DE NOVO CLASSIFICATION REQUEST FOR eXCITEOSA WITH REMOTE AND eXCITEOSA WITHOUT REMOTE

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Neuromuscular tongue muscle stimulator for the reduction of snoring and obstructive sleep apnea: A neuromuscular tongue muscle stimulator for the reduction of snoring and obstructive sleep apnea consists of a removable intraoral mouthpiece that uses electrodes to deliver neuromuscular stimulation to the tongue to strengthen tongue musculature to reduce snoring and obstructive sleep apnea.

NEW REGULATION NUMBER: 21 CFR 872.5575

CLASSIFICATION: Class II

PRODUCT CODE: QNO

BACKGROUND

DEVICE NAME: eXciteOSA without remote, eXciteOSA system with remote

SUBMISSION NUMBER: DEN200018

DATE OF DE NOVO: March 24, 2020

CONTACT: Biotech Research Group
3810 Gunn Highway
Tampa, FL 33618

INDICATIONS FOR USE

eXciteOSA is a removable tongue muscle stimulation device that delivers neuromuscular stimulation to the tongue in order to reduce snoring and mild obstructive sleep apnea (AHI<15) for patients that are 18 years or older.

LIMITATIONS

Prescription use only.

The device is only to be used while awake to avoid the risk of electrocution, burns, fire, or physical injury.

The device is not recommended for use in patients who:

- Are pregnant
- Have a pacemaker or implanted electrodes
- Have temporary or permanent implants, dental braces, intraoral metallic prosthetics/restorations/appliances or metal jewelry in your mouth
- Are suffering from mouth ulcerations
- Have or are suspected of having an AHI 15 or greater as determined by the evaluation by Health Care Professional with a Sleep Study

Patients should have a comprehensive dental examination prior to using this device to rule out cavities and metallic objects in the mouth
The eXcite OSA mouthpiece should not be used beyond 3 months of first use
Patients should maintain regular follow up visits with dentist and sleep health professional
Patients should be followed up with their sleep health clinician for a repeat Home Sleep Apnea Test with (b) (4) after three months of therapy

Use of the device does not replace the need for follow-up testing to determine the initial and ongoing effectiveness of the therapy as recommended by clinical practice guidelines.

Warnings

Consult your doctor/dentist if:

- You have gum disease or have bleeding gums
- You experience pain, numbness or bleeding after using this device
- You have any medical concerns

Use of the eXciteOSA device may cause excess salivation, a tingling sensation of the tongue or tooth sensitivity
Device should not be used by persons under the age of 18

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The eXciteOSA device is an external tongue muscle stimulator that delivers neuromuscular electrical stimulation to intrinsic and extrinsic tongue muscles in the daytime in order to increase muscle tone and prevent excess tongue muscle relaxation during sleep. The device is indicated to reduce snoring and mild obstructive sleep apnea in adults 18 years and older.

The device is placed in the mouth, with (b) (4) electrodes located above and (b) (4) electrodes located below the tongue. The therapy consists of a series of pulse bursts with rest periods and is used for 20 minutes during wakeful state for a period of 6-weeks. The electrical stimulation is directed at the tongue and in particular at a group of muscles comprising the genioglossus muscle, the biggest muscle in the oral cavity.

The device is intended to use the established technology of neuromuscular electrical stimulation (NMES) for the muscles of the oral cavity as a training tool in awake individuals to improve the tone of their throat muscles and reduce the problem of snoring and mild OSA during sleep.
The eXciteOSA is a system made out of different components and sold in different configurations.

The device consists of three components:

1) Washable Flexible Electrode Mouthpiece with electrode array that fits onto the tongue.
2) Rechargeable Control Unit that attaches to the mouthpiece via a USB-C connection.
3) Remote Control Unit and/or Smartphone App that manages the functions of the device.

Figure 4: Mouthpiece design

Figure 1: Control unit enclosure

Figure 2: Remote control enclosure.

