

SEP 10 1996



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K962516

Non-Confidential Summary of Safety and Effectiveness

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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: H&M Anti-snoring device - K882303
Distar, Inc. - TheraSnore - K926382
Dental Services group - PM and 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.

Target population - - Patients who have a problem with snoring.

Environment of Use - - Home and sleep laboratories

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

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Comparison to Predicate Devices:

Attribute	Intended device	H&M anti-snoring	PM Positioner	TheraSnore
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Use

Intended as an intraoral device	Yes	Yes	Yes	Yes
Intended to reduce snoring	Yes	Yes	Yes	Yes
Indicated for use with patients who snore	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 impressible 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	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	Yes	Yes

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

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Comparison to Predicate Devices: (continued)

Attribute	Intended device	H&M anti-snoring	PM Positioner	TheraSnore
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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	Yes	Yes	Yes	Yes
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Differences Between Other Legally Marketed Predicate Devices

The difference between the intended device and predicates is only in the design of the device.

- * Two piece construction (upper and lower trays) design permits patient to talk, drink and breath through the mouth with the appliance in place.

These differences do not have a significant effect on the safety or effectiveness of the device.