DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 15, 2015

Apex Medical Corp.
Mr. Frank Lin
Director of Quality Management Division
No. 9, Min Sheng St.
Tu-Cheng District
New Taipei City, 23679
Taiwan

Re: K150111
Trade/Device Name: iCH CPAP with PVA 9S-007XXX Series
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (Ippb)
Regulatory Class: Class II
Product Code: BZD
Dated: August 14, 2015
Received: August 17, 2015

Dear Mr. Frank Lin:

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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Division of Anesthesiology,
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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)*
K150111

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.

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

Date Prepared:	8/14/2015
Applicant name:	Apex Medical Corp.
Contact Person:	Frank Lin
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: BZD Device Class: II
Predicate Device	APEX MEDICAL CORP. iCH CPAP with PVA 9S-007XXX series (K141522)
Reason for Submission	Modification of original APEX MEDICAL CORP. iCH CPAP with PVA 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 modified iCH CPAP with PVA 9S-007XXX Series is a modification of predicate iCH CPAP with PVA 9S-007XXX (K141522). It changed the material of impeller as well as PCB layout compare to the predicate device. A built-in heated humidifier of iCH CPAP with PVA 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)

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

Device Characteristic	Modified iCH CPAP with PVA 9S-007XXX series (New Device)	Predicate iCH CPAP with PVA 9S-007XXX (K141522)	Comment
Intended user	Adult	Adult	Equivalent
Air Outlet	22mm	22mm	Equivalent
User	single patient reuse	single patient reuse	Equivalent
Operating Environment	+5 ~ 35℃ 15 ~ 95% Non-condensing	+5 ~ 35℃ 15 ~ 95% Non-condensing	Equivalent
Pressure Range	4 ~ 20 cmH2O	4 ~ 20 cmH2O	Equivalent

Device Characteristic	Modified iCH CPAP with PVA 9S-007XXX series (New Device)	Predicate iCH CPAP with PVA 9S-007XXX (K141522)	Comment
Pressure Increment	0.5 cmH2O	0.5 cmH2O	Equivalent
Pressure Ramp Time	0~45 min, 5 minutes per step	0~45 min, 5 minutes per step	Equivalent
Pressure Compensate	Yes	Yes	Equivalent
Altitude Compensate	Yes	Yes	Equivalent
Automatically Titrates Pressure in APAP Mode	Yes (iCH Auto)	Yes (iCH Auto)	Equivalent
Expiration Pressure Release (PVA)	Yes Three Constant Levels (C1, C2, C3)	Yes Three Constant Levels (C1, C2, C3)	Equivalent
Alarm System	Error 001~005 Warning 001~007, Low P	Error 001~005 Warning 001~007, Low P	Equivalent
Impeller Material of Blower	Plastic	Aluminum	Equivalent
Power Supply	60W (DC 24V, 2.5A)	90W (DC 24V, 3.75A)	Equivalent
Heater Platform	60W (DC 24V, 2.5A)	90W (DC 24V, 3.75A)	Equivalent

Table of comparison with predicate devices

Design verification tests were performed on the new device(s) based on the risk analysis and product requirements. In addition, the PVA function test was conducted with predicate device(s). The verified items are as follows:

(1) Safety and EMC: according to ANSI/AAMI ES60601-1: 2005+C1:09+A2:10, IEC 60601-1-2: 2007 (Edition 3) and FDA reviewer guidance 638 (Excerpts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch (includes EMI standard)).
(2) Firmware Validation: FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
(3) Noise Test (Refer to ISO 11201:2010/ ISO 7779:2010)
(4) Performance Tests (Refer to ISO 17510-1:2007):
    a) Pressure Long-term Stability Test
    b) Dynamic Pressure Stability
    c) Static Pressure Stability
    d) Maximum Temperature

e) Maximum Flow
f) Limitation of Maximum Pressure
g) Overflow Test
h) Expected Useful Life Validation
i) Humidification Performance (Refer to ISO 8185:2007)

(5) PVA Function Comparison Test
a) Endurance Operation and Dynamic Testing (Refer to ISO 17510-1:2007)
b) APAP Auto titration & AHI Test
c) The comparison for PVA Waveform with different breathing frequencies and flow volumes
d) PVA feature handling conditions of disordered breathing (apneas and hypopneas)
e) The comparison for PVA Waveform upper and lower pressure control
f) Comparison for PVA Pressure Average and Tolerance Error
g) Performance Characteristics of PVA Comparison

(6) Biocompatibility Assessment
a) Genotoxicity, Carcinogenicity and reproductive toxicity test (ISO 10993-3:2003)
b) In vitro cytotoxicity test (ISO 10993-5:2009)
c) Implantation test (ISO 10993-6:2007)
d) Irritation and skin sensitization (ISO 10993-10:2010)
e) Systemic toxicity (ISO 10993-11:2006)

(7) Particle Test: Refer US EPA PM2.5:1997
(8) VOC Test: Refer US EPA TO-15:1999

The modified iCH CPAP with PVA 9S-007XXX Series complies with the applicable voluntary and mandatory standards as following:

(1) ANSI/AAMI ES60601-1:2005+C1:09+A2:10. Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (FDA recognition number: 19-5)
(2) IEC 60601-1-2:2007. Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests. (FDA recognition number: 19-1)
(3) FDA reviewer guidance 638 (Excerpts Related to EMI from November 1993

Anesthesiology and Respiratory Devices Branch (includes EMI standard)

(4) FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)

(5) ISO 5367:2000. Breathing tubes intended for use with anaesthetic apparatus and ventilators. (FDA recognition number: 1-46)

(6) ISO 11201:2010. Noise emitted by machinery and equipment -- Determination of emission sound pressure levels at a work station and at other specified positions in an essentially free field over a reflecting plane with negligible environmental corrections.

(7) ISO 7779:2010. Measurement of airborne noise emitted by information technology and telecommunications equipment.

(8) ISO 17510-1:2007. Sleep apnoea breathing therapy -- Part 1: Sleep apnoea breathing therapy equipment.

(9) ISO 8185:2007. Respiratory tract humidifiers for medical use -- Particular requirements for respiratory humidification systems.

(10) Determination Of Volatile Organic Compounds (VOCs) In Air Collected In Specially-Prepared Canisters And Analyzed By Gas Chromatography/Mass Spectrometry (GC/MS):1999.

(11) US EPA National Ambient Air Quality Standards (NAAQS) PM2.5:1997.

(12) ISO 10993-1:2009/(R) 2013. Biological Evaluation Of Medical Devices -- Part 1: Evaluation And Testing Within A Risk Management Process. (FDA recognition number: 2-156)

(13) ISO 10993-3:2003. Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity. (FDA recognition number: 2-175)

(14) ISO 10993-5:2009. Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity. (FDA recognition number: 2-153)

(15) ISO 10993-6:2007. Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation. (FDA recognition number: 2-120)

(16) ISO 10993-10:2010. Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization. (FDA recognition number: 2-173)

(17) ISO 10993-11:2006. Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity. (FDA recognition number: 2-176)

(18) IEC 60601-1-11:2010. Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems

Used In The Home Healthcare Environment. (FDA recognition number: 19-6)

In conclusion, the above tests demonstrate that the modified iCH CPAP with PVA 9S-007XXX Series perform as safe and effective as the predicate device - iCH CPAP with PVA 9S-007XXX (K141522). The relevant test reports are described in this submission. Therefore, we state that the modified iCH CPAP with PVA 9S-007XXX Series is substantially equivalent to the predicate device - iCH CPAP with PVA 9S-007XXX Series (K141522).