Five items/options that may be purchased, all of them restricted to sale by or on the order of a physician (Rx only):

1) eXciteOSA system without remote control
2) eXciteOSA system with remote control
3) eXciteOSA remote control
4) eXciteOSA mouthpiece
5) eXciteOSA control unit

4- *Control Unit and Mouthpiece alignment*

Snoozeal system with remote

Snoozeal system without remote

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

The biocompatibility evaluation for eXciteOSA system was conducted in accordance with the International Standard ISO 10993-1 :2009 "*Biological Evaluation of Medical Devices Part-1: Evaluation and Testing Within a Risk Management Process*". Assessment of the device included the following tests which met the prespecified acceptance criteria:

- Cytotoxicity (ISO 10993-5:2009) for Mouthpiece, and for Control unit and Remote
- Sensitization Test (ISO 10993-10:2010) for Mouthpiece, and for Control unit and Remote
- Intracutaneous Reactivity (ISO 10993-10:2010) for Control unit and Remote
- Oral Mucosa Irritation (ISO 10993-10:2010) for Mouthpiece
- Acute Systemic Toxicity (ISO 10993-11 :2006) for Mouthpiece
- Subacute Systemic Toxicity (ISO 10993-11 :2006) for Mouthpiece
- Extractables & Leachables Study (ISO 10993-17,18) for Mouthpiece
- Material-Mediated Pyrogenicity (USP 36 <151>) for Mouthpiece

SHELF LIFE/REPROCESSING/STERILITY

The eXcite OSA device is not provided sterile and is not intended to be sterilized prior to use. The device is a single patient reusable device and instructions have been provided to dispose of the mouthpiece portion of the device after three months from first use.

The eXcite OSA device consists of the following components: a mouthpiece, a control unit, and a remote control. Cleaning instructions have been provided for each of the three components.

Accelerated aging testing was conducted according to EN 60068-2-2 *Dry Heat* and ASTM F1980-16 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.*

ELECTROMAGNETIC COMPATIBILITY, WIRELESS AND ELECTRICAL SAFETY

The eXcite OSA system is made up of Remote Control, Control Unit, and Mouthpiece. The Control Unit can be charged by any pre-approved power supply with a 5Vdc and 1A output. The control unit has a single USB-C connector for charging. The Remote Control is powered by 2 x 1.5 Vdc AAA batteries. The control unit, which is powered by a 3.7 V rechargeable Lithium cell and is connected to the mouthpiece by a male and female USB connector which also delivers electrical pulses to the mouthpiece. The following tests were performed to support electrical safety of their system following the Medical electrical equipment Part 1. *General requirements for basic safety and essential performance*, ANSI AAMI ES60601-1 with FDA recognition of 19-4. These tests include:

- Power Input
- Leakage Currents and patient auxiliary currents
- Dielectric Strength
- Creepage distances and air clearances
- Single Fault Conditions
- Ingress Protection
- Excessive Temperatures
- Limitation of Voltage, Current and Power

Specific tests pertaining to muscle simulators as detailed in IEC 60601-2-10: *Particular requirements for the basic safety and essential performance of nerve and muscle stimulators* were conducted. These tests include:

- Output Amplitude
- Pulse Parameters
- Electrodes
- Limitation of output parameters

Testing to specifically evaluate batteries utilized in the system were conducted according to *Secondary Cells and Batteries Containing Alkaline Or Other Non-Acid Electrolytes - Safety Requirements For Portable Sealed Secondary Cells, And For Batteries Made From Them, For Use In Portable Applications – Part 2: Lithium Systems*, IEC 62133-2 with FDA recognition of 19-33. These tests include:

- Continuous charging at constant voltage
- Over-charging of battery
- Design Evaluation - Forced internal short circuit (cells)
- External short circuit (batteries)

Electromagnetic Compatibility (EMC) according to the Agency recognized standard IEC 60601-1-2:2014 was also conducted. The following tests were performed and passed:

- Electrostatic Discharge Immunity
- Radiate RF Immunity
- Radiated RF Immunity - Intentional Transmitters
- Voltage Dips Short Interruptions and Voltage Variations Immunity
- Radiated Emissions
- Radiated Emissions for Equipment used in an Aircraft Environment

MAGNETIC RESONANCE (MR) COMPATIBILITY

The labeling in the User and Physician's Guide includes the following statement: "The device has not been tested for MRI compatibility and should not be used in the vicinity of an MRI device".

SOFTWARE

The De Novo request provided adequate software documentation consistent with a "Moderate" level of software concern as discussed in the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," issued May 11, 2005.

Software validation and verification testing demonstrated that the device met its design, implementation, and cybersecurity requirements.

