K083656

510(k) Summary- XT Auto CPAP 9S005200

Date Prepared: 8th December, 2008

Applicant name:	Apex Medical Corp. APR 22 2009
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 9S-005200 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
Predicate Device	APEX MEDICAL XT1 CPAP MODEL 9S-005 (K070609) APEX MEDICAL CPAP RT 21XX (K022650) ResMed AutoSet Spirit CPAP (K032480)
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).

Device Description:

XT Auto CPAP Model 9S-005200 is intended to be used to delivery continuous positive airway pressure (CPAP) for Obstructive Sleep Apnea (OSA) for adult patients in the home environment. It is a modification of CPAP XT I MODEL 9S-005 (K070609) & RT2120 (K022650). It shares the same construction with XT-I but adds pressure and flow sensor on the circuit and has same downloading function as RT2120. As for the function of auto CPAP, it refers to the predicate Resmed Autoset Spirit (K032480).

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

Design verification tests were performed on the new device with the predicate device(s) as a result of the risk analysis and product requirements. All 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
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2009

Mr. Alan Chang
Director of President Office
Apex Medical Corporation
Number 9 Minsheng Street
Tucheng City, Taipei County
CHINA (TAIWAN) 236

Re: K083656
Trade/Device Name: XT Auto CPAP 9S-005200
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: April 6, 2009
Received: April 8, 2009

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: XT Auto CPAP 9S-005200

Indications for Use:

This device is intended to provide continuous positive airway pressure (CPAP) for the treatment of adult obstructive sleep apnea (OSA).

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)

Susan Runner

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

510(k) Number: K053662