

12991209

SEP 22 1999

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**Perl-Rad Sleep Disorder Lab.
440 E. Romie Lane
Salinas, CA 93901-4017**

1. Premarket Notification

**510(k) SUMMARY
OF
SAFETY AND EFFECTIVENESS**

2. Submitter: Arthur Perlis
5315 Carmel Valley Rd., A-208
Carmel, CA 93923-9558

Phone: (831) 626-1222

No Fax No.

Contact Person: Arthur Perlis

Date of Preparation: 04/05/99

3. Device Name: Oral Sleep Disorder Aid
Common and
trade name: Anti-Snore Device
Classification: Device Anti-snoring
Product Code: 77LRK

4. Legally Marketed Devices to which I claim equivalence:
Predicates: Class 1
Charles F. Samelson - Inventor: 510(k) 870611
Victor Gardy - Inventor: 510(k) 870871

Description of Predicates

5. Samelson Device:

A prescription anti-snore mouthpiece of integrally molded acrylic. It is positioned and secured within the mouth by dental engaging portions located in the incisor area. It has a rearwardly opening socket for cooperating with the forward portion of the user's tongue so as to increase the nasopharyngeal area for easier nasal breathing. Molds must be used to construct the device.

Gardy Oral Device:

A prescription anti-snore mouthpiece, similar in design and purpose as the Samelson device. The major difference being: the Gardy device has air duct passages on either side of the mouth.

It is composed of medical grade silastic having a tongue retractor compartment, in which a vacuum develops at the tip in proportion to the force generated by tongue relapse.

Summary Describes Intended Use (Predicates):

6. Samelson Device:

To control the effects of snoring with a customized mouthpiece. It substantially eliminates oral breathing and provides improved nasal breathing space in the nasopharyngeal area of the throat.

Gardy Device:

Significantly reduces the effects of snoring with a universal type oral device, offered in 3 sizes. It too provides improved nasal breathing.

Technological Characteristics Comparison

(Similarities)

7. Although the predicates and the new device have some technological differences, they all employ the same tongue restraint principles to encourage nasal breathing and ^{oral} control/snoring.

All are made by prescription.

All are stabilized in the mouth by registering on a dental arch and employing a forwardly tongue restraint vacuum.

All increase the unobstructed dimension of the nasopharyngeal area, to facilitate nasal breathing.

(Differences)

The Samelson device is locked between upper and lower incisor dental engaging portions; the Gardy device on one portion.

The new device registers upon the maxillary dental arch for dentulous use, edentulous, those with mixed dentition; and for “daytime use” over an existing maxillary denture; for patients living in arid geographical areas.

The predicates protrude beyond the lips. The new device is totally concealed.

The Gardy device claims significant reduction in snoring.

The new device, in a non-clinical evaluation showed “total” oral snore control by use of a voice actuated tape recorder at bed-side, unless or until interrupted by nasal congestion.

All three oral devices have automatic fail-safe returns to mouth breathing by reflex action should the nasal passages congest.

Gardy states all oral devices used for snore control have a potential hazard of dislodging and choking the patient.

The new device has been safely used by this applicant for over five (5) years. A precision occlusal match and a snug tongue restraint compartment are stability factors that contribute to safety and effectiveness.

Efficacy: All three devices perform as intended.

Effectiveness: The predicates claim effective use of their oral devices, as does the new device.

Safety: In case of nasal congestion or vomiting, the new device can remain seated upon the maxillary dental arch or be expelled with a push of the tongue.

Coughing or sneezing causes no problem.

The predicates must be detached from teeth and removed when expelling anything.

Bicompatibility:

All three devices use medical grade material and have been used by the dental profession for prosthetic oral devices.

Summary

Non-Clinical Performance

(discussion)

8. **History:**

To mitigate a dry mouth problem and frequent awakenings, I invented a mouth-closure intra-oral device with tongue restraint compartment to prevent mouth breathing, the cause of oral dry-out and oral snoring.

That prompted the invention of a simple external nostril dilator to conjoin with the oral device.

To monitor my progress, I used a "voice actuated" tape recorder at bedside. I soon distinguished between oral and nasal snoring. Oral breathing would resume instantly should the nasal passages congest, without disturbing the oral device.

Performance:

Having proved its worth, I enlisted my wife and son as trial subjects. Her problem was a dry mouth due to mouth drying medication; his was snoring. His dentist made molds of upper and lower dentition, the latter as a reference tool, including a centric wax

bite to precisely occlude the oral device to his teeth.

The trials were a definite success.

9. Clinical tests have not been taken.

10. Non-Clinical Test Conclusions:

They demonstrate the new device to be as safe and effective and perform as well as the legally marketed oral devices as used "without" the nostril dilator, as necessary to qualify for substantial equivalence. There have been no adverse effects.

Since most prior ~~art~~ currently marketed require the patient to sleep with lower jaw extended, in different degrees, I believe the new device will satisfy a long-awaited need.

My "Oral Sleep Disorder Aid" was born of necessity due to a failed nasal operation that aggravated a chronic dry mouth problem. It has spared me years of suffering.



SEP 22 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Arthur Perlis
Perl-Rad Sleep Disorder Lab
5315 Carmel Valley Road
A-208
Carmel, California 93923

Re: K991209
Trade Name: Oral Sleep Disorder Aid
Regulatory Class: Unclassified
Product Code: LRK
Dated: June 30, 1999
Received: July 6, 1999

Dear Mr. Perlis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

Page 2 -Mr. Perlis

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4690. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991209

Device Name: ORAL Sleep Disorder Aid

Indications For Use:

A maxillary "denture-like" mouthpiece with tongue restraint compartment to actuate mouth closure. The device is intended for use as an aid to reduce simple snoring.

It is customized for patients with or without natural teeth and for mixed dentition. Reflex action reverts to mouth breathing instantly should the nasal passages congest

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Praso

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

Device Number K991209

Prescription Use (Per 21 CFR 801.109)

OR

Over-The-Counter Use