DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 24, 2015

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.
C/O Field Fu
Official Correspondent
Shenzen Joyantech Consulting Co., Ltd.
4th Floor, Jinhui Building
Nanhai BLVD, Nanshan District
Shenzhen, Guang Dong, 518000
CHINA

Re: K150685
Trade/Device Name: Skynector CPAP Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: Class II
Product Code: BZD
Dated: July 17, 2015
Received: July 23, 2015

Dear Mr. Fu:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K150685

Device Name
Skynector CPAP Mask

Indications for Use *(Describe)*
The Skynector CPAP Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

The Skynector CPAP Mask is to be used by adult patients (>661b / >30kg) for whom positive airway pressure has been prescribed.

The Skynector CPAP Mask is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital / institutional environment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
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Office of Chief Information Officer
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SECTION 05 510(k) Summary

This summary of 510(K) safety and effectiveness information is submitted as Required by requirements of SMDA and 21 CFR §807.92.

1 Administrative Information

Date of Summary prepared	Feb, 28, 2014
Manufacturer information	Company title: Sky Wise Medical Instrument (Shenzhen) Co., Ltd. Company address: No 12 South Ping Xi Road Xinsheng Community, Longgang Street, Longgang District, Shenzhen, Guangdnog, China Phone: +86-755-28491103 Fax: +86-755-28494339 Contact Person: Hu hanhan E-mail: 942526346@qq.com
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. 4th Floor, Jinhui Building, Nanhai BLVD, Nanshan District, Shenzhen, Guangdong, China. Contact person: Mr. Field.Fu E-Mail: cefda13485@163.com QQ：670312758 Website: www.cefda.com
Establishment registration number	No.

2 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Skynector CPAP Mask
Model:	FM-02, NM-03

Classification name:	Ventilator, Non-Continuous (Respirator).
Review Panel:	Anesthesiology
Product Code:	BZD
Device Class:	II
Regulation Number:	868.5905

3 Predicate Device Information

Sponsor:	ResMed Limited; Respironics, Incorporated.
Device:	Mirage Quattro Full Face Mask; ComfortGel Nasal Mask.
510(K) Number:	K113127, K092835

4 Device Description

The Skynector CPAP masks are designed based on human facial shape and structure, and the operating characteristics during application, they are injection mold of hard PC plastic and soft silicone rubber materials, with high level of air tightness, convenient operation and comfortable to wear, etc. They are used for the interfacing devices that are used to provide users with Continuous Positive Airway Pressure (CPAP) ventilation or biphasic positive airway pressure (BiPAP) ventilation treatment.

5 Intended Use

The Skynector CPAP Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.
The Skynector CPAP Mask is to be used by adult patients (>661b / >30kg) for whom positive airway pressure has been prescribed.
The Skynector CPAP Mask is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital /institutional environment.

6 Indications for Use

The Skynector CPAP Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.
The Skynector CPAP Mask is to be used by adult patients (>661b / >30kg) for whom positive airway pressure has been prescribed.
The Skynector CPAP Mask is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital /institutional environment.

7 Technological characteristics of the proposed device compared to the predicate device

The proposed device and the Predicate device have the same intended use, design principle, and similar material composition. The differences don't impact safety and effectiveness of the device. The proposed device is substantially equivalent to the predicate devices. The compared details are listed in tables below:

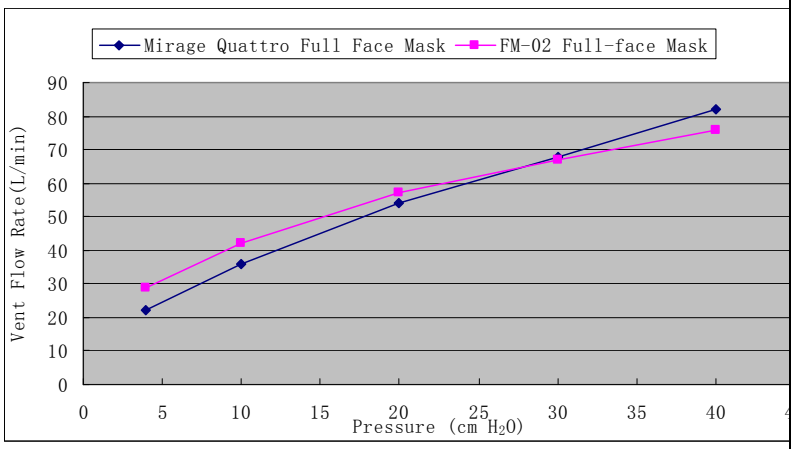
Table 1: Device Comparison Table to K113127

