MAY 14 2008

Non-Confidential Summary of Safety and Effectiveness
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7-May-08

ARCimed Laboratories, LLC
85 Oak Street
Weston, MA 02493 Tel - 781-237-4544

Official Contact: Robert W. Daly, Managing Member

Proprietary or Trade Name: ARCimed CPAP mask

Common/Usual Name: Patient interface for use with CPAP systems

Classification Name: Ventilator, non-continuous (respirator), accessory
BZD – 868.5905

Device: ARCimed CPAP mask

Predicate Devices: ResMed – Quattro Full Face Mask – K063122
Advanced Warming – Adhesive mask – K950771
Respironics Full face mask – K002465

Device Description:

The proposed patient interface face mask incorporates a number of features, which are designed to maximize seal and comfort, and maintain the mask in the correct position throughout use.

- Adhesive foam to seal to the patient face
- One size - medium
- Models with and without Integral fixed leak (exhalation) port

Indications for Use: A patient interface, face mask, for use with CPAP and bi-level systems used in the treatment of adult (>30 kg) OSA and / or ventilatory support. Two styles (with exhalation port and without exhalation port).

Single use only < 24 hours.

Patient Population: Adults (>30 kg) with OSA

Environment of Use: Hospitals, Home, sub-acute care settings

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Comparative table:

Features	Predicates ResMed Quattro Full Face Mask – K063122 Advanced Warming – Adhesive Mask – K950771 Respironics Full face mask – K002465	Proposed Device ARCimed CPAP mask
Indications for use	A patient interface for use with CPAP and bi-level systems used in the treatment of adult (> 30 kg) OSA and / or ventilatory support. Anesthesia face mask with adhesive seal (Advanced Warming – K950771)	A patient interface for use with CPAP and bi-level systems used in the treatment of adult (>30 kg) OSA and / or ventilatory support.
Environment of Use	Home, Hospital, Sub-acute Institutions	Same
Patient Population	Adult	Same
Contraindications	None	None
Disposable, single patient use	No – multi-use – K063122 Yes – K950771	Yes
Components	Shell Cushion Adhesive seal (K950771)	Shell Foam Adhesive seal
Dead space	203 ml (K063122)	91 ml
Fixed leak port Exhaust Flow range	ResMed Quattro K063122 Pressure / Flow (lpm) 3 cm H_2O / 17.8 lpm 10 cm H_2O / 31.5 lpm 20 cm H_2O / 42.6 lpm 30 cm H_2O / 51.7 lpm 40 cm H_2O / 60.1 lpm	 Pressure / Flow (lpm) 3 cm H_2O / 19.9 lpm 10 cm H_2O / 33.3 lpm 20 cm H_2O / 47.1 lpm 30 cm H_2O / 58.0 lpm 40 cm H_2O / 67.8 lpm Pass / fail +/- 15%

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Features	Predicates ResMed Quattro Full Face Mask – K063122 Advanced Warming – Adhesive Mask – K950771 Respironics Full face mask – K002465	Proposed Device ARCimed CPAP mask
Vented and Non-vented styles requires anti-asphyxia valve in the circuit	Yes – ResMed – K063122 Offer a mask with optional anti-asphyxia valve	Vented and Non-vented models requires attachment to a circuit with anti-asphyxia valve incorporated demonstrated to activate AAV valve equivalent to predicates Should be used with AAV with minimum opening pressures of < 3 cm H_2O
Pressure Drop (Resistance to flow)	ResMed - K063122 0.59 cm H_2O @ 50 lpm 1.2 cm H_2O @ 100 lpm	 0.35 cm H_2O @ 50 lpm 0.81 cm H_2O @ 100 lpm
CO_2 rebreathing Measured change from baseline	ResMed – K063122 0.25% $EtCO_2$	 0.06% $EtCO_2$
Adhesive as a seal	Advanced Warming – K950771 Offers a tight seal No performance requirements other have will remain attached to patient's face	We are claiming no performance requirements other than the mask will seal and remain attached to the patient's face.

Differences Between Other Legally Marketed Predicate Devices:

The proposed device is viewed as substantially equivalent to the predicate devices, K950771, K002465, and K063122.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2008

ARCimed Laboratories LLC
C/O Mr. Paul E. Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134-2958

Re: K071915
Trade/Device Name: ARCimed CPAP Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: May 8, 2008
Received: May 9, 2008

Dear Mr. Dryden:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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 Statement

510(k) Number: K071915 (To be assigned)

Device Name: ARCimed CPAP mask

Indications for Use: A patient interface, face mask, for use with CPAP and bi-level systems used in the treatment of adult (>30 kg) OSA and / or ventilatory support. Two styles (with exhalation port and without exhalation port).

Single use only < 24 hours.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (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)

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

510(k) Number: K071915