

K972424

510(k) Premarket Notification Submission
SilentNite™ Snore Prevention Device

501(k) Summary

Submitter:

Glidewell Laboratories
4141 MacArthur Blvd.
Newport Beach, CA 92660
Contact Person:

Keith D. Allred
Telephone: (714) 440-2683
Telefax: (714) 440-2787

SEP 18 1997

Date Summary was prepared: June 25, 1997

Device Name:

- Trade Name - SilentNite™
- Common Name - Snoring Device
- Classification - Unclassified
- Product Code - LRK

Description: The SilentNite™ device is comprised of upper and lower frames that are attached with connectors. The frames are form fitted to the teeth and are meant to be worn at night while sleeping.

Intended Use: The intended use of the SilentNite™ device is for snore prevention.

Substantial Equivalence:

The SilentNite™ device is substantially equivalent to several other legally marketed devices in the United States. Substantially equivalent devices include the following: SILENCER by Silent Knights Ventures, Inc., THERASNORE by Dr. Thomas E. Meade, PM POSITIONER by Dental Services Group, KLEARWAY by Great Lakes Orthodontics, SNOREFREE by Space Maintainers Laboratory, SNORNOMORE by Annalan Labs, and "Z" by "Z" Training.

Safety and Efficacy:

The SilentNite™ device functions in a similar manner to other comparative predicate devices and the intended use is the same. The differences between the device and predicate devices are minor and do not raise new safety concerns. The effectiveness and suitability to the intended purpose of the product is assured through the wide, general use of similar other predicate devices and demonstrates the safe use of the device in many practitioner's hands.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Keith D. Allred
Glidewell Laboratories
4141 Macarthur Boulevard
Newport Beach, California 92660

Re: K972424
Trade Name: Silentnite
Regulatory Class: Unclassified
Product Code: LRK
Dated: June 25, 1997
Received: June 27, 1997

SEP 18 1997

Dear Mr. Allred:

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 (Pre-market 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 pre-market notification submission does not affect any obligation you might have under sections 531

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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): K972424

SILENT NITE

Device Name: _____

Indications For Use:

The SilentNite™ mandibular repositioning (MRP) device is indicated for persons who wish to prevent snoring and is available only from a dentist by prescription. It has been estimated that 6 million or more adults (with men outnumbering women 8 to 1) snores, and that 10% may have sleep apnea. If an examination of the patient, together with the patient's responses to a questionnaire, indicate the possibility of a more serious sleep disorder than "primary" or "social" snoring, the patient should be referred to a physician who can diagnose sleep apnea based on testing in a sleep laboratory and suggest treatment options. Necessary treatment for serious cases of sleep apnea may include surgery, or a medically prescribed treatment called nasal continuous positive airway pressure, or a MRP device. MRP devices may be appropriate treatment for persons with mild sleep apnea when surgical and other medical treatments are ineffective or not desired. Contraindications for use: Based on the dentist's examination and the patient's responses to the questionnaire, obstructive sleep apnea may either be indicated or cannot be excluded. In such event, an examination by a sleep disorder specialist is recommended before prescribing the SilentNite™ snoring device. If the dentist's examination and the patient's responses to the questionnaire indicate the possibility of disease or injury to the mandibular joint, the SilentNite™ snoring device is contraindicated and should not be prescribed, to avoid the possibility of further damage to the mandibular joint.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald Shepper
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972424

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____