SEP 1 0 2004

K042294

SUITER Enterprises Inc. SLUMBERGEAR

510(k) Summary

SLUMBERGEAR™
Traditional 510(k) Premarket Notification

Submitter Name: SUiTER Enterprises Inc.

Submitter Mailing Address: PO Box 567
Milton-Freewater, OR 97862

Official Contact Person: Timothy J.S. Suiter, President
21230 SE 363rd Street
Auburn, WA 98092

Phone Number: 253-833-7418
Fax Number: 253-833-8387

E-Mail Address: SEI_SLUMBERGEAR@msn.com

Date Prepared: August 8, 2004

Device Trade Name: SLUMBERGEAR™

Device Common Name/ Classification Name: Headgear accessory to a non-continuous ventilator/mask (per 21 CFR Section 868.5905)

Predicate Devices: REMstar Pro with C-Flex CPAP System K021861
Mirage Vista™ Mask K031047

Reason for Submission: New Device

Device Description:

SLUMBERGEAR™ is a one-piece headgear with an integrated chinstrap used to secure externally placed masks, nasal pillows, and cannulas to the face of the patient. The headgear is a single strap that splits to wrap around the chin, the back of the head, and the top portions of the patient's head. Velcro® attached to each split portion of the headgear strap is used to fasten the headgear to the required respiratory device.

Intended Use:

SLUMBERGEAR™ headgear is an accessory to a non-continuous ventilator (respirator) intended for adult patients prescribed continuous positive airway pressure (CPAP) and bi-level therapy in hospital, clinical, and home environments. The headgear is reusable and for single patient use.

Substantial Equivalence/Device Technological Characteristics and Comparison to Predicate Devices:

The SLUMBERGEAR™ headgear is intended to secure masks, nasal pillow systems, and cannulas to the patient's face. The masks, nasal pillow systems or cannulas supply positive pressure ventilation via tubing connected to a CPAP or bi-level generator.

SLUMBERGEAR™ is comprised of Velcro® hook and loop fabric and Breath-O-Prene.™ The fabric is a smooth Lycra on the underside and Velcro® loop fabric on the outer side. The fabric has 4-way stretch and does not contain any latex material.
SLUMBERGEAR™ has the following similarities to the previously cleared predicate devices:

-the same intended use
-the same operating principles
-the same technology, same or similar materials in contact with patient's skin
-the same type of manufacturing process

SLUMBERGEAR™ has the following differences to the previously cleared predicate devices:

-seamless one-piece design with integrated chinstrap
-top of the head and back of the head/neck Velcro® closures

SLUMBERGEAR's™ differences add to the effectiveness and safety of the headgear by stabilizing the respiratory device to help eliminate shifting, air escape and mouth breathing during sleep. The top of the head and the back of the head/neck closures permit entering and/or exiting of the headgear while the respiratory device remains secured to the headgear. If ever necessary, the back of the head/neck closure would provide a quick efficient Emergency exit.

Performance Data:

SLUMBERGEAR™ headgear was tested to determine customer satisfaction regarding comfort, stability, and convenience when compared to other headgear on the market.
SLUMBERGEAR™ was found to be safe and effective.
The results of the performance data show SLUMBERGEAR™ headgear is substantially equivalent to the predicate devices and other headgear previously cleared for market.
See Appendix A for data.
There are no recognized consensus standards for headgear.

Conclusion:

SLUMBERGEAR™ headgear is substantially equivalent to the headgear included with REMstar Pro with C-Flex CPAP System K021861 and the headgear included with Mirage Vista™ Mask K031047.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 2004

Mr. Timothy J.S. Suiter
President
Suiter Enterprises, Incorporated
21230 SE 363rd Street
Auburn, Washington 98092

Re: K042294
Trade/Device Name: SLUMBERGEAR™
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: August 8, 2004
Received: August 24, 2004

Dear Mr. Suiter:

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.

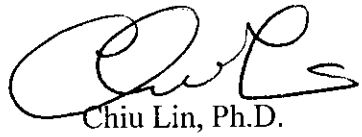
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4646. 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/dsma/dsmamain.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

510(k) Number (if known): K042294

Device Name: SLUMBERGEAR™

Indications for Use:

SLUMBERGEAR™ headgear is an accessory to a non-continuous ventilator (respirator), intended for adult patients prescribed continuous positive airway pressure (CPAP) and bi-level therapy in hospital, clinic, and/or home environments. The headgear is reusable and for single-patient use.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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