K121814

NOV 7 2012

Appendix 3: 510(k) Summary

General Company Information		
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:	July 31, 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

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 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 bone screw 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, and 4) a size #2 braided polyester suspension line.

Similar to the predicate ENCORE System, the modified ENCORE Tongue Suspension System 1) uses a bone screw, 2) a bone screw inserter to place a bone screw into the bone, and 3) a needle to pass a suspension suture submucosally through the base of the tongue. The ENCORE uses a Suture Passer and working suture loops to pass a suture from the posterior to anterior position in the tongue. The ENCORE advances the tongue in the anterior direction with a suspension line. A Threading Tool is provided to ease passage of the suspension line through the bone screw.

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.
Substantial Equivalence
The ENCORE Tongue Suspension System has the following similarities to the previously cleared predicate device: the same intended use, operating principle, technology, and manufacturing process. This submission supports the position that the Siesta Medical, Inc. modified ENCORE Tongue Suspension System is substantially equivalent to the predicate ENCORE Tongue Suspension System (K111179). The 510(k) includes a test report to support extension of the shelf-life to 2 years.
Conclusions
Siesta Medical, Inc. believes that the information provided demonstrates that the modified device is substantially equivalent to the predicate device and does not raise any new issues of safety or efficacy. Based on the indications for use, technological characteristics, and comparison to the predicate device, the modified ENCORE Tongue Suspension System has been shown to be substantially equivalent to predicate device as described under the Federal Food, Drug and Cosmetic Act.

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

November 7, 2012

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

Re: K121814
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 8, 2012
Received: October 9, 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 Digitally signed by Kwame O. Ulmer DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Kwame O. Ulmer, 0.9.2342.19200300.100.1.1=1300183618 Date: 2012.11.07 12:13:55 -05'00' for

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): K121814

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.

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

510(k) Number: K121814

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)