DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 29 2004

Life Sleep Systems, Inc.
c/o Mr. Howard M. Holstein
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004-1109

Re: K990871
Trade/Device Name: PillowPositive Cervical Pillow
Regulation Number: 872.5570
Regulation Name: Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Regulatory Class: Class II
Product Code: MYB
Dated: March 16, 1999
Received: March 16, 1999

Dear Mr. Holstein:

This letter corrects our substantially equivalent letter of June 10, 1999 regarding the PillowPositive regulatory classification. At the time of that letter, FDA incorrectly classified the Cervical Pillow, as indicated, as an unclassified device. This device is classified under 872.5570, Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea. The product code will remain as MYB.

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 (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.

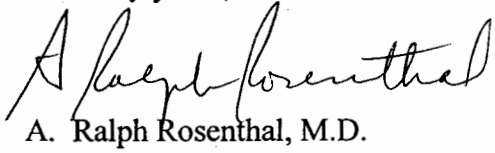
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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) 276-0115. 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,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

JUN 10 1999

K990871

510(K) SUMMARY FOR LIFESLEEP SYSTEMS, INC.'S PILLOWPOSITIVE

Submitter's Name, Address, Telephone Number, and Contact Person

LifeSleep Systems, Inc.
400 Oyster Point Boulevard
Suite 112
South San Francisco, California 94080

Contact: Anthony A. DiTonno
President & Chief Executive Officer
LifeSleep Systems, Inc.
Phone: (650) 616-9933 / (650) 616-1005
Facsimile: (650) 616-9930

Date Prepared

March 16, 1999

Name of the Device

LifeSleep PillowPositive Cervical Pillow

Common or Usual Name

Cervical Pillow

Classification Name

Truncal Orthosis

Product Code

IQK

Predicate Devices

Lifesleep Systems Pillow
Positive Cervical Pillow

(4) Ortho-Rest Company's A-Just Right Pillow

Intended Use

PillowPositive Cervical Pillow ("PillowPositive") is intended for the reduction of symptoms (apnea/hypopnea) associated with mild obstructive sleep apnea by maintaining an open upper airway during sleep.

Principles of Operation

The PillowPositive places and holds the head and neck in a position that is similar to that used in cardiopulmonary resuscitation, the upper airway remains open, thereby reducing the incidence of mild obstructive sleep apnea.

Technological Characteristics

The pillow consists of a custom-fitted high resiliency urethane foundation, an overlying "memory foam" supporting the head and neck, a stretch terry-cloth cover, and removable foam inserts. The PillowPositive is comprised of a thin central area for supine sleeping and two thicker, sloped side panels with earwells for side sleeping.

Performance Data

LifeSleep sponsored a pilot study and a pivotal study to assess the PillowPositive's use in the reduction of symptoms associated with mild obstructive sleep apnea. The pilot study showed a statistically significant reduction in the Respiratory Disturbance Index (*i.e.*, apneas and hypopneas) among subject with mild obstructive sleep apnea. The pivotal study indicated that the PillowPositive produces a statistically significant reduction in subject's Respiratory Disturbance Index, a key indicator of sleep apnea, in subjects with mild sleep apnea.

Summary of the Basis for the Finding of Substantial Equivalence

The LifeSleep PillowPositive for the reduction of the symptoms associated with mild obstructive sleep apnea has the same intended use as the Dr. Jonathan A. Parker's PM Positioner, and Adjustable PM Positioner. The Pillow Positive for the reduction of symptoms associated with mild sleep apnea has similar principles or operation as the PM Positioner, the Adjustable PM Positioner, and the A-Just Right Pillow. The PillowPositive for the reduction of symptoms associated with mild obstructive sleep apnea has the same technological characteristics as the legally marketed PillowPositive for snoring and very similar technological features as Ortho-Rest Company's A-Just Right Pillow. The minor differences between the intended use and

the technological characteristics of LifeSleep's PillowPositive for the reduction of symptoms associated with mild obstructive sleep apnea and its predicate devices present no new issues of safety and effectiveness. Moreover, the clinical data demonstrate that the device reduces the symptoms (apneas/hypopneas) associated with mild obstructive sleep apnea. Therefore, the LifeSleep PillowPositive for the reduction of symptoms associated with mild obstructive sleep apnea is substantially equivalent to its legally marketed predicate devices.

510(k) Number (if known):_____

Device Name: **LifeSleep Systems, Inc. PillowPositive Cervical Pillow**

Indications for Use:

PillowPositive Cervical Pillow ("PillowPositive") is indicated for the reduction of symptoms (apneas and hypopneas) associated with mild obstructive sleep apnea.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

6/9/99

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K990871

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)