## 2. 510 (K) SUMMARY

JUN 6 2013

**Date Prepared:** May 31, 2012 (Revised on Jun 4, 2013)

**Official Contact** Frank Lin

QA Manager

APEX Medical Corp.

No.9, Min Sheng St., Tu-Cheng, New Taipei City , 23679, Taiwan

Tel: +886-2-22685568

Fax:+886-2-22686525



| | |
|---|---|
| **Classification Reference** | 21 CFR 868.590 |
| **Product Code** | BZD non-continuous ventilator |
| **Common/Usual Name** | CPAP Mask |
| **Proprietary Name** | WiZARD 230 Nasal Pillow Mask |
| **Predicate Device** | ResMed Swift™ FX Nasal Pillow Mask (K090244) |
| **Reason for submission** | New device |

**Intended Use/Indications for use**

| | |
|---|---|
| Indications for Use : | WiZARD 230 Nasal Pillow Mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or bi-level therapy. This mask is intended for single-patient reuse in the home and multi-patient, multi-use in the hospital environment. This mask only can 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 should not be placed over open wounds that are prone to infection. |

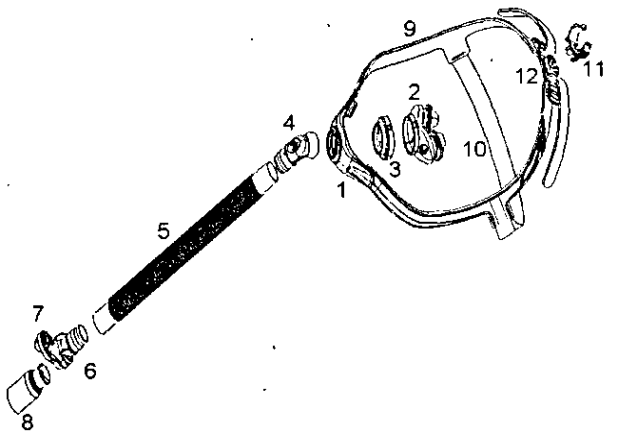
**Device Description**

The WiZARD 230 Nasal Pillow Mask provides an interface such that airflow from a positive pressure source is directed to the patient's nostril. The mask is held in place with adjustable headgear that straps the mask to the face.

WiZARD 230 Nasal Pillow Mask is safe when used under the conditions and

purposes intended as indicated in the labeling provided with the product. WiZARD 230 Nasal Pillow Mask is a prescription device supplied nonsterile.

**Device Feature**




| | Accessory | | Accessory |
|---|---|---|---|
| 1 | Mask Frame | 7 | Quick Release Button |
| 2 | Mask Cushion | 8 | Swivel Hose |
| 3 | Cushion Fixed Base | 9 | Side Strape |
| 4 | Elbow | 10 | Back Strap |
| 5 | Short Tube | 11 | Tube Retainer |
| 6 | Tubing Connector | 12 | Tube Retainer Fixed base |

**Technological Characteristics**

WiZARD 230 Nasal Pillow Mask provides a secure interface via mask frame and cushion. This mask incorporate vent holes on elbow to provide continuous air leak to flush out and minimize the amount of $CO_2$ rebreathed by the patient. The incorporation of these vent holes does not interfere with the intended performance of the mask.

WiZARD 230 Nasal Pillow Mask connects to an air delivery tube between the mask and the positive pressure source via standard conical connectors. The tube has a quick release structure makes it can easily connect/disconnect from positive pressure source.

Strap of WiZARD 230 Nasal Pillow Mask is constructed by using molded plastic and PU foam/fabric/nylon headgear. All the components are fabricated using materials deemed safe. Tube retain structure includes in strap to keep the air delivery tube at fix position.

**SE Comparative Table**

| Features | Predicated Device | Proposed Device |
|---|---|---|
| Trade Name | ResMed Swift™ FX Nasal Pillow Mask | WiZARD 230 Nasal Pillow Mask |
| Indications for Use | The Swift™ FX channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system.<br>The Swift™ FX is:<br>• To be used by adult patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed<br>• Intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment. | Identical |
| Environment of Use | Hospital, home | Same |
| Patient Population | Adult | Identical |
| Single patient, Multi-use | Single patient multi-use | Same |
| Components | Cushion、Elbow、Breath Tube、Strap(back/side) | Similar |
| Materials | Silicon、PC、PP、nylone/neoprene | Similar |
| 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 the mask shall be compliant with ISO 10993-1 | All material which may contact the patient or the clinician must be biocompatible | **PASS** |
| Performance | Overall performance shall be compliant to ISO17510-2 | Test items described in ISO 17510-2 | **PASS** |
| Safety | Overall performance shall be compliant to ISO17510-2 | 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** |

**Substantial equivalence**

This premarket notification section 510(k) shows WiZARD 230 Nasal Pillow Mask substantially equivalent to ResMed Swift™ FX Nasal Pillow Mask.

The characteristics of the WiZARD 230 Nasal Pillow Mask (shown as below) are similar to the predicates device, ResMed Swift™ FX Nasal Pillow Mask. Both masks have the same intended use, environment of use and patient population. Based on verification testing, we conclude that although few minor differences in technological characteristics (e.g. sealing, side strape, mask assembly) of these two masks, but these differences do not affect the safety or effectiveness of the WiZARD 230 Nasal Pillow Mask.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 6, 2013

Apex Medical Corporation
Mr. Frank Lin
Quality Assurance Manager
No. 9, Min Sheng Street
Tu-Cheng City
New Taipei City, Taiwan 23679

Re: K121642
Trade/Device Name: WiZARD 230 Nasal Pillow Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: May 24, 2013
Received: May 28, 2013

Dear Mr. Lin:

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.

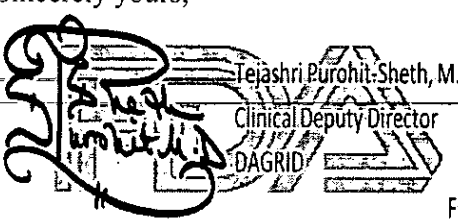
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 contact 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. 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

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, 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):** K121642

**Device Name: WiZARD 230 Nasal Pillow Mask**

**Indications for Use:**

WiZARD 230 Nasal Pillow Mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or bi-level therapy. This mask is intended for single-patient reuse in the home and multi-patient, multi-use in the hospital environment. This mask only can 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)

Anya C Harry

Digitally signed by Anya C. Harry
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry, 0.9.2342.19200300.100.1.1=0011315590
Date: 2013.06.05 17:03:18 -04'00'

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

**510(k) Number:** K121642