SUMMARY OF CLINICAL INFORMATION

HUMAN FACTORS

A human factors assessment was conducted for the eXcite OSA device as per the FDA Guidance Document "*Applying Human Factors and Usability Engineering to Medical Devices*" issued February 3, 2016 and IEC 62366-1 Usability Engineering Standard.

As per the guidance, (b) (4) patients were recruited for the study as intended users who were determined to be snorers. Participants and providers were evaluated for comprehension-based tasks.

The human factors evaluation included the following:

- Opening the eXcite OSA outer packaging box
- Remove all the components and the User Guides
- Inspect the components for defects
- Setting up the eXcite OSA /Remote Control with the eXcite OSA Control Unit
- Pairing the eXcite OSA /Remote Control with the eXcite OSA Control Unit

CLINICAL TESTING

Study Design

A common protocol of recruitment of patients with primary snoring (AHI <5) and mild OSA (AHI 5-14) was undertaken and of the (b) (4) patients recruited, (b) (4) completed the trial. The data on these patients were analyzed in (b) (4) subsections - (b) (4) patients with snoring (AHI<15) and (b) (4) patients with mild OSA (AHI 5-14). Both objective and subjective data was collated to access the efficacy of the product in the (b) (4) indication categories.

In the mild OSA cohort, (b) (4) out of (b) (4) participants included in the study had initial (b) (4) testing, of which (b) (patients had demonstrated AHI>15 or AHI<5 on their original PSG and hence were excluded from the analysis. A total of (b) (4) patients from the original cohort were considered for Statistical analysis for reduction in mild OSA. (b) (additional patients were later added to this cohort. All participants completed baseline and post-therapy sleep studies captured using (b) (4)

The clinical data is provided in (b) (4) subsets:

- Results and data on reduction in snoring in primary snorers and mild OSA
- Results and data on reduction in indices of mild OSA

Results and data on reduction in snoring in primary snorers and mild OSA

Primary Objective
To assess the efficacy of daytime trans-oral neuromuscular stimulation training on nocturnal snoring.

Secondary Objective
To assess the efficacy of daytime trans-oral daytime neuromuscular stimulation training on sleep quality and its safety.

Primary Endpoint

- Reduction of 20% in the percentage of time spent snoring at levels greater than (b) (4). This was achieved using (b) (4)
- Reduction of 40% in bed partner VAS assessment in snoring

Secondary Endpoint

- Reduction in the Epworth Sleepiness Scale
- Reduction in Pittsburg Sleep Index
- Assess safety of the device (record and investigate adverse events, oral status and monitor device integrity through use)

Reduction in Mild OSA (AHI 5-14)

Primary Objective
To assess the efficacy of daytime trans-oral neuromuscular stimulation training on mild OSA.

Secondary Objective
To assess the efficacy of daytime trans-oral daytime neuromuscular stimulation training on sleep quality associated with mild OSA.

Primary Endpoint

- Reduction in AHI. This was conducted using a (b) (4) for the initial screening and a baseline and final assessment was conducted using (b) (4).

Secondary Endpoint

- Reduction in Oxygen Desaturation Index (ODI).
- Change in oxygen saturation indices
- Reduction in the Epworth Sleepiness Scale
- Reduction in Pittsburg Sleep Index
- Assess safety of the device (record and investigate adverse events, oral status and monitor device integrity through use)

Participant Selection

(b) (4) total participants out of the (b) (4) recruited completed the trial. The participants were divided into (b) (4) cohorts which included snoring and mild OSA.

- Snoring: (b) (4) patients whose average age was (b) (4) years (24-79 yrs), with (b) (4) men (64%), and a mean BMI of (b) (4)
- Mild OSA: (b) (4) out of (b) (4) patients were diagnosed with mild OSA; however, of these, only (b) (4) included in the study had a PSG screening prior to the start of the study, of which (b) (4) patients demonstrated AHI>14 or AHI<5 and were therefore excluded from the analysis. However, (b) (4) additional patients were later found to have had a PSG demonstrating mild OSA and added to the cohort. A total of (b) (4) patients were considered for the statistical analysis.