	Subject Device:	**Predicate Device:**	**Remarks:**
	Device: Skynector CPAP Full-face Mask **Manufacturer:** Sky Wise Medical Instrument(Shenzhen) Co.,Ltd. **510(k) Number:** To be determined	**Device:** Mirage Quattro Full FaceMask **Manufacturer:** ResMed LTD. **510(k) Number:** K113127	
Intended Use	The Skynector CPAP Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system. The Skynector CPAP Mask is to be used by adult patients (>661b / >30kg) for whom positive airway pressure has been prescribed. The Skynector CPAP Mask is	The Mirage Quattro channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system. The Mirage Quattro is to be used by adult patients (>30 kg) for whom positive airway pressure has been prescribed. The Mirage Quattro is intended for	Both masks are noninvasive and the meanings of intended use are same.

	Subject Device:	Predicate Device:	Remarks:
	intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital /institutional environment.	single-patient re-use in the home environment and multi-patient re-use in the hospital/institutional environment.	
Patient Population	Patients(>30 kg)	Patients > 66 lbs/30 kg	Same
Environment of use	Home or Hospital/institutional Environment	Home or Hospital/institutional Environment	Same
Product Code	BZD	BZD	Same
Provided Sterile or Non-Sterile	Provided Non-Sterile	Provided Non-Sterile	Same
Patient Usage Type	Single Patient Use in the home or multi-patient use in the hospital/institutional environment.	Single Patient Use in the home or multi-patient use in the hospital/institutional environment.	Same
Design	Face interface and headgear	Face interface and headgear	Same
Material	FM-02： bracket, swivel, connector, elbow: Polycarbonate; forehead pad, cushion, valve: Silicone Rubber; pick off port: Polyvinylchloride; faceplate: Polypropylene; headgear: nylon, polyester. FM-03： bracket, faceplate, swivel, connector, support arm assembly, elbow: Polycarbonate; forehead pad, cushion, valve: Silicone Rubber; pick off port: Polyvinylchloride; headgear: nylon, polyester. FM-05：	Moulded plastic and silicone components and fabric / nylon headgear.	All the materials composed the Skynector CPAP masks were evaluated per ISO 10993-1. Based on the testing performed, the differences will not affect the safety or effectiveness of the device.

	Subject Device:	Predicate Device:	Remarks:
	bracket, faceplate, swivel, connector, support arm assembly, cushion clip, elbow: Polycarbonate; forehead pad, cushion, valve: Silicone Rubber; pick off port: Polyvinylchloride; headgear: nylon, polyester.		
Number of Pick off ports:	One	Two	The design difference will not affect the safety or effectiveness of the device.
Shape and size of faceplate	The shape of the faceplate follows the contours of the face allowing clearance of facial features, covering the mouth and nose for therapy. The faceplate attaches to a silicone cushion via a retaining ring.	The shape of the faceplate and cushion clip offered in various sizes to ensure adequate fit over the extended patient population.	The design difference will not affect the safety or effectiveness of the device.
Shape and size of cushion	The cushions of the FM-02 and FM-05 are made of single layer silicone with damping groove to increase the comfort. The cushion of the FM-03 is made of double layer silicone to increase the comfortable fit.	The previously cleared mask provides characteristics seal via silicone interface. The previously cleared mask offered in various sizes to ensure adequate fit over the extended patient population.	Base on the testing of leakage, the design modification will not affects the safety or effectiveness of the device.
Safety Valve	Contain an anti-asphyxia valve (AAV) to enable the patient to breathe fresh air in the event that airflow from the flow generator is impeded.	Contain an anti-asphyxia valve (AAV) to enable the patient to breathe fresh air in the event that airflow from the flow generator is impeded.	Same
Exhalation device	No accessory exhalation device is required. The full-face masks incorporate intentional vent holes to	No accessory exhalation device is required. The masks incorporate vents to provide continuous air flow to flush out and minimize the amount of CO2	Same

