K062951

Airway Management Inc.
6116 North Central Expressway
Suite 605
Dallas, Texas 75206

DEC 12 2006

Non-Confidential Summary of Safety and Effectiveness
September 28, 2006

Airway Management Inc.
6116 North Central Expressway
Suite 605
Dallas, Texas 75225

Tel- (972) 369-0978

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Official Contact	Darren Edward Henderson
Proprietary or Trade Name	TAP III
Common / Usual Name	Dental Device – Anti Snoring / Obstructive Sleep Apnea device
Classification Name	Anti -Snoring / Obstructive Sleep Apnea Device
Device:	TAP III
Predicate Device	Nellcor Puritan Bennett – TAP-K962516 Thornton Oral Appliance – TOA-K972061 TAP II – K060388

Device Description:

The TAP III Anti-Snoring device is comprised of:

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

Intended Use:

Indicated Use--	The TAP III is intended to reduce or alleviate night time snoring and mild to moderate obstructive sleep apnea, OSA.
Target population --	Adult patients 18 years and older
Environment of Use--	Home and sleep laboratories.

Non-Confidential Summary of Safety and Effectiveness
(continued)
September 28,2006

Comparison to Predicate Devices:

Attribute	TAP III	TOA K972061	TAP K962516	TAPII K060388
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	Yes	Yes
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

Comparison to Predicate Devices:

Attribute	TAP III	TOA K972061	TAP K972516	TAP II K060388
Design (continued)				
Upper and lower tray unhook For easy removal from mouth	Yes	Yes	Yes	Yes
Permits patient to talk and drink With device in place	Yes	Yes	Yes	No
Permits patient to breath through mouth	Yes	Yes	Yes	No
Materials				
Rigid tray material	Yes	Yes	Yes	Yes
Heat sensitive impression material	Yes	Yes	Yes	Yes
Performance Testing				
Non applicable under Section 514	Yes	Yes	Yes	Yes
Reduced AHI in patients	72%	72%	72%	72%

Differences Between Other Legally Marketed Predicate Devices

The difference between the intended device and predicates devices is the design of the base and hook. The TAP III base and hook is a smaller design. This difference does not have a significant effect on the safety or effectiveness of the device,

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2006

Mr. Darren Henderson
Quality Manager
Airway Management, Incorporated
6116 North Central Expressway Suite 605
Dallas, Texas 75206

Re: K062951
Trade/Device Name: TAP III Anti-Snoring Device
Regulation Number: 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring And Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: September 28, 2006
Received: September 29, 2006

Dear Mr. Henderson:

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 application (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 such 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 begin 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" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free 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 Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062951

SECTION 3
INDICATIONS FOR USE

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

Device Name: TAP III

Intended Use: To reduce or alleviate night time snoring and mild to moderate 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)

Prescription Use X or Over-the-counter use_____

(Per CFR 801.109)

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