December 22, 2021

Siesta Medical, Inc.
Michael Kolber
Vice President
101 Church Street
Los Gatos, California 95030

Re: K213159
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: September 25, 2021
Received: September 28, 2021

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K213159

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5 510(k) Summary

510(k) Number	K213159	
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	408-505-6626	
Fax	408-399-7600	
Date Prepared	September 25, 2021	
General Device Information		
Product Name	Encore™ System	
Common Name	Intraoral device for snoring and obstructive sleep apnea	
Classification	21CFR872.5570 Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.	
Device Class	Class II	
Product Code	ORY	
Predicate Device Manufacturer	**Device Name**	**510(k) Number**
Siesta Medical, Inc.	Encore System	K201238

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, 4) a threading tool, and 5) a drill bit. In addition, the following suspension lines are provided depending on the model number: 1) #2 braided polyester suspension line and 2) #2 braided polyethylene suspension line.

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.

Comparison to the Predicate Device

Labeling for the Encore System has been modified with respect to the MRI statement for the Encore Systems packaged with the #2 braided polyester suspension line and the #2 braided polyethylene suspension line. The labeling has changed as follows:

From:

MRI Safety Information: The ENCORE System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the ENCORE System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

To:

MRI Safety Information:
A patient implanted with the Encore Bone Screw may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Nominal value(s) of Static Magnetic Field [T]	1.5 T ro 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, head RF transmit-receive coil
Maximum Whole Body SAR [W/kg]	4.0 W/kg (First Level Operating Mode)
Limits on Scan Duration	4.0 W/kg whole body average SAR for 15 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 12mm

If information about a specific parameter is not included, there are no conditions associated with that parameter.

In addition, the drill bit has been lengthened from 5 mm to 10 mm.

Summary of Non-Clinical Testing

Performance testing was conducted to confirm that the implantable metallic components of the Encore System do not pose a significant risk to a patient in a clinical MRI environment under the conditions presented in the labeling.

Statement of Equivalence

The Encore System has the same design, indications for use and the same technological characteristics as the predicate device. Based on this and the data provided in this pre-market notification, the subject device and the predicate device have been shown to be substantially equivalent.