K131702
DEC - 6 2013

Section 5. 510(k) Summary

510(k) SUMMARY

A 510(k) Summary in accordance with the requirements of 21 CFR 807.92 is provided below.

Submitter:	Curative Medical Inc. 3227 Kifer Road Santa Clara, CA 95051 Establishment Number: 3008361782
Company Contact Person: Phone: Fax: Email:	Cuong Tran, Director Research and Development (408) 414-2188 (408) 413-3000 ctran@curativemedical.com
Submission Correspondent: Address: Phone: Email:	Amy McKinney, Regulatory Affairs Consultant 6518 Tamarind Sky Ln, Fulshear, TX 77441 (979) 236-1622 amckinney29@att.net
Device Name:	K Series CPAP System - Curasa CPAP EUT AutoManager PC Software accessory
Device Classification Name:	Non-continuous ventilator (BZD) 21 CFR 868.5905
Predicate Devices:	K Series CPAP SD System (K123897)
Preparation Date:	December 1, 2013 Revised December 6, 2013

Device Description:

The K Series CPAP systems are used on adult patients for treatment of obstructive sleep apnea (OSA). The K Series CPAP Systems has 3 commercially available models, Curasa CPAP (K120285), Floton CPAP (K120285), and Curasa CPAP SD (K123897). This 510(k) application adds the Curasa CPAP EUT model to the currently commercially available selection of models, as well as the AutoManager PC Software accessory. The K series CPAP system provides a stable continuous positive airway pressure (CPAP). The humidifier, which works with all the K Series CPAP Systems, provides warm, humidified air for comfort to the patient, reducing nose and airway dryness. Each K Series CPAP system also includes the following accessories: a power supply, a Patient Air Circuit, and a U-tube connection between CPAP and humidifier.

The Curasa CPAP EUT has the same electronic design and similar software as the Curasa CPAP SD, except for the addition of EUT (expiratory unload trigger) feature. The EUT feature detects patient exhalation phase and reduces output pressure. EUT feature has 3 levels of pressure reduction.

The CPAP EUT also works with a special accessory PC software tool, AutoManager™. AutoManager™ is used by the service provider to analyze the patient's CPAP compliant data and, if needed, update the CPAP pressure setting via the CPAP's SD card. The AutoManager™ software collects/updates CPAP device data via an SD card. The AutoManager™ PC software is an independent accessory to the CPAP device and runs on a stand-alone PC and not on the CPAP device itself.

The K Series CPAP system, model Curasa CPAP EUT, has the following similarities to the previous cleared predicate device:

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

Intended Use:

The K Series CPAP (Continuous Positive Airway Pressure) systems are intended for the treatment of Obstructive Sleep Apnea only in spontaneously breathing patients weighing >30 kg. It is intended to be used in the home or hospital/institutional environment.

Summary of Performance Data and Substantial Equivalence:

The K Series CPAP system, model Curasa CPAP EUT, was designed and verified in accordance with the risk analysis and product requirements. All tests were conducted on the new model to establish substantial equivalence to the predicate. The K Series CPAP system, model Curasa CPAP EUT, was tested and shown to be compliant with the following standards:

1. EN 60601-1-1:1995 + A1:1993 + A2:1995 - Medical Electrical equipment - Part 1: General requirement for Safety
2. EN 60601-1-2:2001 - Medical Electrical equipment – Part 1-2: General requirement for Safety – Collateral Standard: Electromagnetic compatibility – Requirements and tests
3. EN ISO 8185:2007 - Respiratory Tract humidifiers for medical use – Particular requirements for respiratory humidifier systems
4. EN ISO 17510:2007 - Sleep Apnoea Breathing therapy – Part 1: Sleep apnoea breathing therapy equipment
5. ISO 10993-3:2003 - Biological Evaluation of Medical Devices – Part 3: Genotoxicity, Carcinogenicity and Reproductive Toxicity
6. ISO 10993-5: 2009 - Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
7. ISO 10993-6:2007 - Biological Evaluation of Medical Devices – Part 6: Test for local effect after implantation
8. ISO 10993-10:2010 – Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
9. ISO 10993-12:2007 – Biological Evaluation of medical devices Part 12: Sample Preparation and reference materials

Testing was conducted to demonstrate the performance of K series CPAP system, model Curasa CPAP EUT, is substantially equivalent to its predicate device in its intended environment. This 510(k) submission presents the results of the testing and a detailed description to demonstrate that K series CPAP system, model Curasa CPAP EUT, is substantially equivalent to the K Series CPAP SD with heated humidifier systems (K123897), model Curasa CPAP SD.

