DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 - 2005

Mr. James Bonds
Nellcor Puritan Bennett, Incorporated
4280 Hacienda Drive
Pleasanton, California 94588-2719

Re: K964516
Trade/Device Name: Tap
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: November 04, 1996
Received: November 05, 1996

Dear Mr. Bonds:

This letter corrects our substantially equivalent letter of January 24, 1997, regarding the classification of your device which was incorrectly identified as "unclassified."

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with

all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act fiom the Division of Small Manufacturers, International and Consumer Assistance at its toll-fiee number (800) 638-2041 or (301) 443-6597 or at its internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Chiu S. Lin, PhD

Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

NELLCOR PURITAN BENNETT

JAN 24 1997

K964516

Non-Confidential Summary of Safety and Effectiveness

November 4, 1996

Nellcor Puritan-Bennett, Inc.
10200 Valley View Rd.
Eden Prairie, MN 55344

Tel - (612) 941-3006

Fax - (612) 829-5423

Official Contact:	Chris Hadland, Director, RA and QA
Proprietary or Trade Name:	TAP
Common/Usual Name:	Oral Appliance - anti-snoring device
Classification Name:	Anti-snoring device
Device:	TAP
Predicate Devices:	SnoreFree - OSAP - K960673 Distar, Inc. - TheraSnore - K926382 Dental Services group - Adjustable PM Positioner - K# unknown

Device Description:

The TAP 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 TAP is intended to reduce or alleviate night time snoring and mild to moderate obstructive sleep apnea, OSA.
Target population - -	Adult patients
Environment of Use - -	Home and sleep laboratories

Non-Confidential Summary of Safety and Effectiveness (continued)

November 4, 1996

Comparison to Predicate Devices:

Attribute	TAP K962516	OSAP K960673	PM Positioner Unknown	TheraSnore K92638
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	No	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	No	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	No	No	No

Non-Confidential Summary of Safety and Effectiveness (continued)

November 4, 1996

Comparison to Predicate Devices: (continued)

Attribute	TAP K962516	OSAP K960673	PM Positioner Unknown	TheraSnore K926382
Design (continued)				
Upper and lower tray unhook for easy removal from mouth	Yes	No	No	No
Permits patient to talk and drink with appliance in place	Yes	No	No	No
Permits patient to breath through mouth	Yes	No	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%	Yes	Yes	Yes
AHI performance comparable to CPAP	Yes	Yes	Unknown	Unknown

Differences Between Other Legally Marketed Predicate Devices

The difference between the intended device and predicates 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.