K103174

510k Summary

MAY - 6 2011

Date Prepared: March 09, 2011

General Information

Official Contact :	Alan Chang Director of Regulatory & Quality Division APEX Medical Corp. 9, Min Sheng St., Tu-Cheng, Taipei County , 236, Taiwan,
Classification Reference :	21 CFR 868.5905
Product Code :	BZD-noncontinuous ventilator
Common/Usual Name :	CPAP Mask
Proprietary Name :	WiZARD 210 Nasal Mask WiZARD 220 Full Face Mask
Predicate Device :	Respironics ComfortSelect Nasal CPAP Mask (K000705, K991648) Respironics ComfortFull 2 Full Face CPAP Mask (K002465, K961915)
Reason for submission :	New device

Intended Use/Indications for use

Indications for Use :	The WiZARD series mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or bi-level therapy. These masks are intended for single patient reuse in the home and multi-patient, multi-use in the hospital environment. These masks are to be used on patients greater than 30 kg for whom positive airway pressure (CPAP or bi-level system) has been prescribed.
Patient Population :	Adults with OSA

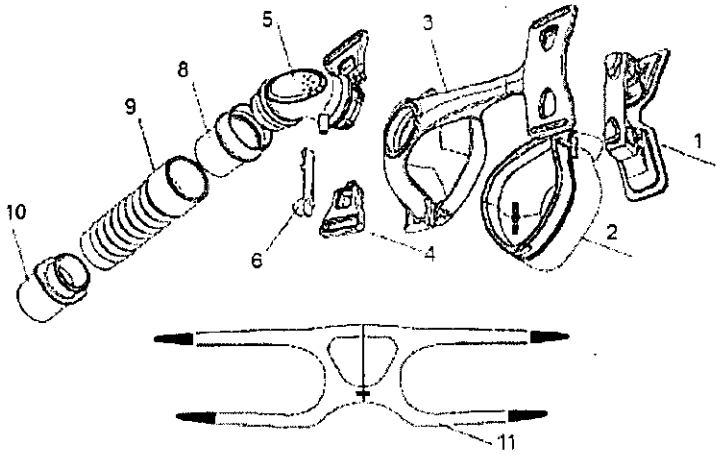
Environment of Use :	Hospital, home
Contraindications :	The masks will not remain sterile between repeated single-patient uses and should not be placed over open

Device Description

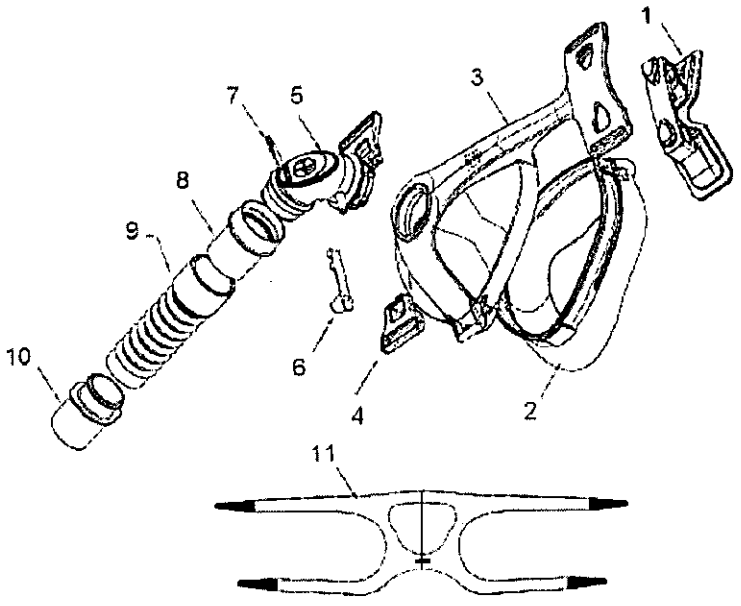
WiZARD series mask consists of a frame with a cushion seal on the face. Different height forehead support pad are offer to user allow fitting forehead better. Series of vents are feature on the elbow that serves as an exhalation vent to purge the exhaled carbon dioxide from the mask. Air coming out from these holes is very diffuse and quiet. There is no whistling or whooshing sound from the exhalation vent and no jet of air blowing on the bed partner. WiZARD serous mask is connected to the CPAP or bi-level system via standard 22 mm breathing tubing. A quickly-release mechanism also includes which allow the mask can be removed quickly

