May 9, 2019

Siesta Medical, Inc
Michael Kolber
Vice President, Regulatory Affairs
101 Church Street, Suite 3
Los Gatos, California 95030

Re: K183310
Trade/Device Name: Encore System
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea
Regulatory Class: Class II
Product Code: ORY
Dated: April 2, 2019
Received: April 9, 2019

Dear Michael Kolber:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Malvina Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

# Section 4 Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

**Indications for Use**

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

Not yet known

Device Name

Encore System

Indications for Use *(Describe)*

The Encore System is intended for anterior advancement of the tongue base and hyoid suspension. It is indicated for the treatment of obstructive sleep apnea (OSA) and / or snoring.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**FORM FDA 3881 (7/17)** Page of PSC Publishing Services (301) 443-6740 EF

# 510(k) Summary

**510(k) Number:** K183310

**Submitter Name and Address**

Name: Siesta Medical, Inc.
Contact: Michael Kolber
Vice President, Regulatory Affairs
Address: 101 Church Street, Suite 3
Los Gatos, CA 95030
Telephone: 408-320-9424
Fax: 408-399-7600
Date Prepared: May 3, 2019

**General Device Information**

Product Name: Encore™ System
Common Name: Bone Screw System
Classification: 21CFR872.5570, Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Device Class: Class II
Product Code: ORY

**Predicate Devices**

Primary: Siesta Medical, Inc., Encore System, K133680
Reference: Medtronic, Inc., AIRvance System, K122391

**Device Description**

The Encore System is designed for anterior tongue base suspension by fixation of the soft tissue of the tongue base to the mandible bone and hyoid bone suspension to the mandible bone using a bone screw and suspension lines. The Encore System consists of 1) an integrated suture passer pre-loaded with size #2-0 braided polyester suture, 2) three (3) bone screws and two (2) bone screw inserters, 3) a suspension line lock tool, and 4) a threading tool. In addition, the following suspension lines are provided depending on the model number: 1) a #2 monofilament polypropylene suspension line with a radiopaque marker, 2) a size #2 braided polyester suspension line, and 3) a size #2 braided polyester suspension line with a radiopaque marker.

**Intended Use (Indications)**

The Encore System is intended for anterior advancement of the tongue base and hyoid suspension. It is indicated for the treatment of obstructive sleep apnea (OSA) and /or snoring.

The intended use has been modified to broaden the intended use from mild and moderate OSA, to now include severe OSA, similar to the MDT AIRvance System (reference predicate). This change does not raise concerns regarding the new intended use since patients who had severe sleep apnea with the Encore System experienced a

comparable reduction in their apnea hypopnea index and complications as that observed with the AIRvance System.

**Comparison of Technology**

The Encore System (subject device) has a modified intended use compared to the predicate devices. The intended use has been modified to simplify and broaden the indications statement. Also, minor changes have been made compared to the Encore System (primary predicate). These changes include adding a Bone Screw, modifying the Tether Line used to hold the Bone Screw in place on the Inserter Shaft by adding loops to ease threading the Suspension Line through the eyelet of the Bone Screw, and using a co-braided Tether Line to more easily differentiate it from the Suspension Line.

The additional Bone Screw is provided as a convenience to the physician in the event that one screw is accidently dropped and deemed non-sterile. The Looped Tether Line allows the physician to thread the Suspension Line through the Bone Screw using fewer steps and without the need for the Threading Tools. Finally, the co-braided Tether Line enables the physician to more easily differentiate it from the Suspension Line during the surgical procedure.

The availability of a spare Bone Screw and use of a co-braided Looped Tether Line prior to the surgical procedure are not differences in technology that raise concerns of safety or effectiveness. A comparison of the Encore System to the primary and reference predicate devices is provided in Table 1. The mechanism of action, design characteristics, dimensions, materials, and procedural steps are unchanged. This information supports substantial equivalence of the Encore System (subject device) to the Encore System (primary predicate) and AIRvance System (reference predicate).

**Table 1. Comparison of the Siesta Medical Encore System (Subject Device) to the Encore System (Primary Predicate) and the Medtronic AIRvance System (Reference Predicate).**

| Point of Comparison | Characteristic | Siesta Medical Encore System K183310 (Subject Device) | Siesta Medical Encore System K133680 (Primary Predicate) | Medtronic AIRvance System K122391 (Reference Predicate) | Equivalent or Effect of Change |
|---|---|---|---|---|---|
| **Product Labeling** | **Indication** | The ENCORE System is intended for anterior advancement of the tongue base and hyoid suspension. It is indicated for the treatment of obstructive sleep apnea (OSA) and / or snoring. | The ENCORE System is intended to be used for anterior advancement of the tongue base. It is also suitable for performing hyoid suspension. It is indicated for the treatment of mild or moderate obstructive sleep apnea (OSA) and /or snoring. | The AIRvance Bone Screw System is intended for anterior tongue base suspension by the fixation of the soft tissue of the tongue base to the mandible bone using a bone screw with pre-threaded suture. It is indicated for the treatment of obstructive sleep apnea (OSA) and/or snoring. The AIRvance Bone Screw System is also suitable for the performance of a hyoid suspension procedure which can be used in combination with other procedures for the treatment of obstructive sleep apnea (OSA). It is indicated for the treatment | Equivalent |

