K112079

510(k) Summary for Safety & Effectiveness

Date Prepared: 28th September, 2012

DEC 06 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
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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:

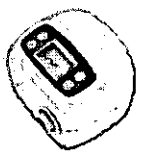
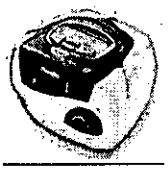
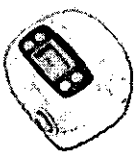
XT Auto CPAP with Pressure Variation Algorithm Model 9S-005720 is intended to be used to deriving continuous positive airway pressure (CPAP) for Obstructive Sleep Apnea (OSA) in adult patients and home environment. It is a modification of XT Auto CPAP Model 9S-005200(K083656). It shares the same construction 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

Device Characteristic	XT Auto CPAP with Pressure Variation Algorithm 9S-005720	Predicate1 RESMED S8 ADVANCE (K082979)	Predicate2 XT Auto CPAP 9S-005200 (K083656)	Comment
Intended user	Adult	Adult	Adult	Equivalent
Outlook				Subject is the same as Predicate 2 (K083656), Outlook is no effect on performance.
Dimensions (HxWxD)	14.5 x 13.0 x 10.0 cm	11.2x16.4x14.5 cm	14.5 x 13.0 x 10.0 cm	Subject is the same as Predicate 2 (K083656),
Weight	0.8kg	1.4kg	0.8kg	Subject is the same as Predicate 2 (K083656)
Tubing	Silicon, 1 x 6'/180cm length	Flexible plastic 6'6" 2 m length	Silicon, 1 x 6'/180cm length	Subject is the same as Predicate 2 (K083656)
Air Outlet	22mm	22mm	22mm	Equivalent
Power Source	100 ~ 240 VAC, 50/60Hz, 60/65 W	100 ~ 240 VAC, 50/60 Hz	100 ~ 240 VAC, 50/60Hz, 60/65 W	Equivalent
Safety Classification	IEC60601-1 Class II	IEC60601-1 Class II	IEC60601-1 Class I	All comply with IEC60601-1
User	Single-user, multi-use	Single-user, multi-use	Single-user, multi-use	Equivalent
Operating Environment	+5 ~ 35℃ 15 ~ 95% Non-condensing	+5 ~ 36℃ 10 ~ 95%	+5 ~ 35℃ 15 ~ 95% Non-condensing	Subject is the same as Predicate 2 (K083656)
Pressure	4 ~ 20 cmH2O	4 ~ 20 cmH2O	4 ~ 20 cmH2O	Equivalent

Device Characteristic	XT Auto CPAP with Pressure Variation Algorithm 9S-005720	Predicate1 RESMED S8 ADVANCE (K082979)	Predicate2 XT Auto CPAP 9S-005200 (K083656)	Comment
Range				
Pressure Increment	0.5 cmH2O	0.5 cmH2O	0.5 cmH2O	Equivalent
Pressure setting	Complex buttons	Complex buttons	Complex buttons	Subject is the same as Predicate 2(K083656), and equivalent to Predicate 1(K082979)
Pressure Ramp Time	0~45 min, 5 minutes per step	0~45 min, 5 minutes per step	0~45 min, 5 minutes per step	Equivalent
Display	LCD display	LCD display	LCD display	Equivalent
Pressure Compensate	Yes	Yes	Yes	Equivalent
Altitude Compensate	Yes	Yes	Yes	Equivalent
Operation Altitude	Up to 8000ft	Sea level to 8500ft	Up to 8000ft	Subject is the same as Predicate 2 (K083656)
Leak Compensate	Yes	Yes	Yes	Equivalent
Data Transfer	By miniUSB	By Data Card & DB9 adaptor	By miniUSB	Subject is the same as Predicate 2 (K083656), besides, Data transfer is no effect on performance.
Leak Alert	Yes	Yes	Yes	Equivalent
Automatically Titrates Pressure in APAP mode	Yes	Yes	Yes	Equivalent and Subject is the same as Predicate 2 (K083656)
Humidity	Yes	Yes	Yes	Equivalent

Device Characteristic	XT Auto CPAP with Pressure Variation Algorithm 9S-005720	Predicate1 RESMED S8 ADVANCE (K082979)	Predicate2 XT Auto CPAP 9S-005200 (K083656)	Comment
compatibility				
Expiration Pressure Release	Yes Three Constant Levels (1, 2, 3 cmH2O)	Yes Three Constant Levels(1,2,3 cmH2O)	No	Subject is equivalent to Predicate1 (K082979)

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

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/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/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 O. 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:

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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

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