K130797

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DEC 18 2013

Luco Hybrid OSA Appliance Inc.
1419 Butternut Creek Road, Kingston, ON K7L5H6

## 510 (k) Summary:

**Reason for 510():** This is a new appliance, Traditional 510(k) request for additional information

**Submission Date:** November 12, 2013

**Submitter Name:**
Luco Hybrid OSA Appliance Inc.
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Kingston, ON K7L5H6

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**Main Contact:** Dr. Ken Luco (same as above)

**Establishment Registration Number:** DUNS 203146907

**Trade Name:** Luco Hybrid OSA Appliance®
**Common Name:** Mandibular Advancement Oral Appliance
**Classification Name:** Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea
**Regulation Number** 21 CFR 872.5570
**Product Code:** LRK

| | | |
|---|---|---|
| **Predicate Appliances:** | SomnoMed MAS | K050592 |
| | Oravan OSA | K121285 |
| | ATG/SM-OSA Appliance | K130130 |

**Description of Appliance:**
The Luco Hybrid OSA Appliance is a two part (upper and lower) mandibular advancement appliance that advances the mandible (and tongue) into a forward position and maintains it there while sleeping. This appliance, as well as all three predicates identified, are made patient specific by a dental lab for each patient. The framework of the Luco Hybrid OSA appliance is constructed of dental alloy (chrome cobalt), similar to a cast partial denture, increasing its strength. The acrylic used for the pads, wings and adjustment blocks is orthodontic methyl methacrylate from Dentaurum. All of the predicate appliances use orthodontic methyl methacrylate from Dentaurum in their design. Orthodontic type ball clasps are placed on the inside (lingual surfaces) of the bicuspids and molars for retention. The SomnoMed MAS and

Oravan OSA also use orthodontic ball clasps and wires for retention. There are acrylic pads on both the upper and lower appliances which cover and protect the posterior teeth (similar to all the predicates). There is no acrylic over the upper and lower incisors; instead there is an orthodontic type retainer wire to prevent flaring of the upper and lower incisors and a cast dental alloy custom fit plate behind the lower incisors. The predicate Oravan OSA appliance similarly does not place acrylic in the anterior of upper and lower teeth. The absence of any acrylic over the incisors in the front of the mouth allows freedom to breathe through the mouth as needed or to evacuate the oropharynx in the case of illness or an emergency such as vomiting. The patient can speak and drink water without removing the appliance. The absence of any material in the anterior region also activates and inhibits pharyngeal reflexes which result in the tongue posturing forward.

The Luco Hybrid and all three predicates use wings on the lower appliance that extend upward contacting adjustable blocks on the upper appliance. These wings retain the lower jaw in a pre-determined position while allowing the patient to open and move laterally with freedom. The adjustment blocks of the upper appliance have adjustment screws that permit fine adjustments (each turn gives ¼ mm advancement, up to 6mm) similar to all of the predicates. The predetermined position is determined by the dentist ordering the appliance; usually as a bite registration taken with a dedicated apparatus such as a George Gauge® (these are readily available from dental supply companies) similar to the predicate appliances. Advancing the mandible prevents blockage of the upper airway permitting normal air exchange, and effectively treating primary snoring and mild to moderate obstructive sleep apnea.

The pads are constructed such that the main area of contact is in the forward 25% of the pads with no contact in the molar regions. The pads (both on the upper and lower appliance) have a chrome cobalt mesh inside for increased strength. The wings of the lower appliance as well as the upper adjustment blocks also have chrome cobalt mesh for strength. This mesh is continuous with the main framework of the appliance providing considerable strength.

**Intended Use Statement:**
This appliance is designed to treat primary snoring, mild to moderate obstructive sleep apnea in adults.

**Substance Equivalents:**
The Oravan OSA, SomnoMed MAS, ATG/SM-OSA and the Luco Hybrid all use a wing/block design to retain the mandible (and tongue) forward and have acrylic pads covering and protecting the teeth. All the predicates are dual arch appliances with the upper and lower components non-connected (no locking mechanism holding them together). The Oravan OSA appliance does not have coverage of the incisal areas of both upper and lower incisors similar to the Luco Hybrid. The predicate devices all treat the same conditions as the Luco Hybrid Appliance. The ATG/SM-OSA Appliance uses cast dental alloy in its design as does the Luco Hybrid.

**Comparison of the Predicates to the Luco Hybrid Appliance:**

The Luco Hybrid and predicate appliances are intended for the treatment of night-time snoring and mild to moderate obstructive sleep apnea in adults. In this respect they are all equivalent. All of the predicates and the Luco Hybrid use the same principle of operation; a wing/block design that retains the lower jaw forward while sleeping. All the predicates and the Luco Hybrid appliances are made patient specific on the prescription of a licensed health care provider, are multi-use, non-sterile, adjustable and removable. All appliances are used in the same environment (home/sleep studies) and are comprised of two removable trays. The following table (table 1) outlines the similarities between these appliances:

**Table 1**

| Comparison | Luco Hybrid OSA Appliance® K130797 | SomnoMED® MAS K050592 | Oravan OSA K121285 | ATG/SM-OSA K130130 |
|---|---|---|---|---|
| Indications for Use | This appliance is designed to treat primary snoring and mild to moderate obstructive sleep apnea in adults. | The SomnoMed MAS is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults. | Oravan OSA is intended to reduce snoring and mild to moderate sleep apnea in adults | The ATC/SM-OSA appliances are intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea in adults. |
| Target Population | Adults | Adults | Adults | Adults |
| Anatomical Sites | Mandibular advancement appliance, worn on upper and lower teeth | Mandibular advancement appliance worn on upper and lower teeth | Mandibular advancement appliance, worn on upper and lower teeth | Mandibular advancement appliance, worn on upper and lower teeth |
| Where Used | At home or clinic setting | At home or clinic setting | At home or clinic setting | At home or clinic setting |
| Energy Source | None | None | None | None |
| Human Factors | Used by patients at home | Used by patients at home | Used by patients at home | Used by patients at home |
| Design | Uses wings on a lower appliance to engage blocks of an upper appliance to hold mandible forward | Uses wings on a lower appliance to engage blocks of an upper appliance to hold mandible forward. | Uses wings on a lower appliance to engage blocks of an upper appliance to hold mandible forward | Uses wings on a lower appliance to engage blocks of an upper appliance to hold mandible forward |
| Performance | Has been successfully used to treat all the conditions listed in the indications for use | Has been used to successfully treat all the conditions in the indications for use | Has been successfully used to treat all the conditions listed in the indications for use | Has been used to successfully treat all the conditions in the indications for use |
| Standard Met | n/a | n/a | n/a | n/a |
| Materials | Uses acrylic for tooth bearing surfaces and dental alloy for the framework. Stainless steel clasps, wires and expansion screws | Uses acrylic for the entire appliance. Stainless steel clasps and expansion screws | Uses acrylic for tooth bearing surfaces and dental alloy for the framework. Stainless steel clasps, wires and expansion screws | Uses acrylic for the entire appliance. Stainless steel clasps and expansion screws |
| Biocompatibility | Uses all FDA approved materials and Class I materials that are used commonly in dentistry. Does not use any dyes. | Uses all FDA approved materials and Class I materials that are used commonly in dentistry. Uses pink dye. | Uses all FDA approved materials and Class I materials that are used commonly in dentistry. Uses pink dye. | Uses all FDA approved materials and Class I materials that are used commonly in dentistry. Uses pink dye. |
| Compatibility with the environment and other devices | Does not release any compounds harmful to the environment. May be used with other devices. | Does not release any compounds harmful to the environment. May be used with other devices. | Does not release any compounds harmful to the environment. May be used with other devices. | Does not release any compounds harmful to the environment. May be used with other devices. |
| Sterility | The appliance is delivered non-sterile | The appliance is delivered non-sterile | The appliance is delivered non-sterile | The appliance is delivered non-sterile |
| Electrical Safety | n/a | n/a | n/a | n/a |
| Mechanical Safety | n/a | n/a | n/a | n/a |
| Chemical Safety | n/a | n/a | n/a | n/a |
| Thermal Safety | n/a | n/a | n/a | n/a |
| Radiation Safety | n/a | n/a | n/a | n/a |

**Non-Clinical Performance Data:**
The primary materials, methyl methacrylate and dental alloy were selected as both have an extensive history of use in dentistry. Vitallium 2000® (K970205) is used for frameworks of cast partial dentures which often last decades. Methyl methacrylate has been and is currently used for dentures, bruxism appliances and orthodontic appliances with excellent results. By combining these recognized materials into one appliance, the Luco Hybrid has proven to be durable and highly resistant to fracture. Some of the original appliances are seven years of age or more without damage. The predicate appliances all use the same acrylic as the Luco Hybrid (Dentaurum ortho acrylic). All predicates use orthodontic expansion screws and orthodontic ball clasps which are commercially available and widely used in dentistry. The cast framework of the Luco Hybrid can last decades if cared for. The acrylic and hardware can be replaced inexpensively and the cast framework re-used at a significant cost savings to the patient. The Oravan OSA also uses dental alloy for its framework.

**Clinical Testing:**
The Luco Hybrid OSA Appliance has been successfully used on over 125 patients who were diagnosed using 16 channel polysomnogram recordings in sleep clinics, in overnight sleep studies, monitored by a sleep specialist. The enclosed data (30 patients) was collected on patients diagnosed with mild to moderate obstructive sleep apnea and primary snoring over a five year period. All were diagnosed and re-tested with their appliance in the same sleep lab using the same parameters. All patients all were successfully treated except one, who suffered from severe claustrophobia and could not tolerate any oral appliance or CPAP/APAP therapy and remains untreated. This appliance was and is being used to treat Canadian Military personnel who have undergone overnight sleep studies (at the same sleep clinic) with excellent results. Before and after sleep studies have verified the efficacy of this appliance.

**Conclusion:**

The Luco Hybrid OSA Appliance is identical to the predicate appliances selected. It uses the same materials, same mechanism of action, carries the same risks and cautions and is substantially equivalent. The dental alloy palate design of the ATG/SM OSA appliance confirms that dental alloy is an acceptable material for OSA appliances. Clinically, the Luco Hybrid has also confirmed this in patients who have worn these appliances for over 5 years with no adverse reactions.

We believe that the analysis provided herein supports the claim that the Luco Hybrid OSA Appliance is substantially equivalent to the predicate devices identified.

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

December 18, 2013

Luco Hybrid OSA Appliance Incorporated
Ken Luco, DDS
1419 Butternut Creek Road
Kingston, Ontario
CANADA K7L5H6

Re: K130797
Trade/Device Name: Luco Hybrid OSA 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: November 20, 2013
Received: November 22, 2013

Dear Dr. Luco:

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 contact 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. 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
-S for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
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Enclosure

# Indications for Use Statement

**510(k) Number:** K130797

**Device Name:** Luco Hybrid OSA Appliance®

**Indications for Use:**

This appliance is designed to treat primary snoring and mild to moderate obstructive sleep apnea in adults.

Prescription Use: **Yes** (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: **No** (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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