510(k) Summary for Safety & Effectiveness

Date Prepared: 28th September, 2012

Applicant name: Apex Medical Corp.

Contact Person: Alan Chang

Address: 9, Min Sheng St. Tu-Cheng, Taipei County, Taiwan, R.O.C.

Phone number: 886-2-22683100

Fax numbers: 886-2-22686525

Device name
- Trade name: Apex medical XT Auto CPAP with Pressure Variation Algorithm 9S-005720
- Common name: CPAP
- Classification name:
  - Non-continuous ventilator Class II in accordance with 21 CFR 868.5905

Classification
- VENTILATOR, NON-CONTINUOUS (RESPIRATOR)
- Regulation Number: 868.5905
- Medical Specialty: Anesthesiology
- Product Code: 73 BZD
- Device Class: II

SE 510(k) number
- RESMED S8 ADVANCE (K082979)
- Apex Medical XT Auto CPAP (K083656)

Reason for Submission: New Device
Indications for Use:
This device is intended to provide continuous positive airway pressure (CPAP) for the treatment of adult Obstructive Sleep Apnea (OSA) patients who are spontaneously breathing. It is intended for use in the home or hospital/institutional environment.

Device Description:
XT Auto CPAP with Pressure Variation Algorithm Model 9S-005720 is intended to be used to deriving continuous positive airway pressure (CPAP) for Obstructive Sleep Apnea (OSA) in adult patients and home environment. It is a modification of XT Auto CPAP Model 9S-005200(K083656). It shares the same construction and auto adjustment algorithm with XT Auto CPAP but adds expiration pressure release with three constant levels in firmware and has the same downloading function as XT Auto CPAP. XT Auto CPAP with Pressure Variation Algorithm provides a release pressure during expiration phase; it is equivalent to Expiratory Pressure Relief (EPR) of the predicate device RESMED S8 ADVANCE (K082979).

Substantial Equivalence

The new device has the following similarities to the previously cleared predicate device(s)

- Similar intended use
- Similar operating principle
- Similar technology
- Similar manufacturing process
## Table of comparison with predicates

