FreePAP


## PHINARAK HAO

**FOUNDER**

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904-651-8349
Visit us at FreePAP.com


**Industry:**
Medical device-Class IIa Intraoral devices for snoring and/or Obstructive Sleep Apnea

**Development stage:**
- Design verification and functional prototype
- Developed prototyping and manufacturing process
- Research and development into embedded sensor devices for future applications.

**Funding opportunity:**
Seeking SAFE investors

**Use of funding:**
- Key resource hirings (CEO, CTO, Quality, Operations, Regulatory, and Clinical Roles)
- Benchtop prototyping and testing
- Manufacturing tooling
- FDA 510(k) application
- FDA investigational device exemption application for clinical studies
- Continued IP FILING (international and domestic)
- Initial commercialization and marketing to sleep medicine physicians and dental sleep medicine providers

**WHO WE ARE -**
3 Little Ladies Inc. is a medical device company focused on the treatment of obstructive sleep apnea (OSA) and snoring. Obstructive sleep apnea is the most common sleep-related breathing disorder. We are on mission to treat the millions of patients who have sought an alternative to current OSA treatments in this country and throughout the world. Our company has designed and developed a patented technology that treats OSA in a novel way that significantly differs from current treatments and therapies that are currently available.

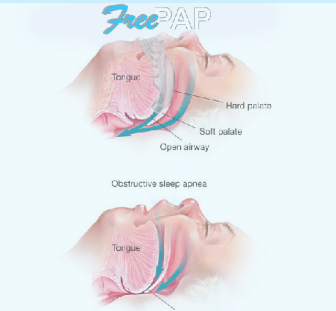
**Problem and Opportunity -**
Due to the multitude of factors that make PAP (positive airway pressure) devices uncomfortable to wear and keep on throughout the night, noncompliance with PAP devices is very high. CPAP (the gold standard for OSA treatment) noncompliance is at least 50% and some studies show CPAP noncompliance in the first year as high as 80%. Most patients find CPAP masks and/or machines very difficult to tolerate. Oral appliances therapies also report a high rate of noncompliance. Only 32% patients reported using the appliance regularly. Most of the non-adherent patients had stopped using their appliances in the first year (55%). Because of the high rate of noncompliance of so many of these therapeutic sleep apnea treatment devices, there is an incredible market opportunity to create a new medical device that can promote better compliance. Also due to the high costs of the current therapeutic devices, there is an opportunity to produce an effective product at a lower cost for higher profitability. Our company seeks to convert and convince the majority of OSA patients who are unsatisfied with their current therapies.

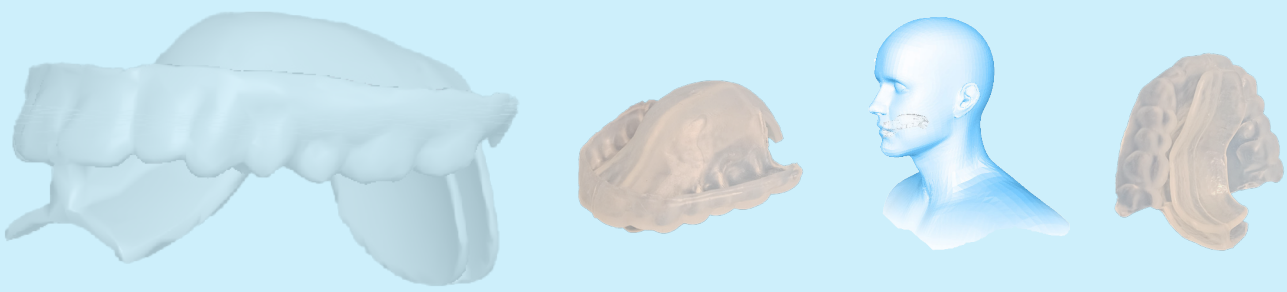
**Solution -**
We have developed an oral appliance that helps support airway patency and treats OSA by creating an airway channel that follows and conforms to each patient's individual anatomy. Each device is custom made for each patient utilizing state of the art 3D scanning and printing technologies.

**Competitive advantage -**
Truly and literally the most custom fit oral appliance on the market.
Very low cost to produce and potential for high recurring profitability.
An opportunity to give alternatives to those who cannot tolerate CPAP and oral appliances.
A suitable treatment for nearly all facial structures and dentition types.

