K971794

SEP 29 1997

DESIGN FRANTZ INCORPORATED

510(k) Summary

Date: May 14, 1997

Donald Frantz, D.D.S.
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400 Medical Center, # 209
Webster, Texas 77598

Phone: (281) 338-6631
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Device Name:

Trade/Proprietary Name: Elastic Mandibular Advancement (EMA) appliance
Common Name: Sleep Apnea/Anti-snoring device
Classification Name: Activator dental appliance

Substantial Equivalence Comparison:
The Elastic Mandibular Advancement (EMA) appliance is substantially equivalent to the NAPA [510(k) # K902790] and the SNOAR [510(k) # K880956] appliances.

Description:
The Elastic Mandibular Advancement appliance is a modified functional orthodontic appliance. The modifications are: 1) clasps are not needed as the appliance is retained firmly to the teeth by pressure formed plastic into the undercut areas. Each tray holds the teeth in their present location not allowing tooth movement. 2) the bite is opened as in the SNOAR and NAPA appliances but not in one fixed position. Multiple bite openings are possible because of removable bite blocks or bite planes of varying thicknesses. 3) the mandible is advanced as in both the SNOAR and NAPA appliances except not in a fixed position , but in various amounts of forward advancement because of removable, replaceable elastic bands or straps to pull the mandible forward.

Intended Use:
Treatment of nasal respiratory dysfunction of obstructive sleep apnea and snoring in those patients where repositioning of the mandible can increase the patients air space.

Technological characteristics:
The NAPA, SNOAR and EMA appliances advance the mandible to an anterior and inferior position with regard to the maxilla. This repositioning of the mandible pulls the tongue forward and increases the patient's airspace, thereby decreasing upper airway obstruction. Such obstruction can be a causative factor in snoring and obstructive sleep apnea. All three devices are prescribed for patients after diagnosis of obstructive sleep apnea by a physician. None of the appliances are indicated for the treatment of central sleep apnea.

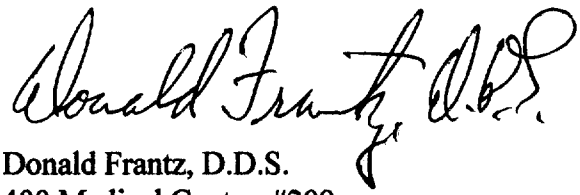
The NAPA, SNOAR and EMA appliances are similar in that they all are individually customized mouthpieces that fit uniquely into patients mouths. None of the appliances allow for movement of the teeth. While the NAPA and SNOAR appliances maintain dental integrity with the use of wire the EMA appliance extends the appliance material into the undercut areas of the teeth, therefore maintaining integrity.

The NAPA, SNOAR and EMA appliances all allow for nasal and/or oral breathing. The NAPA and SNOAR appliances advance the mandible and hold it in place rigidly. The EMA appliance advances the mandible but allows for opening of the mouth therefore eliminating the need for a "breathing beak" as the NAPA appliance has.

Clinical Data:
Clinical testing was done at The University of Texas Medical Branch at Galveston. Overnight sleep studies with and without the EMA device were performed on 13 obstructive sleep apnea (OSA) patients with a mean apnea-hypopnea index of 60 events/hr. without the appliance.. The EMA appliance advanced the mandible by an average 9 mm. EMA reduced the mean apnea-hypopnea index to 21 events/hr.

Clinical tests conclusions:
Use of the EMA device significantly reduced episodes of obstructive sleep apnea.

Sincerely,



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

SEP 29 1997

Donald Frantz, D.D.S.
Frantz Design Incorporated
400 Medical Center, #209
Webster, Texas 77598

Re: K971794
Trade Name: Elastic Mandibular Advancement (EMA) Appliance
Regulatory Class: Unclassified
Product Code: LRK
Dated: July 17, 1997
Received: July 21, 1997

Dear Dr. Frantz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971794

Device Name: Elastic Mandibular Advancement (EMA) appliance

Indications For Use:

Indications for use: Treatment of nasal respiratory dysfunction of obstructive sleep apnea and snoring in those patients where advancement of the mandible and opening the bite can increase the patients air space.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K971794

Prescription Use ✓ OR Over-The-Counter Use _____
(21 CFR 801.109)

(Optional Format 1-2-96)