<table>
<thead>
<tr>
<th>Device Characteristic</th>
<th>XT Auto CPAP with Pressure Variation Algorithm 9S-005720</th>
<th>Predicate1 RESMED S8 ADVANCE (K082979)</th>
<th>Predicate2 XT Auto CPAP 9S-005200 (K083656)</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended user</td>
<td>Adult</td>
<td>Adult</td>
<td>Adult</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Outlook</td>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
<td><img src="image3.png" alt="Image" /></td>
<td>Subject is the same as Predicate 2 (K083656), Outlook is no effect on performance.</td>
</tr>
<tr>
<td>Dimensions (HxWxD)</td>
<td>14.5 x 13.0 x 10.0 cm</td>
<td>11.2x16.4x14.5 cm</td>
<td>14.5 x 13.0 x 10.0 cm</td>
<td>Subject is the same as Predicate 2 (K083656)</td>
</tr>
<tr>
<td>Weight</td>
<td>0.8kg</td>
<td>1.4kg</td>
<td>0.8kg</td>
<td>Subject is the same as Predicate 2 (K083656)</td>
</tr>
<tr>
<td>Tubing</td>
<td>Silicon, 1 x 6'/180cm length</td>
<td>Flexible plastic 6'/6&quot; 2 m length</td>
<td>Silicon, 1 x 6'/180cm length</td>
<td>Subject is the same as Predicate 2 (K083656)</td>
</tr>
<tr>
<td>Air Outlet</td>
<td>22mm</td>
<td>22mm</td>
<td>22mm</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Power Source</td>
<td>100 ~ 240 VAC, 50/60Hz, 60/65 W</td>
<td>100 ~ 240 VAC, 50/60 Hz</td>
<td>100 ~ 240 VAC, 50/60Hz, 60/65 W</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Safety Classification</td>
<td>IEC60601-1 Class II</td>
<td>IEC60601-1 Class II</td>
<td>IEC60601-1 Class I</td>
<td>All comply with IEC60601-1</td>
</tr>
<tr>
<td>User</td>
<td>Single-user, multi-use</td>
<td>Single-user, multi-use</td>
<td>Single-user, multi-use</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Operating Environment</td>
<td>+5 ~ 35°C, 15 ~ 95% Non-condensing</td>
<td>+5 ~ 36°C, 10 ~ 95%</td>
<td>+5 ~ 35°C, 15 ~ 95% Non-condensing</td>
<td>Subject is the same as Predicate 2 (K083656)</td>
</tr>
<tr>
<td>Pressure</td>
<td>4 ~ 20 cmH2O</td>
<td>4 ~ 20 cmH2O</td>
<td>4 ~ 20 cmH2O</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Device Characteristic</td>
<td>XT Auto CPAP with Pressure Variation Algorithm 9S-005720</td>
<td>Predicate 1 RESMED S8 ADVANCE (K082979)</td>
<td>Predicate 2 XT Auto CPAP 9S-005200 (K083656)</td>
<td>Comment</td>
</tr>
<tr>
<td>-----------------------</td>
<td>--------------------------------------------------------</td>
<td>------------------------------------------</td>
<td>-----------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Range</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pressure Increment</td>
<td>0.5 cmH2O</td>
<td>0.5 cmH2O</td>
<td>0.5 cmH2O</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Pressure setting</td>
<td>Complex buttons</td>
<td>Complex buttons</td>
<td>Complex buttons</td>
<td></td>
</tr>
<tr>
<td>Pressure Ramp Time</td>
<td>0~45 min, 5 minutes per step</td>
<td>0~45 min, 5 minutes per step</td>
<td>0~45 min, 5 minutes per step</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Display</td>
<td>LCD display</td>
<td>LCD display</td>
<td>LCD display</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Pressure Compensate</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Altitude Compensate</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Operation Altitude</td>
<td>Up to 8000ft</td>
<td>Sea level to 8500ft</td>
<td>Up to 8000ft</td>
<td>Subject is the same as Predicate 2 (K083655)</td>
</tr>
<tr>
<td>Leak Compensate</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Data Transfer</td>
<td>By miniUSB</td>
<td>By Data Card &amp; DB9 adaptor</td>
<td>By miniUSB</td>
<td>Subject is the same as Predicate 2 (K083655), besides, Data transfer is no effect on performance.</td>
</tr>
<tr>
<td>Leak Alert</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Automatically Titrates Pressure in APAP mode</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Equivalent and Subject is the same as Predicate 2 (K083655)</td>
</tr>
<tr>
<td>Humidity</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Equivalent</td>
</tr>
</tbody>
</table>
Design verification tests were performed on the new device with the predicate device(s) as a result of the risk analysis and product requirements. The verified items are as following:

(1) Safety and EMC: according to XT Auto CPAP (K083656) testing procedures, including FDA reviewer guidance 638.pdf, IEC 60601-1& IEC 60601-1-2.
(2) FDA Draft Reviewer Guidance for Ventilators (July 1995)
(3) FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
(4) Side by side waveform testing at various pressure and frequency levels with the predicate device(s)
(5) Closed-loop control analysis.

Above tests were verified to meet the required acceptance criteria. We have determined that the new device has the same safety and effectiveness features. In summary, the device described in this submission is substantially equivalent to the predicate devices.
December 6, 2012

Mr. Alan Chang
Senior Director of Quality Management Division
Apex Medical Corporation
Number 9, Minsheng Street
Tucheng City, Taipei County 236
Taiwan, China

Re: K112079
   Trade/Device Name: XT Auto CPAP with Pressure Variation Algorithm 9S-005720
   Regulation Number: 21 CFR 868.5905
   Regulation Name: Noncontinuous Ventilator (IPPB)
   Regulatory Class: II
   Product Code: BZD
   Dated: September 28, 2012
   Received: October 1, 2012

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/CDRHI/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” (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 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,

Kwame Q. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number:  K112079

Device Name:  XT Auto CPAP with Pressure Variation Algorithm 9S-005720

Indications for Use:

This device is intended to provide continuous positive airway pressure (CPAP) for the treatment of adult Obstructive Sleep Apnea (OSA) patients who are spontaneously breathing. It is intended for use in the home or hospital/institutional environment.

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)

Lester W. Schultheis Jr
2012.12.04 11:23:55 -05'00'

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

510(k) Number:  K112079