

W. Keith Thornton, D.D.S.
6131 Luther Lane, Suite 208
Dallas, TX 75225

K972061

AUG 21 1997

Non-Confidential Summary of Safety and Effectiveness

page 1 of 3
June 2, 1997

W. Keith Thornton, D.D.S.
6131 Luther Lane Suite 208
Dallas, TX 75225

Tel - (214) 691-5621
Fax - (214) 691-4934

Official Contact: Keith Thornton, D.D.S.
Proprietary or Trade Name: TOA
Common/Usual Name: Oral Appliance - anti-snoring device
Classification Name: Anti-snoring device
Device: TOA
Predicate Devices: Nellcor Puritan Bennett - TAP - K962516
SnoreFree - OSAP - K960673
Distar, Inc. - TheraSnore - K926382

Device Description:

The TOA Anti-snoring device is comprised of -

- * Lower tray fitted over the lower teeth.
- * Upper tray fitted over the upper teeth.
- * Impression material
- * Hook mechanism to attach lower tray to upper tray

Intended Use:

Indicated Use -- The TOA is intended to reduce or alleviate night time snoring and obstructive sleep apnea, OSA.

Target population -- Adult patients

Environment of Use -- Home and sleep laboratories

**Non-Confidential Summary of Safety and Effectiveness
(continued)**

page 2 of 3

June 2, 1997

Comparison to Predicate Devices:

Attribute	TOA	NPB/TAP K962516	OSAP K960673	TheraSnore K92688
------------------	------------	----------------------------	-------------------------	------------------------------

Use

Intended as an intraoral device	Yes	Yes	Yes	Yes
Intended to reduce snoring or help alleviate snoring	Yes	Yes	Yes	Yes
Indicated for use with patients with mild to moderate OSA	Yes	Yes	Yes	Yes
Indicated for single patient multi - use	Yes	Yes	Yes	Yes
Indicated for use at home or sleep laboratories	Yes	Yes	Yes	Yes

Design

Rigid tray pieces	Yes	Yes	Yes	Yes
Heat sensitive impermissible material for fitting to teeth	Yes	Yes	Yes	Yes
Separate tray pieces	Yes	Yes	No	No
Custom fit for each patient	Yes	Yes	Yes	Yes
Works by holding lower jaw forward	Yes	Yes	Yes	Yes
Can be adjusted or refit	Yes	Yes	Yes	Yes
Placed in patient mouth each evening	Yes	Yes	Yes	Yes
Cleaned daily	Yes	Yes	Yes	Yes
Permits lateral and / or vertical jaw movement	Yes	Yes	No	No

**Non-Confidential Summary of Safety and Effectiveness
(continued)**

page 3 of 3

June 2, 1997

Comparison to Predicate Devices: (continued)

Attribute	TOA	NPB/TAP K962516	OSAP K960673	TheraSnore K92638
------------------	------------	----------------------------	-------------------------	------------------------------

Design (continued)

Upper and lower tray unhook for easy removal from mouth	Yes	Yes	No	No
Permits patient to talk and drink with appliance in place	Yes	Yes	No	No
Permits patient to breath through mouth	Yes	Yes	No	No

Materials

Rigid tray material	Yes	Yes	Yes	Yes
Heat sensitive impression material	Yes	Yes	Yes	Yes

Performance Testing

None applicable under Section 514	Yes	Yes	Yes	Yes
reduced AHI in patients	72%	72%	Yes	Yes
AHI performance comparable to CPAP	Yes	Yes	Yes	Unknown

Differences Between Other Legally Marketed Predicate Devices

The difference between the intended device and predicates, except the Nellcor Puritan Bennett - TAP device, is that the intended device is a 2 piece construction. This difference does not have a significant effect on the safety or effectiveness of the device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

W. Keith Thornton, D.D.S.
6131 Luther Lane, Suite 208
Dallas, Texas 75225

AUG 21 1997

Re: K972061
Trade Name: TOA
Regulatory Class: Unclassified
Product Code: LRK
Dated: June 2, 1997
Received: June 3, 1997

Dear Dr. Thornton:

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.

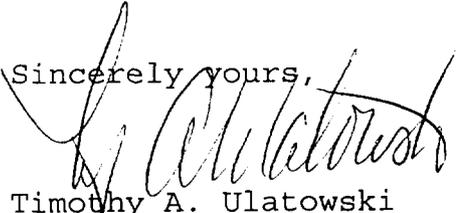
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice 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" (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

SECTION 3
INDICATIONS FOR USE

Pursuant to the Notice of February 6, 1996 regarding listing of Indications for Use on a separate sheet, the following is per that request.

510(k) Number: _____ (To be assigned)

Device Name: TOA Anti-snoring Device

Intended Use : To reduce or alleviate night time snoring and obstructive sleep apnea (OSA)

Environment of use: Home and sleep laboratories

Disposable / Reusable: Single patient - multi- use

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Rimmer

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

510(k) Number KA72061

Prescription Use or **Over-the-counter use**
(Per CFR 801.109)