K971818

510(k) SUMMARY

DEC 18 1997

Submitted by:

Vernon Pribble
8210 Carrleigh Parkway
Springfield, VA 22152

Phone/Fax (703) 866 0694

Contact Person:

Vernon Pribble
(see above)

Prepared:

6 May 1997

Trade Name:

SNOREX

Common Name:

AntiSnoring Device

Classification Name:

AntiSnoring Device

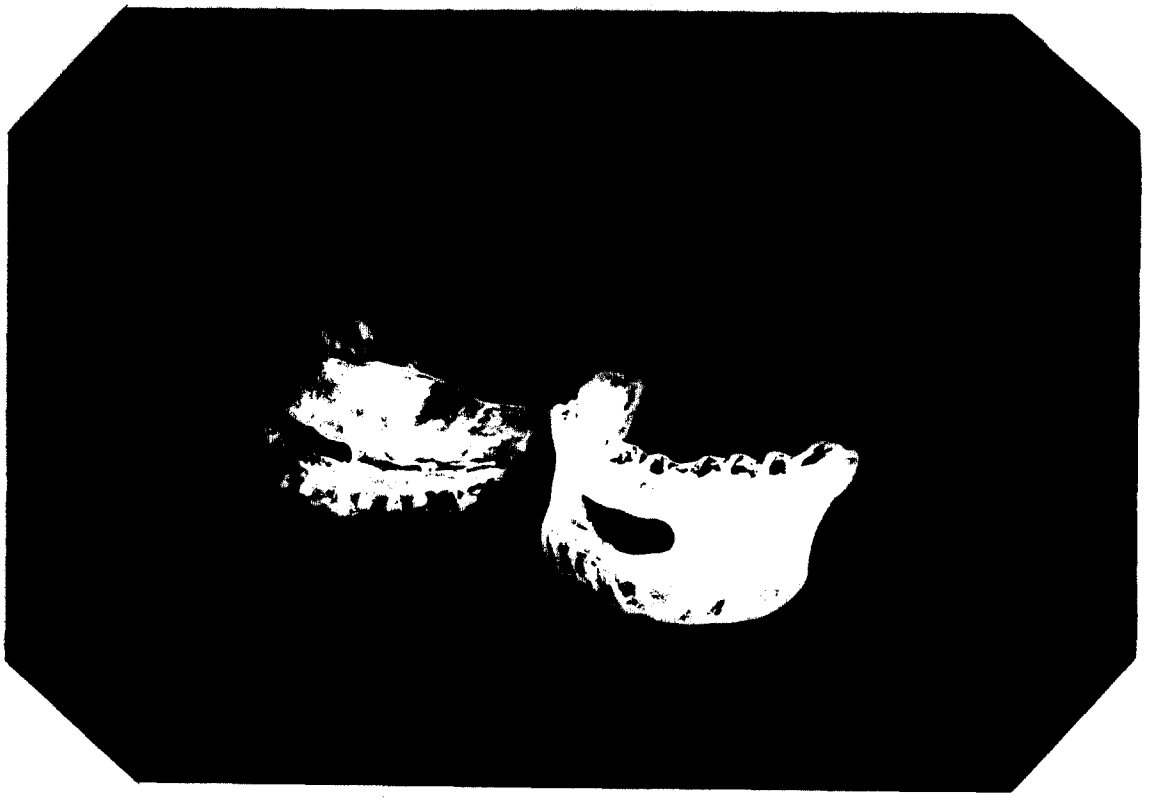
Predicate Device

The SNOREX is claiming significant equivilence to

THE SILENCER APPLIANCE

Photo and Description of SNOREX

The SNOREX is a custom formed mandibular splint designed to hold the lower jaw in a forward position while sleeping.



Intended Use of the Device

To maintain open airways and thereby reduce or eliminate snoring and sleep apnea.

Summary of Technological Characteristics of SNOREX

Compared To

The Silencer Appliance

The SNOREX and the SILENCER are comparable in all aspects with the exception of the "Halstrom Hinge". The amount of advancement of the mandible and precision alignment is achieved by the SNOREX manufacturing procedure without the use of a hinge.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Vernon Pribble
Owner/Operator
Snorex (NZ) Ltd.
12 Kura Place, Torbay
North Shore City, New Zealand

DEC 18 1997

Re: K971818
Trade Name: Snorex
Regulatory Class: Unclassified
Product Code: LQZ
Dated: October 4, 1997
Received: October 10, 1997

Dear Mr. Pribble:

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 current Good Manufacturing Practice requirement, 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) 594-4618. 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): _____

Device Name: **SNOREX**

Indications for Use:

The use of the SNOREX device is indicated for anyone who snores, has a desire to alleviate or eliminate snoring, and has sufficient natural upper and lower teeth to hold the appliance in place while sleeping.

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

Concurrence of DCRHL, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K971818

Prescription Use ✓ **OR** **Over-The-Counter Use**_____
(Per 21 CFR 801.109)