510(k) Summary- iCH CPAP 9S-007XXX series

MAY 16 2012

Date Prepared: December 30, 2011 k 120035

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 iCH CPAP 9S-007XXX series 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 XT Auto CPAP MODEL 9S-005200 (K083656) APEX MEDICAL HumidCare Heated Humidifier MODEL 9S-004 (K062664)
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) for adult patients in the home environment.

Device Description:

9S-007XXX series are intended to provide continuous positive airway pressure for the treatment of adult obstructive sleep apnea (OSA) in home care environment. A built-in heated humidifier of 9S-007xxx series is designed to increase the humidity of the air from the CPAP thereby relieving the symptoms of a dry nose and throat resulting from constant airflow that some patients may experience.

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. 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) Vapor/particle analysis: according to XT Auto CPAP (K083656) testing procedure and EPA PM2.5 as well as EPA TO-15.
(3) Firmware validation activities: according to XT Auto CPAP (K083656) firmware validation procedures and "Guidance for FDA Reviewers and Industry Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

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 Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Alan Chang
Senior Quality Director
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No. 9 Minsheng Street
Tucheng City Taipei County
236, Taiwan ROC

MAY 16 2012

Re: K120035
Trade/Device Name: iCH CPAP 9S-007XXX
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: April 17, 2012
Received: April 23, 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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: iCH CPAP 9S-007XXX
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)

L Schwitters

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

510(k) Number: K120035