Inclusion Criteria

1) Age 18 years and above
2) Subjects must have a live-in partner as the assessment includes partners report
3) More than six month history of habitual snoring (i.e. >5 days per week as reported by partner)

Exclusion Criteria

1) BMI > 35 kg/m2
2) AHI >14/h, i.e. evidence of moderate to severe OSA from sleep study
3) Symptomatic nasal pathology i.e. septal deviation, nasal polyposis or chronic rhinosinusitis
4) Tonsil Hypertrophy (Tonsil size – Grade 3 or greater)
5) Tongue or lip piercing
6) Pacemaker or implanted medical electrical devices
7) Previous oral surgery for snoring
8) Relevant facial skeletal abnormalities (i.e. syndromic facial deficiencies, severe Micrognathia etc.)
9) Oral disease/conditions
10) Any criteria that, in the opinion of the investigator, would make the participant unsuitable for the study due to inability to complete required study procedures

Study Procedure

The study investigated the change in snoring sound, mild OSA, sleep quality and the safe use of intraoral neuromuscular stimulation using the eXciteOSA device. After appropriate screening and assessment, the recruited participants proceeded through three phases of the trial. The Pre-Trial phase collected data on the pre-treatment state of the participant, after which they entered the Therapy phase where they use the device once daily for a six week period whilst continuing to record the required data. The therapy consists of a series of pulse bursts with the basic characteristic of (b) (4) secs burst and (b) (4) seconds rest. During the (b) (4) mins therapy period the pulse frequency changed every (b) (4) mins in a defined sequence (through (b) (4) and (back to) (b) (4) Hz frequencies). The participant stopped using the device at the end of this stage and had a follow up phase for two weeks, during which trial indices were continued to be recorded. The trial period for each participant was 10 weeks.

A specific breakdown of the trial is listed below:

A. Screening
Participants were identified from (b) (4) . A screening phone call was conducted to ensure suitability based on an inclusion criterion and offer first line information about the trial. If suitable, patients were given written information and invited to undertake a 2 day home sleep study (using (b) (4)). If the average AHI from these 2 days was below 15/hr, the participants were be invited for a clinical examination.

For patients with Mild OSA analysis, only patients that were initially screened with PSG from the enrollment site and demonstrated an AHI between 5-14 were included in the analysis.

B. Recruitment visit
- Clinical airway examination by ENT surgeon
- Review of inclusion and exclusion criteria
- Informed consent
- Inclusion into trial

C. Pre-therapy period (day -14 to -1):
- Bed partner daily subjective assessment of snoring (Visual Analog Scale). Participant's bed partner was required to complete daily visual analogue scoring of the participant's snoring, with 1 being "no snoring" and 10 being "intolerable snoring".
- Oral/dental examination
- Participant and bed partner to complete sleep quality questionnaires (Pittsburgh Sleep Quality Index, Epworth sleepiness score and subjective sleep quality questionnaire) on Day-1

D. Therapy phase (day 1-42)
- Face-to-face meeting, instruction on use of the intraoral device
- Participant to use the Snoozeal device for 20 minutes once daily
- Bed partner daily subjective assessment of snoring (VAS)
- Participant daily assessment of side effects/adverse events and time of use
- Participant and bed partner to complete Sleep quality Questionnaires (Pittsburgh Sleep Quality Index, Epworth sleepiness score and subjective sleep quality questionnaire) at day 42
- Weekly follow up phone call from research team to confirm compliance. Compliance cross checked using the total time of use recorded by the device.

E. End of Therapy Review (day 43 – 49)
- Review of device integrity by visual inspection

- Oral/dental examination
- Repeat Sleep Study – 2 night sleep study with (b) (4)

F. Follow Up phase (day 43-56)

- Participant advised to stop using device for this period
- Bed partner daily subjective assessment of snoring (VAS)
- Subject and bed partner to complete Sleep quality Questionnaires (Pittsburgh Sleep Quality Index, Epworth sleepiness score and subjective sleep quality questionnaire) at day 56

G. Post Therapy Review (day 57)

- Face-to-face meeting and feedback
- Device checked for any wear and tear
- Collection of participant data sheets
- Participant subjective overall assessment

Results

The results are presented in (b) (4) Subsets:

- Results and data on reduction in snoring in primary snorers and mild OSA
- Results and data on reduction in indices of mild OSA

A) Results and data on reduction in snoring in primary snorers and mild OSA

Primary Endpoint – Reduction of 20% of time spent snoring at levels above (b) (4)

The mean reduction in snoring time was (b) (4) at (b) (4). The following table shows that the mean reduction in snoring time was (b) (4).

(b) (4)

(b) (4) out of (b) (4) (75.7%) subjects had >20% change in time spent snoring at (b) (4).

