EMERGO GROUP

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FEB 23 2011

SECTION 5 – 510(k) SUMMARY

Submission Correspondent

Company Name:	Emergo Group, Inc.
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Company Contact:	Stuart R. Goldman Senior Consultant CQM, CQA, CBA, QMS-A 512.600.7616
Country:	USA
Phone:	512.327.9997
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Website:	www.emergogroup.com
Submission Date:	September 29, 2010

Submission Sponsor

Company Name:	DynaFlex
Company Address:	10403 International Plaza St. Ann, MO 63074
Country:	USA
Phone:	314.426.4020
Fax:	314.429.7575
Website:	www.dynaflex.com

Device Classification

DynaFlex® Anti-Snoring & Sleep Apnea Devices

Device Sponsor:	DynaFlex
CDRH Product Classification Name:	Device, Anti-Snoring
CDRH Product Code:	LRK
CDRH Regulation Name:	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
CDRH Regulation Number:	872.5570

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CDRH Classification Panel: Dental Devices

CDRH Regulatory Class: Class II

Device Description

The proposed *DynaFlex® Anti-Snoring & Sleep Apnea Devices* are intraoral devices used for treating snoring and sleep apnea, and will consist of two custom fitted trays which fit over the upper and lower teeth and engage by means of adjustable lugs, or by the industry standard *Herbst* mechanism which is a rod and tube type assembly that orientates the jaws in a predetermined relationship. These devices function as a mandibular *re-positioner* which acts to increase the patient's pharyngeal space, improving their ability to exchange air during sleep. The devices will be custom made for each patient and have the ability of the adjustment mechanism enabling the amount of mandibular advancement to be set by the dentist or physician at the time of fitting the device. The devices will be sold by prescription only.

The *LISA Appliance* is a one piece, non-adjustable design. The *LISA II Appliance* is a dynamic, adjustable design. The *Dorsal Appliance* is a two-piece design with separate upper and lower acrylic portions that when engaged posture the mandible into protrusive position via acrylic fins built in the lower acrylic portion. The adjustable *Herbst Appliance* is a one piece construction held together by two adjustment mechanisms on the buccal or outer are of the upper and lower appliance.

Any slight differences in the materials, fit and function of *DynaFlex® Anti-Snoring & Sleep Apnea Devices* with those of the predicate devices do not raise any new concerns over safety and effectiveness.

Intended Use

DynaFlex® Anti-Snoring & Sleep Apnea Devices are intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults. The devices are worn while sleeping to support the lower jaw in a forward position prescribed by the dentist, and is removable by the patient.

Predicate Devices

DynaFlex has selected the following devices as it predicates for its 510(k) submission.

Device Sponsors:

1. Somnomed Limited
2. Specialty Appliances Works, Inc.

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	3. Airway Management, Inc.
Devices:	1. *Somnomed MAS RXA* 2. *Acrylic Splint Herbst Appliance* 3. TAP T
510(k)'s:	1. K050592 2. K083209 3. K061732
CDRH Product Classification Name:	Device, Anti-Snoring
CDRH Product Code:	LRK
CDRH Regulation Name:	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
CDRH Regulation Number:	872.5570
CDRH Classification Panel:	Dental Devices
CDRH Regulatory Class:	Class II

Safety and Effectiveness

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the *DynaFlex®* *Anti-Snoring & Sleep Apnea Devices* and the predicate devices do not raise any questions regarding their safety and effectiveness. *DynaFlex®* *Anti-Snoring & Sleep Apnea Devices*, as designed and manufactured, are therefore determined to be substantially equivalent to the referenced predicate devices.

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

Dynaflex
C/O Mr. Stuart R. Goldman
Emergo Group Incorporated
611 West 5th Street
Third Floor
Austin, Texas 78701

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Re: K103076
Trade/Device Name: DynaFlex® Anti-Snoring & Sleep Apnea Devices (Lisa Appliance, Lisa II Appliance, Dorsal Appliance, Herbst Adjustable Appliance)
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring And Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: February 15, 2011
Received: February 16, 2011

Dear Mr. Goldman:

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.

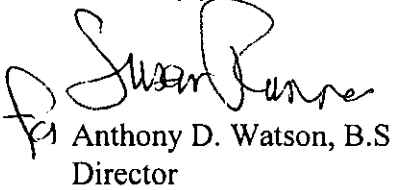
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

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SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): K103076

Device Name:

DynaFlex® Anti-Snoring & Sleep Apnea Devices (Lisa Appliance, Lisa II Appliance, Dorsal Appliance, Herbst Adjustable Appliance)

Indications for Use:

DynaFlex® Anti-Snoring & Sleep Apnea Devices are intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults. The devices are worn while sleeping to support the lower jaw in a forward position prescribed by the dentist, and is removable by the patient.

Prescription Use __X__ AND/OR Over-The-Counter Use ____

(Part 21 CFR 801 Subpart D) (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

510(k) Number: K103076