Attachment 2: 510(k) Summary (per 21CFR 807.92)

DEC 0 6 2012

510(k) Number	K121440	
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:	October 29, 2012	
General Device Information		
Product Name:	ENCORE™ Tongue Suspension 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 Device		
Manufacturer	Device Name	510(k) Number
Siesta Medical, Inc.	ENCORE Tongue Suspension System	K111179

Device Description

The ENCORE Tongue Suspension System is designed for anterior tongue base suspension by fixation of the soft tissue of the tongue base to the mandible bone using a bone screw and suture. The ENCORE Tongue Suspension System consists of an integrated suture passer pre-loaded with size #2-0 braided polyester suture, a titanium bone screw that is pre-mounted on an inserter, a suspension line lock tool, and a Threading Tool. In addition, the following suspension lines are provided depending on the model number: 1) a size #1 monofilament polypropylene suspension line, 2) a size #1 monofilament polypropylene suspension line with a radiopaque marker, 3) a size #2 monofilament polypropylene suspension line with a radiopaque marker, 4) a size #2 braided polyester suspension line, and 5) a size #2 braided polyester suspension line with a radiopaque marker.

Intended Use (Indications)

The Siesta Medical, Inc. ENCORE Tongue Suspension System is intended to be used for anterior advancement of the tongue base by means of a bone screw threaded with suture. It is indicated for the treatment of mild or moderate obstructive sleep apnea (OSA) and /or snoring.

Comparison to the Predicate Device
The modified ENCORE Tongue Suspension System has the same intended use and fundamental scientifc technology as the predicate device. The technological characteristics of the modified ENCORE Tongue Suspension System are substantially equivalent to the predicate device including packaging, biocompatibility, sterilization, and labeling. Through bench performance testing it was demonstrated that the design modifications do not adversely affect safty and effectiveness.
Summary of Non-Clinical and Clinical Testing
The non-clinical test data provided in this submission demonstrated that the ENCORE Tongue Suspension System meets the performance specifications. The submission includes the following test results: Suture Endurance Test, Bone Screw Fixation Strength Test, Radiographic Visibility of Suspension Line Marker, ENCORE System Removability in Chronic Porcine Model. The non-clinical data test results confirm the design modifications do not adverse affect the safety and effectiveness. Clinical testing was not provided in this submission.
Statement of Equivalence
The ENCORE Tongue Suspension System has the same 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 6, 2012

Mr. Michael Kolber
Vice President, Regulatory Affairs
Siesta Medical, Incorporated
101 Church Street, Suite 3
LOS GATOS CA 95030

Re: K121440
Trade/Device Name: ENCORE™ Tongue Suspension System
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: ORY
Dated: October 29, 2012
Received: November 1, 2012

Dear Mr. 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. 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
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121440

Device Name: Siesta Medical, Inc. ENCORE™ Tongue Suspension System

Indications for Use: The Siesta Medical, Inc. ENCORE Tongue Suspension System is intended to be used for anterior advancement of the tongue base by means of a bone screw threaded with suture. It is indicated for the treatment of mild or moderate obstructive sleep apnea (OSA) and /or snoring.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

Susan Runner DDS, MA 2012.12.05 16:17:34 -05'00'

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

510(k) Number:_____