<table>
<tr><th></th><th>Subject Device:</th><th>Predicate Device:</th><th>Remarks:</th></tr>
<tr><td></td><td>reduce carbon dioxide re-breathing.</td><td>re-breathed by the patient.</td><td></td></tr>
<tr><td>Anatomical Sites</td><td>Mouth and nose</td><td>Mouth and nose</td><td>Same</td></tr>
<tr><td>Patient Circuit Connection</td><td>22 mm entrainment valve elbow</td><td>22 mm entrainment valve elbow</td><td>Same</td></tr>
<tr><td>Pressure Range</td><td>4-20 cmH2O</td><td>4-40 cmH2O</td><td>Verification testing of the modified device did not raise any new questions of safety and efficacy.</td></tr>
<tr><td>Number of Mask Sizes</td><td>FM-02: Three- small, medium, and large
FM-03: Three- small, medium, and large
FM-05: Three- small, medium, and large</td><td>Four- extra small, small, medium, and large</td><td>The difference will not affect its function and effectiveness.</td></tr>
<tr><td>Mask Deadspace</td><td colspan="2"><table><tr><th>size</th><th>FM-02 Full-face mask</th><th>Mirage Quattro Full Face Mask</th></tr><tr><td>L</td><td>358</td><td>242</td></tr><tr><td>M</td><td>311</td><td>No information available</td></tr><tr><td>S</td><td>280</td><td>No information available</td></tr></table></td><td>The dead space is calculated by the identical methods. The dead space has no pass/fail criteria, reportable value only. It appears a little larger than the predicate device, but it will not affect its function and effectiveness.</td></tr>
</table>

<table>
<tr><th></th><th colspan="2">Subject Device:</th><th>Predicate Device:</th><th>Remarks:</th></tr>
<tr><td>Leak rate</td><td colspan="2"> 
</td><td></td><td>This leak rate is provided for the healthcare professional to determine if it is compatible with CPAP or bi-level therapy device. It appears the leak rates of CPAP mask is similar with the Mirage Quattro Full Face Mask, leak rate increases stably when air pressure increases.</td></tr>
<tr><td>Pressure Drop</td><td colspan="2"><table>
<tr><th colspan="2">Specifications and models</th><th>Flow (L/min)</th><th>Drop in Pressure（cmH2O）</th><th>Mirage Quattro Full Face Mask</th></tr>
<tr><td rowspan="3">Full-Face mask</td><td rowspan="3">FM-02L
FM-02M
FM-02S</td><td>100L/min</td><td>1.5</td><td rowspan="3">50L/min
0.1cmH2O
100L/min
0.4cmH2O</td></tr>
<tr><td>50L/min</td><td>0.5</td></tr>
<tr><td>50L/min</td><td>0.5</td></tr>
</table></td><td></td><td>The pressure drop is measured by the same test configuration. It appears the pressure drop of the CPAP Full-face mask is a little larger than the Mirage Quattro Full Face Mask. The pressure drop is nominal and it will not affect its function and effectiveness.</td></tr>
<tr><td>Valve Open to Atmosphere</td><td>FM-02 Full-Face mask:0.5cmH2O</td><td>Mirage Quattro Full Face Mask:1.1cmH2O</td><td></td><td>The valve will fully open to atmosphere when the mask pressure reaches the opening</td></tr>
</table>

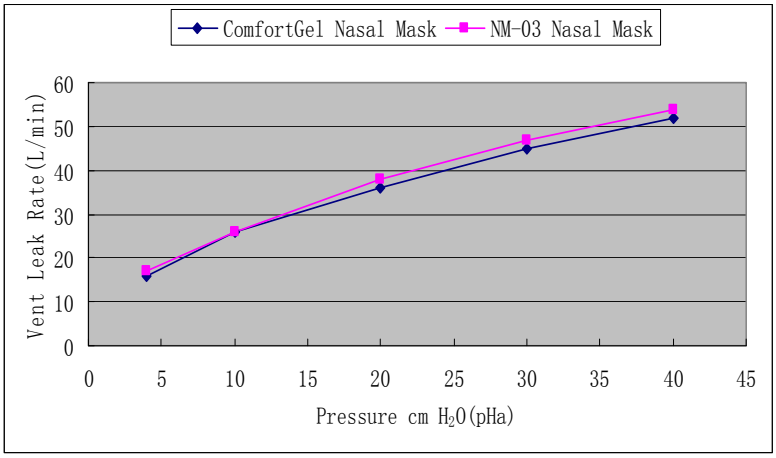
	Subject Device:	Predicate Device:	Remarks:
			pressure and remains fully open as the patient inhales and exhales.
Valve Close to Atmosphere	FM-02 Full-Face mask:0.8cmH2O	Mirage Quattro Full Face Mask:1.6cmH2O	The valve will fully close to atmosphere when the activation pressure is met or exceeded.