Device Feature

Wizard 210 Nasal Mask



Wizard 220 Full Face Mask



Constitute accessories

1	Forehead Support Pad	2	Cushion	3	Plastic Frame
4	Buckle	5	Elbow	6	Port Cap
7	Anti-asphyxia valve	8	Swivel hose	9	Silicon Tubing
10	Silicon Tubing Connector	11	Headgear		

Technological Characteristics

The WiZARD series mask not only provides a comfortable and secure interface on the patient's face, it also offer a reliable mechanism of connection to a CPAP or bi-level positive air pressure source for the treatment of Obstructive Sleep Apnea. WiZARD series mask is connected to the CPAP or bi-level system standard 22 mm breathing tube via swivel hose, silicon tubing and silicon tubing connector.

Performance properties are described as below;

Exhaust Flow	Compliance to ISO 17510-2
Resistance to Flow	Compliance to ISO 17510-2
Anti-asphyxia Valve Pressure	Compliance to ISO 17510-2
Inspiration Resistance	Compliance to ISO 17510-2
Expiration Resistance	Compliance to ISO 17510-2
Noise	Compliance to ISO 17510-2

SE Comparative Table

Features	Predicated Device	Proposed Device
Trade Name	Respironics ComfortSelect	WiZARD 210

	Nasal CPAP Mask (K000705, K991648)	Nasal Mask
Indications for Use	The ComfortSelect Nasal Mask is intended to provide an interface for adult patients when used with CPAP or bi-level therapy.	Identical
Environment of Use	Hospital, home	Same
Patient Population	Adult	Identical
Single patient, Multi-use	Single patient multi-use	Same
Components	Frame、cushion、headgear	Same
Materials	Polycarbonate、silicon、nylone/neoprene	Same
Comparative Testing for Safety and Efficacy	Compliance to ISO 17510-2	Same

Features	Predicated Device	Proposed Device
Trade Name	Respironics ComfortFull 2 Full Face CPAP Mask (K002465, K961915)	WiZARD 220 Full Face Mask
Indications for Use	The ComfortFull 2 Full Face Mask is intended to provide an interface for adult patients when used with CPAP or bi-level therapy.	Identical
Environment of Use	Hospital, home	Same
Patient Population	Adult	Identical
Single patient, Multi-use	Single patient multi-use	Same
Components	Frame、cushion、anti-asphyxia valve、headgear	Same
Materials	Polycarbonate、silicon、nylone/neoprene	Same
Comparative Testing for Safety and Efficacy	Compliance to ISO 17510-2	Same

Summary of Test:

Attribute	Requirement	Parameter	Result
Biocompatibility	All materials used in the construction of	All material which may contact the	**PASS**

	the mask shall be compliant with IS0 10993-1	patient or the clinician must be biocompatible	
Performance	Overall performance shall be compliant to ISO 17510-2	Test items compliance to ISO 17510-2	**PASS**
Safety	Overall safety shall be compliant to ISO 17510-2	Test items including cleaning/disinfection and CO_2 rebreathing (normal and single fault condition)	**PASS**
Shelf Life	Should be compliant to product specification	5 years shelf life	**PASS**

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

MAY - 6 2011

Mr. Alan Chang
Director of Regulatory & Quality Division
APEX Medical Corporation
9, Min Sheng St.
Tu-Cheng, Taipei Country, 236
Taiwan

Re: K103174
Trade/Device Name: Wizard 210/220 Series CPAP Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: April 29, 2011
Received: May 2, 2011

Dear Mr. Chang:

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 m/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

1. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): _____
Device Name: Wizard 210/220 series CPAP Mask
Indications for Use:
WiZARD 210/220 series CPAP Mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or bi-level therapy. These masks are intended for single-patient reuse in the home and multi-patient, multi-use in the hospital environment. These masks are to be used on patients greater than 30 kg for whom positive airway pressure (CPAP or bi-level system) has been prescribed.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

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

Page 1 of 1

510(k) Number: K103174