



Scope Healthcare Technologies Pty Ltd  
Ben Olsen  
Director  
Suite 5, 20 Taylors Avenue  
Morphett Vale, South Australia 5162  
AUSTRALIA

January 2, 2018

Re: K171529

Trade/Device Name: Snorer's Friend

Regulation Number: 21 CFR 872.5570

Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive  
Sleep Apnea

Regulatory Class: Class II

Product Code: LRK

Dated: November 19, 2017

Received: December 13, 2017

Dear Ben Olsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
**Mary S. Runner -S**

For Tina Kiang, Ph.D.  
Acting Director  
Division of Anesthesiology,  
General Hospital, Respiratory,  
Infection Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K171529

Device Name

Snorer's Friend

Indications for Use (Describe)

Snorer's Friend is an intra-oral mandibular advancement device used during sleep to reduce snoring and treat mild to moderate Obstructive Sleep Apnea (OSA) in adults.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**SNORER'S FRIEND 510(K) SUMMARY**  
**510(K) NUMBER K171529**

**I. GENERAL INFORMATION**

**Submitter (510k Owner):** Scope Healthcare Technologies Pty Ltd  
Suite 5, 20 Taylors Avenue Morphett  
Vale SA 5162 Australia  
Establishment Registration No. TBD  
Owner Operator Number: TBD

**Contact Person:** Ben Olsen  
Scope Healthcare Technologies Pty Ltd  
Suite 5, 20 Taylors Avenue  
Morphett Vale SA 5162 Australia  
Email: [support@snorers-friend.com](mailto:support@snorers-friend.com)

**Date Prepared:** December 22, 2017

**II. DEVICE DETAILS**

**Trade Name:** Snorer's Friend

**Common or Usual Name:** Anti-Snoring Device

**Classification:** Device, Anti-Snoring  
Product Code: LRK  
Class: II

**Regulation:** CFR 872.5570  
Intraoral devices for snoring and intraoral devices  
for snoring and obstructive sleep apnea.

**Review Panel:** Dental

**III. PREDICATE DEVICE**

**Predicate Device(s):** SomnoGuard (original) manufactured by TOMED  
Dr. Toussaint, GmbH (K061688)  
(This predicate has not been subject to any product  
recalls).

**Reference Device(s):** SleepPro manufactured by Michael D. Williams  
DDS PA (K132506)

#### **IV. DEVICE DESCRIPTION**

The 'Snorer's Friend' is an intra-oral mandibular advancement device used during sleep to reduce snoring by advancing the lower jaw and thereby minimizing air obstruction and turbulence. It advances the lower jaw and tongue forward so the airway will remain open during sleep.

The device is fitted to the patient by, or under the direction of, physicians (e.g., ENT doctors, sleep lab doctors or dentists) or their trained medical staff by immersing it in boiling water for approximately 17 seconds. Once removed from the hot water, it is very gently rotated to allow excess water to run off.

Snorer's Friend is custom fitted to the upper and lower teeth, in a similar fashion to an athletic mouth guard. When boiled, the material softens which allows the device to be molded to the shape of the patient's teeth. To prepare for the fitting, the spatula provided is used to place the device in boiled water for 17 seconds. Holding the mouth of the patient open and the lower jaw forward, the physician or their trained medical staff places the device in the mouth and the patient bites down firmly. The device is then placed in cold water.

The Snorer's Friend is simple to fit and does not require impressions or lab-fabrication. As such, it is a more economical and timesaving alternative to more costly lab-fabricated mandibular advancement devices.

Snorer's Friend intra-oral mandibular advancement devices are only to be fitted/re-fitted by, or under the direction of, physicians (e.g., ENT doctors, sleep lab doctors or dentists) or their trained medical staff. The patient should undergo a comprehensive oral health assessment by a dentist before the device is fitted to the patient. The maximum mandibular advancement to be performed with this device is 5 mm.

#### **V. INDICATIONS FOR USE**

Snorer's Friend is an intra-oral mandibular advancement device used during sleep to reduce snoring and treat mild to moderate Obstructive Sleep Apnea (OSA) in adults.

#### **VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

The Snorer's Friend presented in this 510(k) is substantially equivalent to the predicate in terms of intended use, fundamental scientific technology, operating principles and mechanism of action.

A summary comparison between the Snorer's Friend and predicate is provided in Table 1 below. A more detailed comparison is provided in Section 12 of this submission.

**Table 1. Summary Comparison of the Snorer's Friend and Predicate**

	<b>Predicate (SomnoGuard)</b>	<b>Snorer's Friend</b>
<b>Indications for Use</b>	The SomnoGuard series of mandibular advancement devices is intended for the treatment of night-time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	Snorer's Friend is an intra-oral mandibular advancement device used during sleep to reduce snoring and treat mild to moderate obstructive sleep apnea (OSA) in adults.

