K102224

510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

DEC 10 2010

Date Prepared	3 August, 2010
Submitter	Ms. Tracey Bullivant
Official Contact	Mr. David D'Cruz – V.P. US Medical and Regulatory Affairs 9001 Spectrum Center Boulevard, San Diego, CA 92123 Tel: (858) 836-5984
Device Trade Name	Pixi™ Pediatric Mask
Device Common Name/ Classification Name	Vented Nasal Mask; Accessory to Noncontinuous Ventilator (IPPB)
Classification	21 CFR 868.5905, 73 BZD (Class II)
Predicate Devices	MiniMe Pediatric Mask (K090935)
Description	The Pixi Pediatric Mask provides an interface such that airflow from a positive pressure source is directed to the patient's nose. The mask is held in place with adjustable headgear that straps the mask to the face. The Pixi Pediatric Mask is safe when used under the conditions and purposes intended as indicated in the labeling provided with the product. The Pixi Pediatric Mask is a prescription device supplied non-sterile.
Intended Use	The Pixi Pediatric Mask channels airflow noninvasively to a patient from a continuous positive airway pressure (CPAP) or bilevel device. The Pixi Pediatric Mask is: • to be used by children aged between 2 and 7 for whom continuous positive airway pressure (CPAP) or bilevel therapy has been prescribed • intended for single-patient re-use in the home environment and single-patient re-use in the hospital/institutional environment
Technological Characteristics	The new device provides a seal to the patient's face via a silicone elastomer interface whereas the predicate mask uses an alternative elastomer. Both the masks incorporate vent holes to provide continuous air leak to flush out and minimize the amount of CO_2 re-breathed by the patient. The design of the mask components in the new mask is such that the incorporation of these vent-holes does not interfere with the intended performance of the mask. Both masks connect to a conventional air delivery hose

between the mask and the positive airway-pressure source via standard conical connectors.

The new device is constructed using molded plastic and silicone components and fabric / nylon headgear. All the components are fabricated using materials deemed safe (ref: ISO 10993-1).

The main differences between the new device and the predicate is in the components, their design/geometry and how individual components interface with each other.

Non-Clinical Performance Testing

Bench testing of the physical and functional deadspace was conducted on both the new and predicate devices to demonstrate that the mask design provides adequate venting.

The new device has undergone assembly integrity testing to demonstrate mechanical integrity of the mask during normal use and reasonable abuse scenarios, as well as material safety testing to demonstrate biocompatibility of components.

The mask has also been subjected to bench testing to validate cleaning, transport and storage conditions, and to measure the pressure-flow and flow- impedance characteristics.

Clinical Data

Use of vented nasal masks with CPAP or Bilevel therapy is proven technology and is well accepted by the medical community. Bench testing is sufficient to demonstrate safety and efficacy of the new device.

Performance Data

The CO_2 performance of the new device has been demonstrated to be substantially equivalent to the predicate.

Substantial Equivalence Conclusion

The new device, the Pixi Pediatric mask, is substantially equivalent to the predicate device, the MiniMe Pediatric mask:

- it has the same intended use;
- it is intended for a subset of the patient population;
- it has similar technological characteristics;
- it does not raise new questions of safety and effectiveness;
- it is at least as safe and effective.

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

RESMED Limited
C/O Mr. David D'Cruz
RESMED Corporation
9001 Spectrum Center Boulevard
San Diego, California 92123

DEC 10 2010

Re: K102224
Trade/Device Name: Pixi™ Pediatric Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: October 18, 2010
Received: October 21, 2010

Dear Mr. D'Cruz:

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.

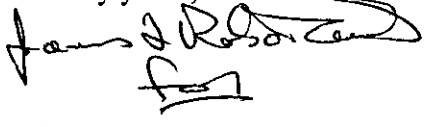
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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

Indication for Use

DEC 10 2010

510(k) Number (if known):

Device Name: **Pixi™ Pediatric Mask**

Indication for Use

The Pixi Pediatric mask channels airflow noninvasively to a patient from a continuous positive airway pressure (CPAP) or bilevel device.

The Pixi Pediatric mask is:

- to be used by children aged between 2 and 7 for whom continuous positive airway pressure (CPAP) or bilevel therapy has been prescribed
- intended for single-patient re-use in the home environment and single-patient re-use in the hospital/institutional environment

Prescription Use ___X___ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (Part 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)

3 August 2010

(Division Sign-Off)
Division of Anesthesiology, General Hospital 14
Infection Control, Dental Devices

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