510(k) Summary

Submitted by:

Owner's Name:	Sleep Science Partners, Inc.
Address:	900 Larkspur Landing Circle, Suite 207 Larkspur CA 94939 USA
Contact:	Noel P. Lindsay
Title:	Chairman & CEO
Tel:	+1 (415) 484-1452
Fax:	+1 (415) 925-1575
Email:	noel@sspi.com

Contact Person:

Name:	Valerie Followell
Title:	Senior RA & QA Consultant at Lean RAQA, LLC
Tel:	+1 (847) 400-6187
Email:	followell@leanraqa.com

Date Prepared:	January 10, 2019
Trade Name:	PureSleep®
Common Name:	Antisnoring device
Classification Name:	Intraoral devices for snoring and obstructive sleep apnea
Classification:	Class II
Product Code:	LRK
Regulation Number:	872.5570
Predicate Device:	PureSleep® (Rx use), Sleep Science Partners, Inc. (K113022)
Reference Device:	SnoreRx®, Apnea Sciences, Inc. (K170825)

DEVICE DESCRIPTION:

The PureSleep® device for Over-the-Counter (OTC) use is an intraoral mandibular repositioning device that increases the pharyngeal space to improve the user's ability to exchange air and to decrease air turbulence, a causative factor in snoring. The device consists of two dental trays designed to conform to the shape of the upper and lower jaws.

INTENDED USE:

PureSleep® (OTC) is indicated for use for adults 18 years and above as an aid in the reduction of snoring during hours of sleep

COMPARISSION OF TECHNOLOGICAL CHARACTERISTICS:

The proposed OTC device and the PureSleep® (Rx) predicate device are identical in all their technological characteristics (design, materials, functionality, principles of operations, etc.). Both the PureSleep® for OTC use and its predicate device consist of intraoral mouth pieces that are molded to the user's teeth using a standard 'boil and bite' method and allows slight adjustment of the positioning of the jaw to the user's comfort. The PureSleep® for OTC use is provided non-sterile and uses the same packaging system as the Rx predicate device, except for adapted product documentation (Instructions for Use and package labeling) for the retail consumers. The table below compares the indications for use and technological aspects of the proposed device against the predicate as well as a reference device that FDA had cleared that has a similar technology with OTC indications.

		Proposed device	Predicate device	Reference device
Device Proprietary Name		PureSleep®	PureSleep®	SnoreRx®
Manufacturer		Sleep Science Partners, Inc.	Same	Apnea Sciences, Inc.
510(k)		K190058	K113022	K170825
LABELING				
Classification	**Regulation**	21 CFR 872.5570	Same	Same
	Product Code	LRK	Same	Same
	Class. Name	Intraoral Device for Snoring and Obstructive Sleep Apnea	Same	Same
Intended use		An intraoral mandibular repositioning device used on adults as an aid during sleep to reduce snoring.	An intraoral mandibular repositioning device used during sleep to reduce snoring and treat mild to moderate obstructive sleep apnea in adults.	Intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.
Indication for use	**Rx or OTC**	OTC	Rx	OTC
	Patient population	Adults	Same	Same
Labeling		Language, visuals and structure have been adapted for OTC use based on FDA guidance documents, HFE/UE study and RWD gained with K113022.	Instructions divided into 1) instructions for use for the dentist to prepare and fit the device and 2) patient information on use and care.	Similar contraindications and warnings
TECHNOLOGY				
Mode of action		Mandibular repositioning device (MRD) that advances the lower jaw to increase pharyngeal space and alleviate snoring	Same	Same
Environment		During sleep, at home	Same	Same
Placement of device		In the mouth, on the lower and upper jaws	Same	Same
Preparation / Set-up		Connect upper and lower parts per bite type.	Same	Squeeze mouthpiece in a 'C' position and adjust.
Molding / Fitment		Custom impression to each individual's mouth using a "boil and bite" approach and thermal setting (heat sensitive) resins. Molded to the entire upper and lower arch of teeth.	Same	Same
Design		Consists of an upper and lower tray. Outer shell provides with structural support and inner shell is lined with softer material that is heat sensitive and thus allows for custom fitting.	Same	Same
Adjustments		• Adjustable jaw advancement position. • Adjustably positions the mandible forward in three positions, 4mm apart anteriorly, while maintaining a 9mm inferior placement for user comfort	Same	Similar • Adjustable jaw advancement position. • Ability to reset the adjustment. • The upper and lower trays are adjustable in 1mm increments up to 6mm.
Single Use / Reusable		Single user, multi-use	Same	Same
Cleaning instructions		Clean/rinse daily with toothbrush and toothpaste or with effervescent oral device cleaning tablets. Deep clean once per week.	Same but recommended frequency is less prescriptive (i.e. periodic cleaning)	Clean/rinse daily. Deep clean every two weeks.
Sterile		No	Same	Same
Materials		Polypropylene homopolymer and ethylene vinyl acetate copolymer	Same	The specific materials are unknown.
Biocompatibility		Meets ISO 10993-1 for a surface device contacting mucosal membrane for a prolonged contact duration (> 24h to 30 days): cytotoxicity, sensitization and irritation	Same	Same

NON-CLINICAL TESTING

The materials and methods of manufacture of the product are biocompatible and meet the applicable requirements of ISO 10993.

A Human Factors and Usability Engineering (HFE/UE) study was performed for the use of PureSleep® in the OTC environment that support the safe and effective use of the product without assistance from a dental professional.

Documentation provided by Sleep Science Partners, Inc. presents real-world data gleaned from actual use of the PureSleep® Rx predicate device, along with the HFE/UE study which support the conclusion that the proposed device is clinically safe for OTC use.

Finally, Sleep Science Partners, Inc. conducted a risk analysis on the proposed device in accordance with ISO 14971:2007 and by considering the issues raised in the FDA guidance document "*Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea*" (November 12, 2002). All identified risks have been addressed through device design, verification/validation or through documentation (labeling and Instructions for Use) provided to the consumer.

CLINICAL PERFORMANCE TESTING

Real-world data is included in support of this submission.

CONCLUSION

Based upon the similarities in technology and in intended use, as well as indications for use similar to the reference predicate, together with performance testing, we believe that PureSleep® for OTC use is substantially equivalent to the predicate devices.