Table 2: Device Comparison Table to K092835

	Subject Device:	Predicate Device:	Remarks:
	Device: Skynector CPAP Nasal Mask **Manufacturer:** Sky Wise Medical Instrument(Shenzhen) Co.,Ltd. **510(k) Number:** To be determined	**Device:** ComfortGel Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K092835	
Intended Use	The reusable CPAP masks with headgear are intended for use as patient interface for a CPAP or bi-level system by adult patients(>30 kg) for whom CPAP or bi-level therapy has been prescribed. The nasal mask covers the nose, and it is to be for single-patient re-use in the home and multi-patient re-use in the hospital/institutional environment.	The ComfortGel Nasal Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used by patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed using a CPAP or bi-level system.	Both masks are noninvasive and the meanings of intended use are same.
Patient Population	Patients(>30 kg)	Patients > 66 lbs/30 kg	Same
Environment of use	Home or Hospital/institutional Environment	Home or Hospital/institutional Environment	Same
Product Code	BZD	BZD	Same

	Subject Device:	**Predicate Device:**	**Remarks:**
Provided Sterile or Non-Sterile	Provided Non-Sterile	Provided Non-Sterile	Same
Patient Usage Type	Single Patient Use in the home or multi-patient use in the hospital/institutional environment.	Single Patient Use in the home or multi-patient use in the hospital/institutional environment.	Same
Design	Nasal interface and headgear	Nasal interface and headgear	Same
Material	NM-01： bracket, faceplate, swivel, support arm assembly, quick clip, elbow: Polycarbonate； forehead pad, cushion: Silicone Rubber； headgear: nylon, polyester; pick off port: Polyvinylchloride. NM-03： bracket, faceplate, swivel, support arm assembly, cushion clip, elbow: Polycarbonate; forehead pad, cushion: Silicone Rubber; headgear: nylon, polyester; pick off port: Polyvinylchloride.	Faceplate: Polycarbonate Face seal: Gel cushion with polyester overlay Cushion Flap: Silicone Exhalation Elbow: Polycarbonate Exhalation Port: Delrin Forehead Pad: Silicone Headgear: UBL, Urethane Foam, and Lycra	All the materials composed the Skynector CPAP masks were evaluated per ISO 10993-1. Based on the testing performed, the modification will not affect the safety or effectiveness of the device.
Number of Pick off ports:	One	None	The design difference will not affect the safety or effectiveness of the device.
Shape and size of faceplate	The shape of the faceplate follows the contours of the face allowing clearance of facial features, covering the nose only for therapy. The faceplate attaches to a silicone cushion via a retaining ring.	The shape of the faceplate follows the contours of the face allowing clearance of facial features, covering the nose only for therapy. The faceplate attaches to a silicone sealing flap via a retaining ring.	Same

