OCT 14 1998

K981744

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

Non-Confidential Summary of Safety and Effectiveness

May 8, 1998

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

Tel - (214) 691-5621

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Official Contact:	Keith Thornton, D.D.S.
Proprietary or Trade Name:	Nasal Mask Holder
Common/Usual Name:	Nasal Mask Holder
Classification Name:	Accessory to Non-continuous Ventilator
Device:	Universal Nasal Mask Holder and Combination Oral Appliance
Predicate Devices:	Thornton - TOA - K972061
	Respironics, Inc. - Standard Head Gear for Nasal Mask - no K#.

Device Description:

1. The Universal Nasal Mask Oral Appliance Holder includes the Extension Bracket with Mask Flange which attaches to the upper tray of the Oral Appliance, approved under K972061. This device would be considered an accessory to the Nasal Mask and is designed to hold the Nasal Mask in place. It is an alternative to the use of standard headgear. It is adaptable to several different nasal masks styles.

2. In combination with the already approved, K972061, Oral Appliance which has both an upper and lower tray. The upper tray has a fitting which permits the attachment of the Extension Bracket with Mask Flange. This combined device permits therapy for OSA and snoring by an oral device and a positive airway pressure delivery device.

Intended Use:

Indicated Use -- The intended use for the Nasal Mask Oral Appliance Holder is that is may be used with or without the complete Oral Appliance approved for Snoring and OSA to serve as an accessory to hold a Nasal Mask on a patient's face. The designed attachment can be

fitted to hold the nasal mask in place via an oral appliance secured by the upper teeth of the patient. The accessory will have the same indications for use as those of the equipment to which it is an accessory.

Target population - - Adult patients

Environment of Use - - Hospital, home and sleep laboratories

Comparison to Predicate Devices:

Attribute	Combination OA (New device)	Thornton TOA K972061	Respironics Head gear
Use			
Intended as an intraoral device	Yes	Yes	No
Indicated for use with nasal mask	Yes	No	Yes
Indicated for single patient / multi - use	Yes	Yes	Yes
Indicated for use at home, hospital, sleep laboratories	Yes	Yes	Yes
Targeted patients - Adult	Yes	Yes	Yes
Design			
Rigid tray piece	Yes	Yes	No
Heat sensitive impressionable material for fitting to teeth	Yes	Yes	No
Custom fit for each patient	Yes	Yes	No
Method of adjusting for mask fit	Yes	No	Yes
Can be adjusted or refit	Yes	Yes	Yes
Placed in patient mouth each evening	Yes	Yes	N/A
Cleaned daily	Yes	Yes	Yes
Permits patient to talk and drink with appliance in place	Yes	Yes	N/A
Permits patient to breath through mouth	Yes	Yes	Yes

Attribute	Combination OA (New device)	Thornton TOA K972061	Respironics Head gear
Materials			
Rigid tray material	Yes	Yes	N/A
Heat sensitive impression material	Yes	Yes	N/A
Elastic and Velcro strapping	No	No	Yes
Performance Testing			
None applicable under Section 514	Yes	Yes	Yes
Equivalent leak rates at various pressures	Yes	N/A	Yes

Differences Between Other Legally Marketed Predicate Devices

There is no significant difference between the intended device, Combination OA and Nasal Mask Holder and the Thornton TOA device approved under K972061 and the Respironics Head Gear, no separate 510(k) K#. (Included as a accessory in the mask submissions.)

The differences between the intended device, OA, and the predicates are -

1. The Combination Oral Appliance and Holder as compared to the Thornton TOA, K972061, is that the intended device permits the addition of a nasal mask to be attached to the oral appliance.
2. The Universal Nasal Mask Holder as compared to the Thornton TOA, K972061, utilizes only one tray and has an extension bracket to hold the nasal mask in place.
3. The Universal Nasal Mask Holder as compared to Respironics Head Gear utilizes a different method to hold a nasal mask in place. The oral tray with attached bracket vs. straps around the head.

There is no significant difference between the intended device, Combination OA and Nasal Mask Holder and the Thornton TOA device approved under K972061 and the Respironics Head Gear, no separate 510(k) K#. (Included as a accessory in the mask submissions.)

The differences between the intended device, OA, and the predicates are -

1. The Combination Oral Appliance and Holder as compared to the Thornton TOA, K972061, is that the intended device permits the addition of a nasal mask to be attached to the oral appliance.
2. The Universal Nasal Mask Holder as compared to the Thornton TOA, K972061, utilizes only one tray and has an extension bracket to hold the nasal mask in place.
3. The Universal Nasal Mask Holder as compared to Respironics Head Gear utilizes a different method to hold a nasal mask in place. The oral tray with attached bracket vs. straps around the head.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 1998

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

Re: K981744
Combination Nasal Mask/Oral Appliance and Nasal Mask Holder
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: October 8, 1998
Received: October 9, 1998

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 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). 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 (Premarket 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) 594-4648. 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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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: K981744 (To be assigned)

Device Name: Nasal Mask Oral Appliance Holder

Intended Use : The intended use for the Nasal Mask Oral Appliance Holder is that is may be used with or without the complete Oral Appliance approved for Snoring and OSA to serve as an accessory to hold a Nasal Mask on a patient's face. The designed attachment can be fitted to hold the nasal mask in place via an oral appliance secured by the upper teeth of the patient. The accessory will have the same indications for use as those of the equipment to which it is an accessory.

Environment of use: Hospital, Home, and Sleep laboratories

Disposable / Reusable: Single patient - multi- use

Concurrence of CDRH, Office of Device Evaluation (ODE)

10/14/98

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

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____