Primary Endpoint – Reduction of 40% in bed partner VAS assessment of snoring

(b) (4) out of (b) (4) patients had VAS data. There were (b) (4) patients whose VAS data were missing due to incomplete ratings by their partner. The table

below shows that the mean pre and post therapy VAS (average VAS over week 5/6) was (b) (4) and (b) (4), respectively.

Paired Samples Statistics

	Mean	N	Std. Deviation	Std. Error Mean
Average Pre VAS	(b) (4)			
Av Tx VAS W5/6				

Secondary Endpoint – Reduction in the Epworth Sleepiness Scale
The mean reduction in ESS was (b) (4).

Secondary Endpoint – Reduction in the Pittsburgh Sleep Index
The mean of PSQI was (b) (4).

Secondary Endpoint – Assess safety

No serious adverse events were noted. Of the (b) (4) participants on the trial, (b) (4) participants reported a total of 46 adverse events, all of which were temporary. They are categorized in the below eight groups:

Description	No. of participant
Excessive salivation	(b) (4)
Tongue discomfort	
Tooth discomfort	
Tongue tingling	
Filling sensitivity	
Metallic taste	
Gagging	
Tight jaw	

B) Results and data on reduction in indices of mild OSA

Primary Endpoint – Reduction in AHI
The mean reduction in AHI was (b) (4) and the relative reduction was about 48%.

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Pre AHI	(b) (4)			
	Post AHI				

Secondary Endpoint – Reduction in the Oxygen Desaturation Index
The mean change in ODI was (b) (4).

Secondary Endpoint – Change in Oxygen Saturation Indices
There was no significant improvement in mean oxygen saturations (b) (4) or percent of time spent at less than 90% oxygen saturation (b) (4)

Secondary Endpoint – Reduction in the Epworth Sleepiness Scale
The mean change of ESS was (b) (4)

Secondary Endpoint – Reduction in the Pittsburgh Sleep Index
The mean change of PSQI was (b) (4).

Secondary Endpoint – Assess safety
No serious adverse events were noted. (b) (4) participants of the mild OSA cohort experienced the following adverse events, all of which were temporary. They are categorized in the below eight groups:

Description	No. of participant
Excessive salivation	(b) (4)
Tongue discomfort	
Tooth discomfort	
Tongue tingling	
Filling sensitivity	
Metallic taste	
Gagging	
Tight jaw	

Pediatric Extrapolation

The eXciteOSA System is indicated for patients age 18 and older. For medical devices, the FD&C Act defines patients before their 22nd birthday as pediatric patients. In this De Novo request, existing clinical data were leveraged from patients aged 24 and older to support the use

of the device in patients over the age of 18. Extrapolation of this data is appropriate because patients between 18 and 24 do not carry additional risks relative to the patient population studied.

LABELING

The labeling (User Instructions) meets the requirements of 21 CFR Part 801.109 for prescription devices.

The User Guide instructions for use includes the following:

a. Complete instructions on device components, set-up, use instructions, cleaning, and storage
b. The User Profile is described as the following:
    - As a dentist who will be responsible for dispensing the device, instructing the patient, assessing suitability, and prescribing treatment
    - As patients who will be using the prescription home use device to assist in the reduction of snoring and mild obstructive sleep apnea
c. Device specifications
d. Cybersecurity information
e. Warnings, contraindications, and precautions
f. A description of error messages and alarms
g. Instructions on when to discontinue study
h. A statement that the patient should maintain regular follow up visits with dentist and sleep specialist
i. A statement that patients should have a comprehensive dental examination prior to using this device.

The following contraindications and precautions are included in the IFU to advice the user on safe and appropriate use:

Contraindications – eXciteOSA should not be used an individual:

- Is pregnant or may be pregnant
- Has a pacemaker or implanted electrodes
- Has temporary or permanent implants, dental braces, metallic prosthetics/restorations/appliances or jewelry in the mouth
- Are suffering from mouth ulceration
- Have or are suspected of having obstructive sleep Apnea with AHI 15 or greater

Precautions – an individual should consult their doctor or dentist if they:

- Have gum disease, or have bleeding from their gums
- Experience pain, numbness or bleeding after using this product

This device should not be used:

- While asleep (device only to be used when **awake**)

- The eXcite OSA mouthpiece should not be used beyond three months from first use

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of the tongue neuromuscular stimulation device oral appliance for reduction of snoring and obstructive sleep apnea the measures necessary to mitigate these risks.

