliance Therapy that has been demonstrated to provide effective therapy within the two years prior to the screening home sleep test
- Anticipated change in medical therapy during the study protocol that could alter the severity of your Obstructive Sleep Apnea
- Loose teeth or advanced periodontal (gum) disease
- History of temporomandibular (jaw) joint disorder
- Resistant hypertension (high blood pressure)
- Presence of congestive heart failure, recurrent atrial fibrillation (irregular heart beat), or coronary artery disease
- Presence of neuromuscular diseases, hypoventilation (shallow breathing) disorders, or cerebrovascular
- (brain blood vessel) disease
- Presence of pulmonary (lung) disease resulting in significant desaturation
- History of cerebrovascular incident within the last 12 months
- Use of pacemaker or other life supporting device
- Anticipated change in body weight > 5% during the study period
- Participation in other studies that could interfere with the study protocol
- Pregnancy or lactation (breast feeding)
- In the opinion of the investigator, unsuitable for inclusion in the study

For more information or to volunteer for this study, please call 315.671.8796

This study has been approved by WCG IRB (protocol # 20223306; approval # 34582316.0)

Advanced ENT
Physicians & Surgeons of CNY PC

ProSomnus® SLEEP TECHNOLOGIES

PRO3-381-A