510(k) Summary K122350 NOV 1 2012
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Date Prepared 31-Oct-12

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Official Contact: Dale Siebenmorgen – Manager of Quality and Regulatory

Proprietary or Trade Name: TAP PAP Nasal Pillow Mask

Common/Usual Name: CPAP Patient interface

Classification Code/Name: BZD – non-continuous ventilator (IPPB)
21 CFR 868.5905
Class 2

Predicate Devices: K992384 - Stevenson CPAP/Pro

Device Description:
The TAP PAP Nasal Pillow Mask consists of a boil & bite type dental appliance. A small bracket that extends beyond the lips to attach the mask frame (Mask – Upper Mouth Piece Adjustment Joint). Two soft silicone nasal pillows are located on the mask frame to seal against the nostrils. The nasal pillows come in three sizes and can be individually rotated to align with the user's nares. A corrugated flexible tube extends upwards from the mask frame to a 22 mm connector which connects to a breathing tube of a CPAP or bi-level device.

The mask frame has exhalation vents (bias holes) that allow exhaled gases to be continually flushed.

Indications for Use:
The TAP PAP Nasal Pillow Mask is intended to be used by individuals who have been diagnosed by a Physician as requiring CPAP or Bi-Level ventilator treatment. The TAP PAP Nasal Pillow Mask is intended for single patient adult (>66lb/30kg) use in the home, hospital or other clinical setting.

Patient Population: Adults (>66 lbs / 30 kg)

Environment of Use: Home, hospital or other clinical settings

Predicate Device Comparison:

The TAP PAP Nasal Pillow Mask has been compared to the predicate and is viewed as substantially equivalent because:

Indications –

- The TAP PAP Nasal Pillow Mask is intended to be used by individuals who have been diagnosed by a physician as requiring CPAP or Bi-Level ventilator treatment. The TAP PAP Nasal Pillow Mask is intended for single patient adult (>66lb/30kg) use in the home, hospital or other clinical setting.
- The predicate CPAP/Pro (K992384) is intended to treat adult OSA, but it is a patient interface which must connect to CPAP and bi-level devices, therefore the indications for use are considered substantially equivalent.
- Substantially equivalent to Stevenson CPAP/Pro (K992384).

Discussion – The indications for use are equivalent to the predicate.

Patient Population –

- The TAP PAP Nasal Pillow Mask and the predicate CPAP/Pro are both intended for adults (>66 lbs. / 30 kg.).

Discussion – The intended patient population is identical to the predicate.

Technology –

- Technology is the use of an upper dental tray with boils & bite impression material which has a bracket to hold nasal pillows and tubing. The nasal pillows are offered in multiple sizes and fit in the nares of the patient. They each on a means for relieving excess flow, vent holes, and connect to the positive pressure equipment with a standard 22 mm corrugated tubing.

Discussion – The technology of tubing, nasal pillow2s and a manifold is identical to the predicate. The difference in placing the manifold closer to the patient in the proposed device is a matter of comfort for the user vs. the manifold remote from the patient and bracket holding 2 separate tubes with the nasal pillows as the predicate has. The difference in this design configuration increases the dead space, but the performance of the proposed device in Pressure vs. Flow and CO2 washout testing demonstrates that it is equivalent and the differences are not clinically significant and safety and effectiveness is not affected.

Materials –

- The materials are standard medical grade materials and have been tested per ISO 10993.

Discussion – The materials have been tested per ISO 10993-1 and passed the requirements of each test.

Environment of Use –

- The masks are intended for use in the home, hospital, or sleep laboratories.

Discussion – The environments of sue are identical to the predicate.

Differences –
There are no differences between the predicate and the proposed device which would raise any new safety or risks and thus can be found to be substantially equivalent.

Attributes	**TAP PAP Nasal Pillow Mask**	**Stevenson CPAP/Pro K992384**
Intended Use	Non-invasive ventilator interface for CPAP or bi-level treatment	Non-invasive ventilator interface for CPAP or bi-level treatment
Indications for Use	The TAP PAP Nasal Pillow Mask is intended to be used by individuals who have been diagnosed by a Physician as requiring CPAP or Bi-Level ventilator treatment. The TAP PAP Nasal Pillow Mask is intended for single patient adult (>66lb/30kg) use in the home, hospital or other clinical setting.	Intended to treat adult OSA
Patient Population	Adults (>66 lbs. / 30 kg.)	Adults (>66 lbs. / 30 kg.)
Environment of Use	Home Hospital Other clinical settings	Not specified
Duration of Use	Single patient, multi-use	Single patient, multi-use
Prescriptive	Yes	Yes
Method of fixation	Boil & bite dental tray with bracket attachment	Boil & bite dental tray with bracket attachment
Sealing method	Soft nasal pillows	Soft nasal pillows
Positive pressure source	CPAP or bi-level equipment	CPAP or bi-level equipment
Means to relieve excess flow	Vent holes	Diffuser near pillows
Tray configurations	Boil & Bite with heat sensitive impression material	Boil & Bite with heat sensitive impression material
Bracket for adjusting tubing and nasal pillows	Yes	Yes
Tubing from pillows to connector to gas source	Yes	Yes
Different Pillow sizes	3	3
Technical Specifications / Performance Testing		
Operating Pressure range	4 – 20 cm H_2O	4 – 18 cm H_2O
Dead Space	95 ml	45 ml
Pressure Drop	Flow / Drop 50 lpm / 0.2 cm H_2O 100 lpm / 0.6 cm H_2O	Not available or reported
Exhaust flow / Pressure	Pressure (cm H_2O) / Flow (lpm) 6 / 23 10 / 30 20 / 42	Pressure (cm H_2O) / Flow (lpm) 6 / 15 10 / 21 20 / 33
Weight	59 gm	55 gm
Gross Dimensions (no head gear)	280 mm (H) x 67 mm (W) x 220 mm (D)	260 mm (H) x 100 mm (W) x 100 mm (D)