The following testing was conducted to demonstrate that the performance of Curasa EUT CPAP with the AutoManager™ software accessory is substantially equivalent to its predicate device in its intended environment:

Design Verification Test	**Result**
System and User Interface Testing	Pass
ESD / EMC / EMI	Pass
IFU Validation Testing (patients)	Pass
Provider IFU Validation Testing	Pass
Software Verification Testing	Pass
AutoManager Software Verification Testing	Pass
AutoManager Software IFU & User Interface testing	Pass

Test data leveraged from the predicate device, Curasa CPAP SD (K123897) includes the following:

- Reliability Test
- Sound Testing
- VOC and PM2.5 Testing
- Shock and Vibration Testing
- Packaging Test
- Humidity ISO 8185 Test
- Biocompatibility Tests

The table below provides a design comparison of the Curasa CPAP EUT to the predicate Curasa CPAP SD with heated humidifier.

Physical Features	**Predicate Device - K Series Curasa CPAP SD (K123897)**	**K Series Curasa CPAP EUT Proposed Device**
CPAP Device:		
Device Size (cm)	17 x 11.8 x 9.7	Same
Weight (kg)	Curasa: 1.4	Same
Humidifier	Yes	Same
Memory Card	Yes	Yes
CPAP Technology	Stable, continuous positive airway pressure	Same

Physical Features	**Predicate Device - K Series Curasa CPAP SD (K123897)**	**K Series Curasa CPAP EUT Proposed Device**
Indications	The K Series CPAP System, is designed for the treatment of Obstructive Sleep Apnea only in spontaneously breathing patients weighing >30 kg. It is intended to be used in the home or hospital/institutional environment.	Same
Product Use, Transport, Storage		
Operation (degree Celsius.)	5 to 35	Same
Transport & Storage (degree Celsius.)	-20 to 60	Same
Atmosphere Pressure (Operation)	70 to 106 kPa	Same
Standards Compliance		
IEC-60601-1	Yes	Same
IEC-60601-2	Yes	Same
ISO 17510-1	Yes	Same
Mode of Operation	Continuous	Same
AC Power Consumption	90 to 264 VAC, 50-60 Hz, 2A@115VAC and 1A@230VAC	Same
DC Power Consumption	24 VDC, 2.5 A	Same
Type of Protection Against Electric Shock	Class II Equipment	Same
Degree of Protection Against Electric Shock	Type B Applied Part	Type BF - Better, New power supply compliant to IEC-60601-1 3rd edition
Degree of Protection Against Ingress of Water	IPX1	Same
Pressure Range (cm H2O)	4-20	Same
Pressure Stability (cm H2O), as measured by ISO 17510-1	4-20 cm H20 +/- 2.0 cm H20 ISO17510 compliant	Same
Maximum Flow (LPM), as measured by ISO 17510-1	35	Same
Power Consumption		
	24VDC derived from A/C power supply	Same
Electrical shock protection	Class II	Same
Drip Proof Equipment	IPX1	Same
Heater Setting	continuous	Same

The table below provides a comparison of the features of the Curasa CPAP EUT to the predicate Curasa CPAP SD with heated humidifier.

Functional Features	Same/Different
Software	Same with the addition of EUT function and SD card Therapy Pressure setting update
Hardware Components	Same, except for new power supply compliant with IEC-60601-1 3rd edition
Humidifier	Same
User Interface	Same
Packaging	Same
Accessory	The PC AutoManager™ software collects/updates CPAP device data via an SD card. It is used on a stand-alone PC with not interaction with the CPAP device. AutoManager™ is used by the service provider

Conclusion:

The differences outlined in the tables above do not raise new questions of safety and effectiveness from the predicate device. The information and data provided in this 510(k) Notification establishes that the Curasa CPAP EUT with the accessory AutoManager™ PC software, is substantially equivalent to the legally marketed predicate device (K123897).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 6, 2013

Curative Medical, Incorporated
C/O Ms. Amy E. McKinney, MS, RAC
Regulatory Affairs Consultant
6518 Tamarind Sky Lane
FULSHEAR TX 77441

Re: K131702
Trade/Device Name: K Series CPAP System - Curasa CPAP EUT AutoManager PC Software accessory
Regulation Number: 21 CFR 868.5905
Regulation Name: Non-continuous ventilator
Regulatory Class: II
Product Code: BZD
Dated: November 5, 2013
Received: November 6, 2013

Dear Ms. McKinney:

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.

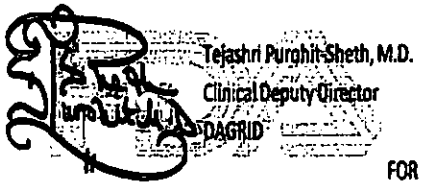
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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,



FOR

Erin Keith, M.S.
Acting Division 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131702

Device Name
K Series CPAP System – Curasa CPAP EUT and AutoManager PC Software Accessory

Indications for Use *(Describe)*
The K Series CPAP System, is designed for the treatment of Obstructive Sleep Apnea only in spontaneously breathing patients weighing >30 kg.
It is intended to be used in the home or hospital/institutional 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anya C. Harry -S

Digitally signed by Anya C. Harry -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry -S, 0.9.2342.19200300.100.1.1=0011315590
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