Table 6: Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measures**
Adverse tissue reaction	Biocompatibility evaluation
Interference with other devices/electrical shock	Electrical safety testing Electromagnetic compatibility (EMC) testing Wireless coexistence testing Battery safety testing Labeling
Use error leading to pain, discomfort, or injury	Human factors assessment Software verification, validation, and hazard analysis Electrical safety testing Labeling
Mucosal or skin overheating or burn	Software validation, verification, hazard analysis Electrical safety testing Electromagnetic compatibility (EMC) testing Labeling
Infection	Labeling

SPECIAL CONTROLS:

In combination with the general controls of the FD&C Act, the neuromuscular tongue stimulator for reduction of snoring and obstructive sleep apnea is subject to the following special controls:

(1) Performance testing must demonstrate the wireless compatibility, electrical safety, and electromagnetic compatibility of the device in its intended use environment.

(2) Software verification, validation, and hazard analysis must be performed.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Patient labeling must include:
   (i) Information on device components, setup, and use of the device including placement of sensors and mouthpieces, and images or illustrations;

(ii) A detailed summary of technical specifications
(iii) Instructions on how to clean and maintain the device
(iv) A statement that the patient should maintain regular follow up visits with dentist and sleep specialist
(v) A statement that patients should have a comprehensive dental examination prior to using this device.

(5) A human factors assessment must evaluate simulated use of the device to demonstrate that the user can correctly use device based on the labeling and instructions for use.

BENEFIT/RISK DETERMINATION

The known probable risks of the device are based on the data collected in the clinical study described above. The device exhibited an acceptable safety profile in the clinical studies which were conducted, and any adverse events that occurred were temporary and had complete resolution. No device-related serious adverse events were observed, such as electrical injury, burns, or permanent injury to tongue nerve or muscle function.

As described above, the eXciteOSA device consists of a mouthpiece, a control unit, a USB cable, and an optional remote control. The mouthpiece is to be disposed of after three months of use. The device is to be prescribed and dispensed by a healthcare professional and to be used in a home-use setting. Risks of a harmful event would be related to improper use or device malfunction that may cause excess salivation, tongue discomfort or tingling, tooth or filling sensitivity, metallic taste, or a tight jaw. All of these risks were seen in the clinical study. No serious adverse events such as burns, electrical injury, or permanent damage to hard or soft tissue or the tongue were noted and the probability of these harmful event with the use of this device is low. Any adverse events reported would likely be temporary in nature. If patients cannot tolerate the eXciteOSA device, they may simply remove it from their mouth and opt for a traditional mandibular advancement oral appliance.

The probable benefits of the device are also based on the data collected in the clinical study described above. The benefit of this device is that patients may be able to reduce unwanted snoring and decrease levels of mild obstructive sleep apnea without full time night wear of a mandibular advancement device which is the common alternative for snoring and obstructive sleep apnea. The eXciteOSA device is used while the patient is awake, and not sleeping as seen with other snoring and obstructive sleep apnea devices. This may decrease the risk of more serious injury such as electrical injury or burns as the patient is awake and alert during the 20 minute use time. This may lead to a better sleep quality and quantity from the user as well as the bed partners. In addition, it may allow for less adverse events commonly seen in other mandibular advancement devices such as temporomandibular joint pain and inadvertent tooth movement that arise from pulling the mandible forward in traditional mandibular advancement device in order to increase the airway in the oropharynx.

Patient Perspectives

The eXciteOSA study collected data on patients diagnosed with snoring and mild obstructive sleep apnea based on (b) (4) assessments and PSG screenings for the mild obstructive sleep apnea population. The conducted study demonstrated that there was a statistically significant reduction in both snoring and mild obstructive sleep apnea in the population tested. No severe adverse events were reported during the clinical trial and the adverse reactions reported by the participants were temporary and transient in nature.

Benefit/Risk Conclusion

In conclusion, given the available information above, the data provide support for reduction of snoring and mild obstructive sleep apnea through the use of the eXciteOSA device. The data demonstrate that the probable benefits outweigh the probable risks for the eXciteOSA device. The risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the eXciteOSA is granted and the device is classified under the following:

Product Code: QNO
Device Type: Neuromuscular tongue muscle stimulator for the reduction of snoring and obstructive sleep apnea
Class: II
Regulation: 21 CFR 872.5575