Non-clinical Testing Summary -

We have performed a number of tests typical of CPAP patient interfaces. These tests include:

Pressure Drop

- Standard test method of using a standard flow and measuring pressure drop
- No pass / fail criteria, reportable values only
- Discussion – The proposed device has a low pressure drop at 50 and 100 lpm and is only a reported value. CPAP machines are able to supply the required flow at these low resistance values. As the patient exhaled through their mouth there is no resistance to breathing.

Bias (vent) Flow (Pressure / Exhaust Flow

- Standard test method using CPAP unit at various flow rates and measuring the leak at the patient interface
- No pass / fail criteria, reportable values only. It should be comparable to the predicate.
- Discussion – The proposed device has a slightly higher "Leak or Flow" rate at all pressure vs. the predicate which means greater CO_2 washout. The differences do not have any clinical significance.

Dead space

- Standard test method of measuring the volume of the parts near the patient.
- No pass / fail criteria, reportable values only. It should be comparable to the predicate.
- Discussion – The proposed device has a "manifold" near the patient with a single hose coming from the CPAP unit and the nasal pillows attached to the manifold. The predicate has the manifold remote from the patient and then 2 separate tubes with individual nasal pillows coming from the manifold to the patient. The higher reported dead space is based upon measuring the proposed device with the manifold, tubing, and nasal pillows vs. the predicate was the tubing and nasal pillows only but not the remote manifold. While the reported value for the proposed is higher 95 ml vs. 45 ml, the Pressure vs. Flow and the CO_2 washout data demonstrated that the proposed device effectively flushed the patient interface as it had higher leak rates than the predicate at the same pressures and the proposed device passed the CO_2 washout per ISO 17510-2 criteria. Therefore the higher dead space is not clinically significant nor does it affect safety and effectiveness.

CO_2 washout per ISO 17510-2

- Tested per ISO 17510-2
- Pass / fail criteria per ISO 17510-2 allow for changes in CO_2 at various pressures to be < 20% and < 60% from baseline).

Pressure	Mask $ETCO_2$	% Increase
4 cm H_2O	5.4 %	4%
5 cm H_2O	5.4 %	4%
10 cm H_2O	5.3 %	2 %
Occluded	5.6 %	7 %

- Discussion – The proposed mask demonstrated that it meet the requirements of CO_2 washout per ISO 17510-2.

Mask Weight

- Simply weighed the devices
- No pass / fail criteria, reportable values only. It should be comparable to the predicate.
- Discussion – The proposed device vs. the predicate were equivalent.

Cleaning durability

- Repeated cleaning was performed per the recommended cleaning instructions
- Visual and performance testing was performed and compared pre – and post- cleaning and found to be similar
- Discussion – The proposed mask can be cleaned as intended and meet the performance specifications

Environmental (Hot / cold exposure and drop test)

- Test method was subjected the samples to 50°C for 72 hours and – 20°C for 24 hours
- Pass / fail criteria was that they would meet the performance specifications which was performed after the cleaning durability
- Discussion – The proposed device met the performance specifications after conditioning and cleaning.

Biocompatibility of Materials –
Materials were evaluated per ISO 10993-1. There are parts and thus their respective materials which have the following patient contact and duration.

Parts which are Externally communicating, Tissue – gas pathway contact, permanent duration require the following tests. They are the mask shell, assembly, pillow seals and mouth tray and tubing.

- Cytotoxicity (tested per ISO 10993-5)
- Sensitization (tested per ISO 10093-10)
- Irritation (tested per ISO 10993-10)
- Genotoxicity (Tested per ISO 10993-3)
- Implantation (tested per ISO 10993-6)
- Pass / fail criteria was for the each respective ISO 10993 test

Parts which are Surface communicating, Skin, permanent duration require the following tests. They are the headgear and chin strap.

- Surface communicating, Skin, permanent duration
  - Cytotoxicity (tested per ISO 10993-5)
  - Sensitization (tested per ISO 10093-10)
  - Irritation (tested per ISO 10993-10)
  - Pass / fail criteria was for the each respective ISO 10993 test

Parts which are Surface communicating, Skin, limited duration require the following tests. They are the nut and bolt.

- Cytotoxicity (tested per ISO 10993-5)
- Sensitization (tested per ISO 10093-10)
- Irritation (tested per ISO 10993-10)
- Pass / fail criteria was met for each respective ISO 10993 test

Discussion –
All materials were tested according to ISO 10993-1 for the appropriate level of patient contact and duration and found pass the applicable ISO 10993-1 test requirements.

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 1 2012

Airway Management, Incorporated
C/O Paul Dryden
President
Promedic, Incorporated
Bonita Springs, Florida 34134

Re: K122350
Trade/Device Name: Tap PAP Nasal Pillow Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: August 2, 2012
Received: August 3, 2012

Dear Mr. Dryden:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.

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

Enclosure

Indications for Use Statement

510(k) Number: K122350

Device Name: TAP PAP Nasal Pillow Mask

Indications for Use:

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Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheis

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

510(k) Number: K122350