<table>
<tr><th></th><th>Subject Device:</th><th>Predicate Device:</th><th>Remarks:</th></tr>
<tr><td>Shape and size of cushion</td><td>The cushions of the NM-01 and NM-03 are made of double layer silicone to increase the comfortable fit.</td><td>Gel cushion to allow for a more comfortable fit and improved mask performance (fewer leaks).</td><td>The materials of cushion are different. The design modification will not affect the safety or effectiveness of the device.</td></tr>
<tr><td>Safety Valve</td><td>N/A- nasal mask</td><td>N/A- nasal mask</td><td>Same</td></tr>
<tr><td>Exhalation device</td><td>No accessory exhalation device is required. An exhalation vent is integrated.</td><td>No accessory exhalation device is required. 54 pin holes exhalation ports are integrated.</td><td>Based on the testing performed, the design difference will not affect the safety or effectiveness of the device.</td></tr>
<tr><td>Anatomical Sites</td><td>Nose</td><td>Nose</td><td>Same</td></tr>
<tr><td>Patient Circuit Connection</td><td>22 mm exhalation elbow</td><td>22 mm exhalation elbow</td><td>Same</td></tr>
<tr><td>Pressure Range</td><td>4-20 cmH2O</td><td>4-30 cmH2O</td><td>Verification testing of the modified device did not raise any new questions of safety and efficacy.</td></tr>
<tr><td>Number of Mask Sizes</td><td>NM-01: Four- petite, small, medium, and large;
NM-03: Three- small, medium, and large.</td><td>Four- petite, small, medium, and large</td><td>The difference will not affect its function and effectiveness.</td></tr>
<tr><td>Mask Deadspace</td><td colspan="2"><table><tr><th>size</th><th>NM-03 nasal mask</th><th>The ComfortGel Nasal Mask</th></tr><tr><td>L</td><td>180</td><td>142.6</td></tr><tr><td>M</td><td>160</td><td>121.3</td></tr><tr><td>S</td><td>150</td><td>111.4</td></tr></table></td><td>The dead space is calculated by the identical methods. The dead space has no pass/fail criteria, reportable value only. It appears a little larger than the predicate device, but it will not affect its function and effectiveness.</td></tr>
</table>

<table>
<tr><th></th><th colspan="2">Subject Device:</th><th>Predicate Device:</th><th>Remarks:</th></tr>
<tr><td>Leak rate</td><td colspan="2"> 
</td><td></td><td>This leak rate is provided for the healthcare professional to determine if it is compatible with CPAP or bi-level therapy device. It appears the leak rates of CPAP mask is similar with the ComfortGel Nasal Mask, leak rate increases stably when air pressure increases.</td></tr>
<tr><td>Pressure Drop</td><td colspan="2"><table>
<tr><th colspan="2">Specifications and models</th><th>Flow (L/min)</th><th>Drop in Pressure（cmH2O）</th><th>ComfortGel Nasal Mask</th></tr>
<tr><td rowspan="2">Nasal mask</td><td rowspan="2">NM-03L
NM-03M
NM-03S</td><td>100L/min</td><td>0.3</td><td rowspan="2">50L/min
0.1cmH2O
100L/min
0.25cmH2O</td></tr>
<tr><td>50L/min</td><td>0.1</td></tr>
</table></td><td></td><td>The pressure drop is measured by the same test configuration. It appears the pressure drop of the CPAP Nasal mask is a little larger than the ComfortGel Nasal Mask.
The pressure drop is nominal and it will not affect its function and effectiveness.</td></tr>
<tr><td>Valve Open to Atmosphere</td><td colspan="2">N/A- nasal mask</td><td>N/A- nasal mask</td><td>Same</td></tr>
<tr><td>Valve Close to Atmosphere</td><td colspan="2">N/A- nasal mask</td><td>N/A- nasal mask</td><td>Same</td></tr>
</table>

8 Brief discussions of the nonclinical tests

Skynector CPAP Masks conform to the following standards:

- ISO 5356-1:2004 Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets;

- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity;
- ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization;
- ISO 10993-6:2007 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation;
- ISO 10993-3:2003 Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity;
- ISO 17510-2:2007 Sleep apnoea breathing therapy - Part 2: Masks and application accessories;
- ASTM D3045-92 Standard Practice for Heat Aging of Plastics Without Load.

The performance test based on ISO 17510-2:2007 are as follow:

No.	**The title of test report**	**Items or Annex in ISO 17510-2:2007**
01	001_Connecting Test Report for the Connector Used on FM-05 Apnea Mask	Item 5.1
02	002_Leak rate test report	Annex B
03	003_ Resistance to flow (Pressure drop) test report	Annex C
04	004_Anti-asphyxia valve pressure test report	Annex D
05	005_Breathing during single fault condition-Determination of the inspiratory and expiratory resistance	Annex E
06	006_CO2 re-breathing test report	Annex F
07	007_Vibration and noise test report	Annex G
08	008_Dead space test report	Not requested by standard, but conducted on predicate device

9 Brief discussions of clinical tests

Not applicable.

10 Other information (such as required by FDA guidance)

No other information.

11 Conclusions

The subject device--- Skynector CPAP Masks (FM-02, NM-03) are respectively substantially equivalent to Mirage Quattro Full Face Mask(K113127), ComfortGel Nasal Mask(K092835).