**Competitors -**
Our main market competitors are existing PAP devices and mandibular advancement devices. High noncompliance rates with popular current therapies are for a multitude of reasons. Poor compliance with the other current therapies is a great reason and opportunity for our device to capture market share.

**Value Proposition -**
Our oral appliance directly aligns with the needs of OSA patients. Most patients are unable to tolerate CPAP treatment and to a lesser extent MADs. There needs to be an alternative to existing therapies with better patient compliance and our medical device can directly fill this need in the market. The benefits of an effective oral appliance with greater compliance would be tremendous for OSA patients. Our device requires no electricity, has great custom fit, and is easy to use. Some initial effort to become acclimated to the oral appliance over the first few days to weeks will require some energy and effort from patients to get the desired results. But once the patients have become acclimated, the use of the oral device is quite effortless. There is no pressure of wearing a mask, or no stress on the dentition or jaw. The risk of this oral appliance therapy just like any treatment for OSA is noncompliance. We believe the rate of compliance for our medical device will be much better than existing therapies because of its ease of use and comfort after acclimation to the device.

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**Investment appeal:**

- IP protected and vast pipeline of products with continued foreign and domestic IP protection
- Established reimbursement codes
- High potential profit margins with recurring monthly consumables at also high profit.

**Business model - Payers:**

- Insurance, Medicare, Medicaid, Self-pay, Retail customers
- Established medical and dental reimbursement codes
- The oral appliance material has been approved by the FDA for molded medical parts for use <30 days without further biocompatibility studies.
- Consumables that require monthly recurring purchases.

**Initial commercialization and go to market strategy:**
Marketing to sleep medicine specialists and dental sleep specialists, to the millions of noncompliant OSA patients and many more millions undiagnosed and newly diagnosed patients. Possible over-the-counter retail sales for the treatment of snoring.

**Priority target:** US launch followed by worldwide commercialization

**Markets -**
Nearly 1 billion adults aged 30 to 69 are estimated to have OSA globally, with the majority (60%) with mild disease and the remaining 40% with moderate to severe disease. Approximately 170 million individuals in North and South America have some degree of OSA. The estimated prevalence of OSA in 50 European countries was approximately 175 million. According to the American Medical Association, more than 30 million people in the United States have sleep apnea, however, only 6 million people are officially diagnosed. According to the American Sleep Apnea Association, undiagnosed moderate to severe level obstructive sleep are estimated to represent 80% of those who have this sleep disorder. Because of massive underdiagnosis and now increasing awareness of OSA, the numbers of those affected will continue to rise. The global sleep apnea devices market size was valued at USD 4.2 billion in 2022 and is expected to expand at a compound annual growth rate (CAGR) of 6.2% from 2023 to 2030. The markets around the world will continue to grow because of increasing awareness and improving diagnostic tools.

**Go to Market Strategy and Revenue Model -**
Our strategy will be to initially market our devices through medical and dental sleep medicine specialists. When the FreePap device is used to treat the sleep-related breathing disorder OSA, it is intended to be prescribed by a sleep physician. Once patients are diagnosed with OSA by a sleep physician, they can be referred to a dental sleep medicine specialist where they will have a dental impression made. Our company will make a set of custom oral appliances based on each patient's individual anatomy and dentition. A unique aspect of our device that sets us apart from our competitors is that our device is made of class VI medical grade silicone which can only be used inside the mouth for 29 days. For this reason and good oral hygiene purposes, patients will require new devices every 29 days, thus necessitating a recurring monthly purchase by the patient or their insurance company if they are to remain compliant with the device. A monthly recurring business model is a necessity for this particular product. The patient could be charged on a monthly or annual basis and would be sent a new oral device every month.

When FreePap is used to reduce the severity, intensity, volume, or occurrence of snoring, but not to treat a medical condition such as OSA, it is intended to be used over-the-counter (OTC). OTC sales will be through our retail website.

**Milestones -**

- Granted US Patent 11,607,336 with future patents pending (CIP applications)
- International patent (PCT) applications
- Successful alpha prototypes and proof of concept.

**Future milestones -**

- Beta prototypes
- Continued international and domestic IP filings
- Continued R & D into future versions
- FDA 510(k) approval and clinical trials
- Develop and initiate reimbursement strategy for CMS and insurance

**Regulatory Issues -**

- Need for FDA 510(k) application for OTC version
- FDA IDE application for clinical trials for prescription-only version.