K113516

JAN 0 4 2013

## 510(k) Summary

This summary of substantial equivalence for the purposes of assessing safety and effectiveness under Section 510(k) of the Federal Food, Drug, and Cosmetic Act is being submitted in accordance with the requirements of 21 CFR 807.92.

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Device Name/
Trade Name: TheraSom-CAST™

Classification Name: Intra Oral Devices for Snoring and Intra Oral Devices for Snoring and Obstructive Sleep Apnea (21 CFR 872.5570)

Panel: Dental

Classification Product Code: LRK
Subsequent Product Code: LQZ

**Predicate Devices:**

| Device Trade Name | Manufacturer | 510(k) Reference Number | Product Code |
|---|---|---|---|
| Myerson EMA | Frantz Design, Inc. | K971794 | LRK |
| Adjustable PM Positioner | Jonathan A. Parker, D.D.S. | K955503 | LQZ |
| Lowe Klearway | Dr. Alan A. Lowe, Inc. | K950763 | LRK |
| SomnoMed MAS RXA | SomnoMed, Ltd. | K050592 | LRK |

**Intended Use:** The TheraSom-CAST is used to reduce or alleviate the occurrence of snoring and/or for the treatment of mild to moderate obstructive sleep apnea (OSA) in patients 18 years of age or older.

**Target Population:** Adult patients who have been medically diagnosed with snoring and/or mild to moderate OSA.

**Environment of Use:** The device is intended for use by patients at home and in sleep laboratories.

**Device Description:**

The TheraSom-CAST™ anti-snoring device is a removable, adjustable intraoral device intended for the treatment of snoring and mild to moderate obstructive sleep apnea (OSA) in adult patients 18 years or older. The device functions as a mandibular repositioner, which acts to improve the patient's ability to breathe without obstruction of the pharyngeal airway. The TheraSom-CAST is customized by molding to conform to the patient's dentition. Like the predicate devices, this device is comprised of an upper and lower component, each fitted over the corresponding dentition and coupled together by a locking mechanism. The locking mechanism of the TheraSom-CAST is formed by stainless steel tension springs connected to the upper and lower components externally on either side of the device. The springs may vary in lengths and may be moved to adjust the relative positions of the upper and lower components so as to set the distance of the mandibular advancement. While the device includes no plastic parts (the upper and lower components are made from dental cast alloy and the springs are formed of stainless steel); this difference in materials and the construction by customized dental cast molding do not introduce any new safety issues.

**Brief Discussion of Feasibility Study:**

A feasibility study was conducted wherein five (5) participants were assessed with polysomnographic study in a sleep center, with and without the device in place. AHI post-treatment with the device was measured for each patient. Visual screening of gingival health and physical assessment of tooth mobility were performed after use of the device for a period of time of at least 8 months. The patients reported that use of the device at night reduced the symptom of snoring.

**Substantial Equivalence**
**Comparison of TheraSom-CAST™ to Predicate Devices**

| Substantial Equivalence Characteristics | TheraSom-CAST | Myerson EMA | Adjustable PM Positioner | SomnoMed MAS | Lowe Klearway |
|---|---|---|---|---|---|
| **Use** | | | | | |
| For intraoral use | Yes | Yes | Yes | Yes | Yes |
| Intended to treat snoring | Yes | Yes | Yes | Yes | Yes |
| Indicated for treatment of mild to moderate OSA | Yes | Yes | Yes | Yes | Yes |
| Indicated for single, adult patient multi-use | Yes | Yes | Yes | Yes | Yes |
| **Design** | | | | | |
| Molded upper and lower pieces | Yes | Yes | Yes | Yes | Yes |
| Separate upper and lower components connected by locking mechanism | Yes | Yes | Yes | Yes | Yes |
| Side placement of buccal locking mechanisms | Yes | Yes | Yes | Yes | Yes |
| Metallic buccal locking mechanisms | Yes | No | Yes | Yes | Yes |
| Coiled spring locking mechanisms | Yes | No | No | No | No |
| Titrateable, can be adjusted or re-fit | Yes | Yes | Yes | Yes | Yes |
| Inserted by patient at night | Yes | Yes | Yes | Yes | Yes |
| Allows for nasal/oral breathing | Yes | Yes | Yes | Yes | Yes |
| Permits patient to speak or drink while installed | Yes | Yes | Yes | Yes | Yes |
| **Materials** | | | | | |
| Upper and lower pieces constructed from acrylic material | No | Yes | Yes | Yes | Yes |
| Upper and lower pieces constructed of dental alloy material | Yes | No | No | No | No |

*Substantial Equivalence Discussion*

The TheraSom-CAST™ is believed to be substantially equivalent to the referenced predicate devices. The TheraSom-CAST and the predicate devices function as mandibular repositioners which displace the patient's mandible during sleep. The mechanical components of the TheraSom-CAST and the predicate devices are similar, i.e. they include an upper and lower appliance component and a locking mechanism that is designed to advance the position of the lower component in relation to the upper component, thereby advancing the mandible. As with the predicate devices, the TheraSom-CAST is customized to fit each patient, and the mandibular advancement is adjusted by the dentist or physician at the time of fitting. All the contact surfaces of the TheraSom-CAST are constructed of metal and include no plastics, however this difference does not affect the mode of operation of the device as a mandibular repositioner, and it has not introduced any new safety issues.

## CONCLUSION

The construction, intended use and mode of operation of the TheraSom-CAST are substantially similar to the predicate devices, and clinical study data demonstrates that the device is substantially equivalent in effectiveness and safety to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 4, 2013

Family Dental Services, P.C.
C/O Ms. Deanna L. Baxam
Baxam Law Group, Limited Liability Company
2180 Satellite Boulevard, Suite 400
DULUTH GA 30097

Re: K113516
Trade/Device Name: TheraSom-CAST™
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, LQZ
Dated: November 20, 2012
Received: November 27, 2012

Dear Ms. Baxam:

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,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
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Center for Devices and
Radiological Health

Enclosure

**Indications for Use**

**510(k) Number:** K113516 (To be assigned)

**Device Name:** TheraSom-CAST™

**Indications for Use:** The TheraSom-CAST is used to reduce or alleviate the occurrence of snoring and/or for the treatment of mild to moderate obstructive sleep apnea (OSA) in patients 18 years of age or older.

Prescription Use ___YES___ AND/OR Over-The-Counter Use ___NO___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2013.01.04 07:50:13 -05'00'

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

**510(k) Number:** k113516