Special 510(k) SUMMARY K121705

[As required by 21 CFR 807.92(c)]

OCT 23 2012

Date Prepared	6th June, 2012
Submitter Name	Mr. Kim Kuan Lee
Official Contact	Mr. Jim Cassi Vice President - Quality Assurance Americas 9001 Spectrum Center Boulevard San Diego CA 92123 USA Tel: (858) 836 6081
Device Trade Name	Geo
Device Common Name	Non continuous Ventilator (IPPB)
Classification	21 CFR 868.5905 (Class II)
Product Code	73 BZD
Predicate Device	Tasman (K112393)
Reason for submission	Device modification
Intended Use	The Geo is indicated for the treatment of obstructive sleep apnea (OSA) in adult patients weighing more than 66 lbs (30 kg). The Geo mask system delivers airflow noninvasively to a user from the integrated CPAP device. The Geo system is intended for single-patient re-use in the home environment and while traveling.
Substantial Equivalence	The modified device has the following similarities to the previously cleared Tasman device. • Same intended use • Similar operating principle • Similar technologies • Similar manufacturing process Design and Verification activities were performed on the modified device a result of the risk analysis and design requirements. All tests confirmed the product met the predetermined acceptance criteria. This included pressure stability, jitter, swings, ISO 17510-1 pressure performance and functional dead space tests against the previously cleared device using common protocols for

	both devices. ResMed has determined that the modified device has not altered the safety and effectiveness of CPAP treatment for adult patients with Obstructive Sleep Apnoea (OSA) who weigh more than 66 lb (>30 kg). The modified device complies with the applicable requirements referenced in the FDA guidance documents: • FDA Draft Reviewer Guidance for Ventilators (July 1995)
Device Description	The Geo is a portable CPAP device where the blower, mask and tubing are integrated and mounted to the headgear. The blower generates the required CPAP pressure via the integrated mask to maintain an "air splint" for effective treatment of OSA.
Conclusion	The Geo is substantially equivalent to the previously cleared Tasman 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

OCT 23 2012

Resmed, Limited
C/O Resmed Corporation
Mr. Jim Cassi
Vice President, Quality Assurance Americas
9001 Spectrum Center Boulevard
San Diego, California 92123

Re: K121705
Trade/Device Name: Geo
Regulation Number: 21 CFR 868.5905
Regulation Name: Non Continuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: September 21, 2012
Received: September 24, 2012

Dear Mr. Cassi:

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.
Directo
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K121705

Device Name: **Geo**

Indication for Use

The Geo is indicated for the treatment of obstructive sleep apnea (OSA) in adult patients weighing more than 66 lbs (30 kg). The Geo mask system delivers airflow noninvasively to a user from the integrated CPAP device. The Geo system is intended for single-patient re-use in the home environment and while traveling.

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

510(k) Number: K121705

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)