K973884

DESIGN FRANTZ INCORPORATED

JAN - 9 1998

510(k) Summary

Date: October 10, 1997

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

Phone: (281) 338-6631
Fax: (281) 554-3033

Device Name:

Trade/Proprietary Name: Elastic Mandibular Advancement Titration (EMA-T) appliance

Common Name: Temporary sleep apnea/anti snoring device

Classification Name: Activator dental appliance

Substantial Equivalence Comparison:

The Elastic Mandibular Advancement Titration (EMA-T) appliance is substantially equivalent to the Elastic Mandibular Advancement (EMA) appliance [510(k) # K 971794].

Description:

Currently, there is no method to predict which patients will respond to treatment of obstructive sleep apnea (OSA) and snoring with an oral mandibular advancement device. The disposable Elastic Mandibular Advancement - Titration appliance will allow sleep laboratories to identify those OSA and snoring patients who will respond to mandibular advancement with an oral device avoiding the unnecessary costs of manufacture of a custom made appliance for treating patients who do not respond.

The EMA-T 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 dental impression material into undercut areas. Each tray holds the teeth in their present location not allowing tooth movement. 2) the bite is opened with bite planes as in the Elastic Mandibular Advancement appliance. 3) the mandible is advanced with an elastic strap similar to the Elastic Mandibular Advancement appliance.

The appliance is designed for universal application in adults with the use of one-size-fits all maxillary and mandibular hard plastic trays. On the night of the titration polysomnogram, the sleep technician makes impressions of the maxillary and mandibular teeth by placing a fast setting dental silicone putty material (such as E and D Dental Products Incorporated) in the tray and pushing the tray onto the patient's teeth. The trays and putty with the patient's impression are removed from the mouth. Just before the start of the sleep study, the impression and the patient's teeth are dried off. A liquid silicone "wash" is placed onto the patient's impression and placed on the maxillary and mandibular teeth and arches for the duration of the study. This "wash" holds the trays firmly on the patient's teeth and prevents their dislodgment during sleep. On the anterior of the maxillary tray is a rod that protrudes at the midline in front of the patient's central incisors. A Styrene Block Copolymer strap with a pull tab and holes 3 millimeters apart is connected to the mandibular tray. Mandibular advancement is achieved by pulling the tab forward and inserting the rod into one of the holes on the pull tab. The mandible is thereby held in an advanced position by the stationary maxilla, and is advanced in 3 millimeter increments. As the sleep lab technician advances the mandible, the polysomnogram will show a decrease, or even an elimination, of the patient's apneas on those responding. A prescription will then be given to the patient for a permanent custom made oral appliance.

Intended Use: Temporary treatment of nasal respiratory dysfunction of obstructive sleep apnea and snoring to determine in which patients mandibular advancement and opening the bite will increase the patients air space.

Technological characteristics:
The EMA and EMA-T 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 pharyngeal airway. Both devices are prescribed for patients after diagnosis of obstructive sleep apnea by a physician. Neither of the appliances is indicated for the treatment of central sleep apnea.

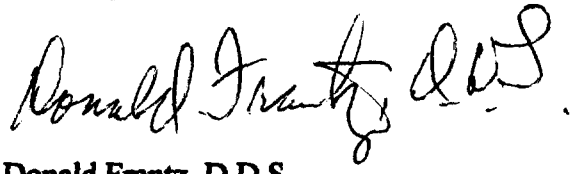
The EMA and EMA-T appliances are similar in that they both are individually customized mouthpieces that fit uniquely into patients mouths. Neither of the appliances allow for movement of the teeth.

The EMA and EMA-T appliances all allow for nasal and/or oral breathing.

Clinical Data:
Clinical testing was done at The University of Texas Medical Branch at Galveston. Overnight sleep studies with the EMA - T device were performed on 12 obstructive sleep apnea (OSA) patients. To date 5 of those patients have been given a permanent oral device to treat their OSA and snoring as a result of the titration testing. To this date 100 % of the patients obtaining a permanent custom appliance have responded favorably.

Clinical tests conclusions:
The EMA-T device effectively determined which obstructive sleep apnea and snoring patients will respond favorably to mandibular advancement and bite opening.

Sincerely,



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K973884
Trade Name: Elastic Mandibular Advancement - Titration (EMA-T) Appliance
Regulatory Class: Unclassified
Product Code: LRK
Dated: October 10, 1997
Received: October 14, 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,

Susan Runner for

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

Enclosure

Attachment VII
Indications for Use Statement

510 (k) Number: Being applied for

Device Name: Elastic Mandibular Advancement Titration (EMA-T) appliance

Indications For Use: Temporary treatment of obstructive sleep apnea and snoring to determine in which patients mandibular advancement and opening the bite will 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)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973884
Prescription Use: ✓ OR Over-The-Counter Use_____