K093124

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MAR 10 2010

510 (K) Summary

510 (K) Summary as required by 21 CFR 807.92

510 (K) Submitter:

CardinalHealth 207
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Contact Person:

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Establishment Registration Number: 2050001

Date Prepared: March 3, 2010

Name of the Device: Puresom Nasal Mask

Common/ usual name: Mask for use with ventilator

Classification: The Puresom Nasal Mask System is classified as a class II device under the following classification code

Product code	CFR Section	Panel
73 BZD	21 CFR 868.5905	Anesthesiology

Reason for the submission: This Special 510 (K) Premarket Notification is a submission for changes to a current device for use with obstructive sleep apnea. The design change is to the latex-free silicone cushion durometer. Also the PureSom mask has replaceable cushions (3 sizes of cushions with a single frame) with adjustable forehead pads.

Intended Use: The Puresom Nasal (CPAP) Mask system is for use with continuous positive airway pressure devices (CPAP), operating at or above 3cmH2O for the treatment of obstructive sleep apnea. The mask is intended for single patient use and can be used in the home or in a hospital/ institutional environment. The mask is to be used on adult patients (>30Kg) for whom continuous positive pressure airway has been prescribed.

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Device Description: The Puresom Nasal (CPAP) Mask is intended to be used with positive airway pressure devices such as CPAP. It provides a seal such that positive pressure from positive pressure source is directed into the patient's nose. It is held in place with an adjustable headgear. It may be cleaned with a mild detergent, such as Ivory® dishwashing liquid or unscented baby shampoo in water.

The design consists of latex-free silicone cushion designed to fit over the patients' nose. The cushion is designed in such a way that it minimizes leaks and is comfortable for the patient. The cushion shall be connected to a polycarbonate frame that supports the cushion and provides a connection for a 90º elbow. The elbow shall be capable of rotating freely through 360º. The silicone cushion is designed in such a way that it can be easily removed by the patient, from the polycarbonate frame for cleaning or replacement purposes.

The elbow connects to a conventional air delivery hose between the mask and the positive airway pressure source via a 22mm polycarbonate fitting on the elbow. The 22 mm connector is designed in such a way that it can rotate freely through 360º.

The built in vent openings are molded into the front side of the elbow and a snap-on shroud is assembled to the elbow to direct the air away from the patient's face and chest. The vent openings may be visually inspected for obstruction prior to use.

Predicate Device Information: The predicate devices are Advantage Series II mask (K031935), Advantage Series mask (K012207) and Mirage Echo (K090490).

Summary of Technological Characteristics of Device Compared to the Predicate Device:

The Puresom Nasal (CPAP) is the same device as the Advantage Nasal Mask which was cleared for market under 510(k) (Advantage Nasal Mask No.K012207).

Modifications to the Nasal Mask that are associated with this submittal are as follows:

- Use of a lower durometer silicone durometer that is more pliable and will tend to conforms better to the patients face.
- Use of 3 replaceable cushion sizes allows the physician to select the proper cushion sizes that accommodate the patient.
- The Elbow Connection Method was changed from a clip to snap fit

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The modified Nasal Puresom mask has the following similarities to those which previously received 510(k) concurrence:

- have the same indicated use,
- use the same nasal mask operating principle,
- incorporate the same basic nasal design with the exception of modifications described in this submittal.
- are manufactured and packaged utilizing the same basic processes.

Summary of Nonclinical Testing For The Device and Conclusions:

Attribute	Requirement	Parameter	Result
Biocompatibility	All materials used in the construction of the Puresom Nasal Mask shall be compliant with ISO10993-1	All material which may contact the patient or the clinician must be Biocompatible	Pass
Interconnections	Interconnections to the patient circuit shall be compliant with ISO 5356-1 (EN1281-1) and ISO 5367	Interconnections to the patient circuit shall be compliant with ISO 5356-1 (EN1281-1) and ISO 5367	Pass
Dead Space	Dead space volume: the maximum dead space for the Nasal mask shall be as follows: 1-Small ≤180CC 2- Regular ≤ 190CC 3- large ≤200 CC	The cavities of each model shall not exceed maximum dead space volume of: 1- Small ≤ 180 CC 2- Regular ≤ 190 CC 3- Large ≤ 200 CC	Pass
Carbon dioxide retention during operation requirement	Under normal condition, the relative CO_2 increase shall not exceed 20% when tested at the min. rated, 5hPa (5cmH_2O) and 10hPA (10cmH_2O) pressure	The relative CO_2 increase shall not exceed 20% when tested at the min. rated, 5hPa (5cmH_2O) and 10hPA (10cmH_2O) pressure	Pass
No flow maximum carbon dioxide level requirement	Under single fault condition, the relative CO_2 increase shall not exceed 60% after monitor stabilizes	The relative CO_2 increase shall not exceed 60% after monitor stabilizes	Pass

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CPAP pressure vs. Flow requirements & Sound pressure level	Characteristics as follow: 1- Pressure of 3cmH_2O the flow shall be 20 LPM±10%; SPL≤42.2 dBA 2- Pressure of 5cmH_2O the flow shall be 26 LPM±10%; SPL≤43.9 dBA 3- Pressure of 7cmH_2O the flow shall be 30.4 LPM±10%; SPL≤45.3 dBA 4- Pressure of 10cmH_2O the flow shall be 36 LPM±10%; SPL≤47.7 dBA 5- Pressure of 12cmH_2O the flow shall be 30.4 LPM±10%; SPL≤45.3 dBA 6- Pressure of 16cmH_2O the flow shall be 44.4 LPM±10%; SPL≤51.1 dBA 7- Pressure of 20cmH_2O the flow shall be 50.1 LPM±10%; SPL≤53.7 dBA	All sample plots shall be within the ±10% tolerance limit of the flow rate. All sound pressure levels shall be ≤ stated max. values.	Pass
Drop Test	The Puresom Nasal Mask shall be capable of withstanding 6 (six) drops from 6' without damage	All units shall not have any damages.	Pass
Shipping Test	The device when enclosed in a bulk shipping box, shall comply with ISTA Pre-shipment test 2A (2004)	Device shall not have any damage	Pass
Storage Test	The device shall operate within specification (-20 to 70C, up to 95% non-condensing)	Device shall perform and meet specification within the temperature and humidity range specification	Pass

In conclusion verification testing performed verified that the Pursom Nasal meets it's performance requirements and that this device is substantially equivalent to medical devices currently legally marketed in the United States.

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

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Mr. Monther Abushaban
Regulatory Affairs Manager
Cardinal Health 207, Incorporated
22745 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K093124
Trade/Device Name: Puresom Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: November 19, 2009
Received: February 16, 2010

Dear Mr. Abushaban:

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 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/Centers_Offices/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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

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

Enclosure

CardinalHealth

510 (K) Number (if Known): _____
Device Name: Puresom Nasal Mask

Indications for Use

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Prescription Use_____X_____ (Part 21CFR 801 subpart D) AND/ OR Over the Counter Use:_____ (Part 21CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

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

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