DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 6,2014

Apex Medical Corporation
Mr. Alan Chang
Vice President
No. 9, Minsheng Street
Tucheng, New Taipei City 23679
TAIPEI

Re: K141522
Trade/Device Name: iCH CPAP with PVA 9S-007XXX Series
Regulation Number: 21 CFR 868.5905
Regulation Name: Ventilator, Non-Continuous (Respirator)
Regulatory Class: II
Product Code: BZD
Dated: September 2, 2014
Received: September 4, 2014

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 contact 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. 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141522

Device Name
iCH CPAP with PVA 9S-007XXX Series

Indications for Use *(Describe)*

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 single patient reuse in the home 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

Date Prepared:	September 2, 2014
Applicant name:	Apex Medical Corp.
Contact Person:	Alan Chang
Address:	No.9, Min Sheng St., Tu-Cheng, New Taipei City, 23679, Taiwan
Phone number:	886-2-22683100
Fax numbers:	886-2-22686525
Device name	Trade name: Apex Medical Corp. iCH CPAP with PVA 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 iCH CPAP 9S-007XXX series (K120035) APEX MEDICAL XT Auto CPAP with PVA 9S-005720 (K112079)
Reason for Submission	Modification of original APEX MEDICAL iCH CPAP 9S-007XXX series

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 single patient reuse in the home environment.

Device Description:

The iCH CPAP with PVA 9S-007XXX Series are intended to provide continuous positive airway pressure for the treatment of adult obstructive sleep apnea (OSA). It is a modification of iCH CPAP 9S-007XXX (K120035) with the same algorithm of XT Auto with PVA 9S-005720 (K112079). It shares the same construction and auto adjustment algorithm with iCH CPAP 9S-007XXX but adds the identical Pressure Variation Algorithm with the predicate device XT Auto with PVA 9S-005720 (K112079). The Pressure Variation Algorithm provides a release pressure during expiration phase which is designed for patients who have difficulty exhaling against high CPAP pressure. It works by reducing the CPAP setting pressure in the normal breath status of expiratory phase from the treatment pressure in either CPAP or APAP mode.

A built-in heated humidifier of iCH CPAP with PVA 9S-007XXX Series are 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. The modified iCH CPAP series (with PVA) are from the iCH CPAP 9S-007XXX (K120035), but the algorithm for pressure variation algorithm(PVA) of the device comes from XT Auto with PVA (K112079).

The PVA Pressure Variation Algorithm for the subject and predicated device (K112079) is an exhalation pressure relief function which is designed for patients who have difficulty exhaling against high CPAP pressure. Pressure can be reduced to three different levels (according to patient need) during the transition from Inspiration to Expiration phase. This reduced pressure level (depending on the PVA setting) will be maintained during Expiration phase and will return to the therapeutic pressure in the end of Expiration phase. In order to ensure the effectiveness of CPAP therapy, PVA will be automatically suspended if apneas are detected. After apneas disappear, PVA will re-start.

Substantial Equivalence

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

- Same intended use
- Same operating principle
- Same technology
- Same manufacturing process

Device Characteristic	iCH CPAP with PVA 9S-007XXX series (New Device)	Predicate1 iCH CPAP 9S-007XXX (K120035)	Predicate2 XT Auto with PVA 9S005720 (K112079)	Comment
Intended user	Adult	Adult	Adult	Equivalent
Outlook & Construction				Subject is identical to Predicate 1 (K120035),
Air Outlet	22mm	22mm	22mm	Equivalent
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	Equivalent
Pressure Range	4 ~ 20 cmH2O	4 ~ 20 cmH2O	4 ~ 20 cmH2O	Equivalent
Pressure Increment	0.5 cmH2O	0.5 cmH2O	0.5 cmH2O	Equivalent
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
Pressure Compensate	Yes	Yes	Yes	Equivalent
Altitude Compensate	Yes	Yes	Yes	Equivalent
Automatically Titrates Pressure in APAP mode	Yes (iCH Auto)	YES (iCH Auto)	Yes	Identical

Device Characteristic	iCH CPAP with PVA 9S-007XXX series (New Device)	Predicate1 iCH CPAP 9S-007XXX (K120035)	Predicate2 XT Auto with PVA 9S005720 (K112079)	Comment
Expiration Pressure Release (PVA)	Yes Three Constant Levels (1, 2, 3 cmH2O)	No	Yes Three Constant Levels(1,2,3 cmH2O)	Subject is Identical to Predicate2 (K112079)

Table of comparison with predicate devices

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 follows:

(1) Safety and EMC: according to iCH CPAP 9S-007XXX series (K120035) verification 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) Algorithm analysis; by comparing the test items as below:
    a. Step function
    b. PVA waveform with different breathing frequencies and flow volumes
    c. PVA feature handling conditions of disordered breathing (apneas and hypopneas)
    d. PVA waveform upper and lower pressure control
    e. PVA pressure average and tolerance error
    f. Performance characteristics of PVA

In conclusion, the above tests demonstrate that the iCH CPAP with PVA 9S-007XXX Series is as safe, as effective, and performs as well as the predicate device - XT Auto CPAP with PVA 9S-005720 (K112079). The relevant test reports are described in this submission. Therefore, we state that the iCH CPAP with PVA 9S-007XXX Series is substantially equivalent to the predicate device - XT Auto CPAP with PVA 9S-005720 (K112079).