JUL 2 2012

510(k) SUMMARY K120285

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter:		Curative Medical Inc. 3227 Kifer Road Santa Clara, CA 95051 Establishment Number: 3008361782
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Device Name:		K Series CPAP Systems - Curasa Model (Product # 31011321) - Floton Model (Product # 31015121)
Device Classification Name:		Non-continuous ventilator (BZD) 21 CFR 868.5905
Predicate Devices:		Respironics Remstar Pro M Series with heated humidifier (K072996)
Date of Preparation:		May 28, 2012

Device Description:

The K Series CPAP Systems with heated humidifier are used on adult patients for treatment of obstructive sleep apnea (OSA). The K Series CPAP Systems are available in two models: Curasa model and Floton model. The CPAP system provides a stable continuous positive airway pressure (CPAP). The humidifier works only with the K Series CPAP Systems and provides warm, humidified air for comfort to the patient, reducing nose and airway dryness. The K Series systems also include the following accessories: a power supply, a Patient Air Circuit, and a U-tube connection between CPAP and humidifier.

The K Series CPAP with heated humidifier system has the following similarities to the previous cleared predicate device:

- Same intended use
- Same operating principle
- Similar technologies

The following table provides a comparison to the predicate device:

Comparison Parameter	Respironics Remstar Pro M Series (K072996)	Curative Medical Inc. K Series CPAP
Device Size (cm)	19x12.7x7.9	Curasa: 17x11.7x9.3 Floton: 18x21x10.5
Weight (kg)	1.0	Curasa: 1.4 Floton: 1.6
Product Use, Transport, Storage		
Operation (degreeCelsius.)	5 to 35	5 to 35
Transport & Storage (degree Celsius.)	-20 to 60	-20 to 60
Atmosphere Pressure (Operation)	77 to 101 kPa	70 to 106 kPa
Mode of Operation	Continuous	Continuous
Type of Protection Against Electric Shock	Class II Equipment	Class II Equipment
Degree of Protection Against Electric Shock	Type BF Applied Part	Type B Applied Part
Degree of Protection Against Ingress of Water	IPX1	IPX1
Pressure Range (cm H2O)	4-20	4-20
Pressure Stability (cm H2O)	4-20 cm H2O, +/- 1.0 cm H2O	4-20 cm H20 +/- 2.0 cm H20
Maximum Flow (LPM)	35	35
Humidifier		
Water reservoir	1 2/3 cup	240 ml
Dimensions:	8.25" x 8.75" x 4"	6.5" x 3.3" x 4"
Weight	2.2 lbs	< 0.9 lbs
Power Consumption		
Electrical shock protection:	Class II	Class II
Drip Proof Equipment	IPX1	IPX1
Heater Setting	1 - 5	continuous
Standards Compliance		
IEC-60601-1	Yes	Yes
IEC-60601-2	Yes	Yes
ISO 17510-1	Yes	Yes
ISO 8185	Yes	Yes

Intended Use:

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

Contraindications:

- Bullous Lung Disease
- Pathologically Low Blood Pressure
- Bypassed Upper Airway
- Pneumothorax
- Pneumocephalus has been reported in a patient using nasal Continuous Positive Airway Pressure. Caution should be used when prescribing CPAP for susceptible patients such as those with: cerebral spinal fluid (CSF) leaks, abnormalities of the cribriform plate, prior history of head trauma, and/or pneumocephalus.
- The use of positive airway pressure therapy may be temporarily contraindicated if you exhibit signs of sinus or middle ear infection. Not for use with patients whose upper airways are by-passed.

Summary of Performance Data and Substantial Equivalence:

The K Series CPAP with heated humidifier systems were designed and verified in accordance with the risk analysis and product requirements. All tests confirmed the products met the pre-defined acceptance criteria. Curative Medical Inc. has determined that the K Series is safe and effective for CPAP treatment of OSA in adults. The K Series CPAP with heated humidifier systems have been tested and shown to be compliant with the following standards documents:

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 8185:1997
   Respiratory Tract humidifiers for medical use – Particular requirements for respiratory humidifier systems
4. EN ISO 17510:2002
   Sleep Apnoea Breathing therapy – Part 1: Sleep apnoea breathing therapy equipment

This 510(k) submission presents the results of the testing and detailed descriptions to demonstrate that K series CPAP with heated humidifier system is substantially equivalent to the Respironics Remstar Pro M Series (K072996).

Testing was conducted to demonstrate the performance of K series CPAP with heated humidifier system is as safe and effective as its predicate device in its intended environment.

Conclusion:

The information and data provided in this 510(k) Notification establishes that the K Series CPAP with heated humidifier systems are substantially equivalent to the legally marketed predicate device.

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

Curative Medical, Incorporated
C/O Ms. Amy Mckinney, MS, RAC
Regulatory Affairs Consultant
63 Chicory Court
Lake Jackson, Texas 77566

JUL 2 2012

Re: K120285
Trade/Device Name: K Series CPAP Systems
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: June 1, 2012
Received: June 4, 2012

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 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

Section 4. Indications for Use Statement

510(k) Number (if known): K12XXXX

Device Name: K Series CPAP Systems

Indications For Use:

The K Series CPAP with Heated Humidifier 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.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K12 0285