K981923

AUG 24 1998

The Snore Peace®
Premarket Notification
510(K) Summary

Submitter:

The Snore Peace® Group
24791 Via San Felipe
Mission Viejo, California 92692
Contact Person:
David V. Sheehan
Phone: 949-380-8323
FAX: 949-454-0211

Date Summary was prepared: June 1, 1998

Device Name:

Trademark:	The Snore Peace®
Common Name:	Anti-snoring device
Classification:	Unclassified
Product Code:	LRK

Description:

The Snore Peace® is a single piece device which is form custom fitted to the users upper and lower teeth and inner lips. It is meant to be worn at night while sleeping.

Intended Use:

The intended use for The Snore Peace® is for snore reduction/prevention.

Substantial Equivalence:

The Snore Peace® is substantially equivalent to many legally marketed devices in The United States including Snore-Ezzer by Snore-Ezzer, LLC: Snore Tec by Marketing Technologies, Inc; and Therasnore by Dr. Thomas E. Meade.

Safety & Efficacy:

The Snore Peace® works in a similar manner to other comparative predicate devices and the intended use is the same. Any differences between our product and predicate devices are minor in nature and raise no new safety concerns. The effectiveness and suitability to the intended purpose of The Snore Peace® is assured via the widespread use and length of use of the many similar devices on the market. As such, the safe use of The Snore Peace® by many users, under the prescription and custom fitting of a physician is assured.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 1998

Mr. DaviD V. Sheehan
Managing Director
The Snore Peace® Group
24791 Via San Felipe
Mission Viejo, California 92692

Re: K981923
Trade Name: The Snore Peace®
Regulatory Class: Unclassified
Product Code: LRK
Dated: June 1, 1998
Received: June 1, 1998

Dear Mr. Sheehan:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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 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) 594-4692. 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"(21CFR 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/dsma/dsmamain.html".

Sincerely yours,

S. Nutman for

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

Enclosure

The Snore Peace®
Premarket Notification
Statement for Indications of Use

Device Name: **The Snore Peace®**

Indication For Use: **To reduce or alleviate snoring by holding the tongue and lower jaw in a 60-75% of patient maximum protrusion forward position during sleep.**

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **or** **Over-The-Counter Use** _____

(Per 21 CFR 801.109)

Susan Runner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981923