| | | | | | |
|---|---|---|---|---|---|
| | | | | of obstructive sleep apnea (OSA) and/or snoring. | |
| **Surgical Procedure** | **Anatomical Site** | Mandible bone through submental incision and the tongue and hyoid | Mandible bone through submental incision and the tongue and hyoid | Mandible bone through submental incision and the tongue and hyoid | Equivalent |
| | **Bone Screw to Suture Method of Attachment** | Surgeon threads both suture ends through bone screw, locks suture in place with lock screw | Surgeon threads both suture ends through bone screw, locks suture in place with lock screw | Suture pre-attached to bone screw | Equivalent |
| **Components** | | | | | |
| **Bone Screw** | **Purpose** | Secures suture in mandible | Secures suture in mandible | Secures suture in mandible | Equivalent |
| | **Material** | Titanium 6AL-4V | Titanium 6AL-4V | Titanium 6AL-4V | Equivalent |
| | **Diameter X Length** | 2.8 mm X 5.5 mm | 2.8 mm X 5.5 mm | 2.8 mm X 5.5 mm | Equivalent |
| **Suspension Line Lock Tool** | **Purpose** | Locking mechanism to attach the Suspension Suture to the Bone Screw | Locking mechanism to attach the Suspension Suture to the Bone Screw | None | Equivalent |
| **Bone Screw Inserter** | **Purpose** | Places the bone screw into the bone (n=3) | Places the bone screw into the bone (n=2) | Places the bone screw into the bone | Equivalent |
| **Threading Tool** | **Purpose** | Threads Suspension Suture through Bone Screw eyelet | Threads Suspension Suture through Bone Screw eyelet | None | Equivalent |
| **Suture Passer** | **Purpose** | Passes suture through the tongue | Passes suture through the tongue | Passes suture through the tongue | Equivalent |
| **Suspension Line** | **Purpose** | Anterior advancement of the tongue and hyoid suspension | Anterior advancement of the tongue and hyoid suspension | Anterior advancement of the tongue and hyoid suspension | Equivalent |
| | **Material** | #2 monofilament polypropylene with a radiopaque marker<br>#2 braided polyester<br>#2 braided polyester with a radiopaque marker | #2 monofilament polypropylene with radiopaque marker<br>#2 braided polyester<br>#2 braided polyester with a radiopaque marker | #1 monofilament polypropylene | Equivalent |
| **Working Suture** | **Purpose** | Pull Suspension Suture through tongue anteriorly | Pull Suspension Suture through tongue anteriorly | Pull Suspension Suture through tongue anteriorly | Equivalent |
| | **Material** | #2-0 braided PTFE-coated polyester | #2-0 braided PTFE-coated polyester | #1 polypropylene monofilament | Equivalent |
| **Tether Line** | **Purpose** | Hold Bone Screw on Inserter Shaft | Hold Bone Screw on Inserter Shaft | None | Equivalent |
| | **Material** | Co-braided polyester / PTFE coating, with loops | Polyester/PTFE coating, no loops | None | Equivalent |
| **Test Results** | | | | | |
| **Biocom-patibility** | - | Biocompatible, same materials as predicate device | Biocompatibility, same materials as predicate device | Not reported | Equivalent |
| **Bench** | **Suspension Line Endurance** | Pass | Pass | Pass | Equivalent |
| | **Bone Screw-to-Suspension Line Fixation Strength** | Pass | Pass | Pass | Equivalent |
| **Clinical** | **Literature Review** | Product similar to the Siesta Encore System (K133680) | Literature review comparing Encore System to AIRvance | Literature review comparing Encore System to AIRvance | Equivalent |

**Summary of Non-Clinical Performance Testing**

**Bench Test**

Tether Loop Strength Test – Assess Tether Loop strength as Suspension Line is pulled through eyelet of Bone Screw

**Risk Assesment/Analysis**

A Failure Modes and Effects Analysis (FMEA) was used to assess changes made to the subject Encore System compared to the predicate Encore System. The analysis determined that the Tether Loop strength exceeds the suture loading force, resulting in an acceptable low risk category.

**Referenced Standards**

ISO 10993-7: 2012 - Ethylene oxide sterilization residuals
ISO 11135: 2014 - Sterilization of health care products – Ethylene oxide: Requirements for development, validation and routine control of a sterilization process for medical devices

**Summary of Clinical Performance Testing**

The published clinical experiences utilizing the Siesta Medical Encore System and the Medtronic AIRvance System are presented. Data is presented from 16 peer-reviewed clinical studies which include a total of 377 treated moderate-severe or severe patients (Table 2).

**Table 2. Clinical Studies from the Medical Literature.**

| Treatment Method | Studies (n) | Total Patients (n) | AHI* Reduction (range) | Average AHI Reduction (weighted average) |
|---|---|---|---|---|
| Encore System | 2 | 45 | 41.7 – 69.9% | 61.8% |
| AIRvance System | 14 | 332 | 34.7 – 77.4% | 57.8% |
| Total | 16 | 377 | - | - |

* AHI - apnea hypopnea index

Patients with severe sleep apnea were treated with the Encore System and experienced a significant reduction in their apnea hypopnea index (AHI) (61.8%) that was similar to the reduction observed with the AIRvance System (57.8%). In addition, the complications are similar between the subject and predicate devices.

The medical literature supports the safety and efficacy of suture based hyoid and tongue suspension for the proposed intended use. The Medtronic AIRvance System, a device with similar features, is well documented in the medical literature with extensive clinical data supporting its use, as well as regulatory recognition in the form of marketing clearance.

The literature review of published clinical articles demonstrated that the modified intended use does not adversely affect safety and effectiveness.

**Statement of Equivalence**

Based on similarities in indications for use and technological characteristics, as well as non-clinical and clinical performance (medical literature) testing, we believe the Encore System is substantially equivalent to the predicate devices.