**Snorer's Friend Abbreviated 510(k)  
510(k) Summary K171529 (as required by section 807.92(c))**

<b>Design</b>	Prefabricated "boil & bite" one piece mandibular advancement device designed to be fitted to upper and lower teeth.	Prefabricated "boil & bite" one piece mandibular advancement device designed to be fitted to upper and lower teeth.
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**Snorer's Friend Abbreviated 510(k)**  
**510(k) Summary K171529 (as required by section 807.92(c))**

<b>Components</b>	<ul style="list-style-type: none"> <li>• Monobloc mouthpiece.</li> <li>• Filler material.</li> <li>• Storage case.</li> <li>• Wooden spatula.</li> <li>• User instructions.</li> </ul>	<ul style="list-style-type: none"> <li>• 2 x mandibular advancement devices.</li> <li>• Storage case.</li> <li>• 2x Wooden spatulas.</li> <li>• User instructions.</li> </ul>
<b>Environments of use</b>	Home, Sleep laboratories	Home, Sleep laboratories
<b>Patient Population</b>	Adult patients 18 years and older	Adult patients 18 years and older
<b>Contraindications</b>	<p>SomnoGuard is contraindicated for patients who have:</p> <ul style="list-style-type: none"> <li>• Central sleep apnea,</li> <li>• Mandibular joint disorder,</li> <li>• (Strong) gag reflex, larger gaps between the teeth, unstable dental crowns, decay, periodontitis –</li> <li>• Limited mandibular advancement. Patients with sleep apnea should be able to extend their lower jaw forward at least 7mm.</li> <li>• Restricted breathing through the nasal passages</li> </ul>	<p>Snorer's Friend is contraindicated for patients who:</p> <ul style="list-style-type: none"> <li>• people under the age of 18 years old,</li> <li>• those whom have been diagnosed with central sleep apnea,</li> <li>• have a severe respiratory disorder/s,</li> <li>• have loose teeth or advanced periodontal disease.</li> <li>• Have loose dental work, dentures, unstable dental crowns, or other oral conditions which would be adversely affected by wearing dental appliances</li> </ul>
<b>Prescription</b>	Prescription use	Prescription use
<b>Patient use</b>	Single patient, multiple use.	Single patient, multiple use.
<b>Duration of use</b>	No limitation	No limitation
<b>Principle of operation/means of mandibular advancement</b>	Repositions the lower jaw and thereby holds the base of the tongue forward. The airway remains open, by increasing the clearance between the back of the tongue and the back of the throat.	Repositions the lower jaw and thereby holds the base of the tongue forward. The airway remains open, by increasing the clearance between the back of the tongue and the back of the throat.
<b>Fixed tray sizes</b>	Yes	Yes
<b>Fitting procedure</b>	Custom Fitting (boil & bite)	Custom Fitting (boil & bite)
<b>Movement</b>	Lateral and vertical	Lateral and vertical
<b>Cleaning procedure</b>	Brushing with a soft toothbrush and 2 to 3 drops of a washing-up liquid or a liquid denture cleaner	Brushing with a normal toothbrush and toothpaste, as often as required.
<b>Sterile</b>	No	No
<b>Material</b>	Thermoplastic copolymers	Thermoplastic copolymers
<b>Biocompatibility</b>	Biocompatible	Biocompatible
<b>Expected Lifetime</b>	Up to two years	4-24 months

## **VII. PERFORMANCE DATA**

The Snorer's Friend is equivalent in terms of intended use, design and performance requirements to the predicate device.

The Snorer's Friend complies with the FDA Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA, including:

- Section 4 - Scope;
- Section 5 - Risks to Health;
- Section 6 - Material Composition;
- Section 7 - Biocompatibility;
- Section 9 - Labeling;

NOTE: Snorer's Friend has similar design, technology, and indications for use as the predicate SomnoGuard and therefore Section 8 - Clinical Data is not applicable.

All design verification and validation (V&V) activities were performed according to 21 CFR 820.30 including dimensional analysis, visual inspection, product testing and evaluation of returned product.

The Snorer's Friend complies with the FDA guidance document "*Use of International Standard ISO 10993 Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*", as demonstrated by using the reference device K132506.

## **VIII. CONCLUSIONS**

Based on the information provided in this submission, the Snorer's Friend is substantially equivalent to the predicate SomnoGuard device and does not raise any new questions relating to safety and/or effectiveness.

The Snorer's Friend and SomnoGuard have the same intended use for treating snoring and mild to moderate obstructive sleep apnea (OSA). Both devices have similar designs, technology, materials, and performance characteristics. Both devices employ a 'boil and bite' design to provide a custom impression for each patient. Both devices have similar environments of use and intended user populations, with similar warnings and contraindications.

Any differences between the Snorer's Friend and SomnoGuard are not significant and do not affect the substantial equivalence of the proposed device to the predicate device.

