The Center for Craniofacial & Dental Sleep Medicine
% Cheryl Fisher
Prinicipal Consultant
FisherMed Consulting LLC
260 Howard Drive, Santa Clara California 95051

November 28, 2017

Re: K170053
Trade/Device Name: Meridian PM
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: LRK, LQZ
Dated: October 2, 2017
Received: October 20, 2017

Dear Cheryl Fisher:

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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170053

Device Name
Meridian PM

Indications for Use *(Describe)*
The Meridian PM is intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

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.

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510(k) Summary

Meridian PM

K170053

1. **Submission Sponsor**

Center for Craniofacial and Dental Sleep Medicine

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Sugarland

TX, 77479

United States

Contact: Sam Cress D.D.S.

Title: Director

2. **Submission Correspondent**

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Office Phone: (408) 410-5920

Contact: Cheryl Fisher

Title: Principal Consultant, RA/QA

3. **Date Prepared**

6/15/2017

4. **Device Identification**

Trade/Proprietary Name:	Meridian PM
Common/Usual Name:	Intraoral Devices for Snoring and /or Obstructive Sleep Apnea
Classification Name:	Intraoral Devices for Snoring and /or Obstructive Sleep Apnea
Regulation Number:	872.5570

Product Code: LRK, Device, Anti Snoring- Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.

LQZ, Device, Jaw Repositioning- Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea

Device Class: Class II

Classification Panel: Dental

5. Legally Marketed Predicate Device(s)

Main Predicate
K153291 OptiSleep Device by SICAT

Secondary Predicate
K113516 CAST device by TheraSom

6. Indication for Use Statement

The Meridian PM is intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

7. Device Description

The Center for Craniofacial & Dental Sleep Medicine wishes to submit their Anti-Snoring & Sleep Apnea Device(s) trade name, Meridian PM, that falls under FDA Regulation Number §872.5570 and Product Codes LRK and LQZ defined as follows:

Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea are devices that are worn during sleep to reduce the incidence of snoring and to treat obstructive sleep apnea. The devices are designed to increase the patency of the airway and to decrease air turbulence and airway obstruction. The classification includes palatal lifting devices, tongue retaining devices, and mandibular repositioning devices.

The summary report is submitted in accordance with FDA's "Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Sleep Apnea; Guidance for Industry and FDA."

For discussion purposes only, the Meridian PM is a single device consisting of two parts and upper appliance and lower appliance it is collectively known as the Meridian PM : The Meridian PM treats snoring and Obstructive Sleep Apnea (OSA).

The Meridian PM device is used in a patient treatment model for specific diagnosis of simple snoring, and/or Obstructive Sleep Apnea (OSA).

The upper and lower appliances help to reposition the lower jaw such that it is moved to a forward position during sleep.

The Meridian PM system is used for treating snoring and obstructive sleep apnea and consists of two custom fitted trays which fit over the upper and lower teeth and engage by means of adjustable vertical wings, or by the industry standard "*Herbst* mechanism" which is a rod and tube type assembly that orientates the jaws in a predetermined relationship. These device(s) function as a *mandibular repositioning or mandibular advancment device* (MAD) as Meridian PM acts to increase the patient's pharyngeal space, improving their ability to exchange air during sleep, decreasing symptoms of OSA. The devices will be custom made for each patient and allow the dentist or physician to control the degree of mandibular advancement at the time of device delivery. The device(s) will be sold by prescription only.

8. Substantial Equivalence Discussion

The following table compares the Meridian PM to the predicate device(s) with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics

Feature	**Meridian PM**	**SICAT OPTISLEEP**	**TheraSom-CAST**	**Comparison**
510 (k) Number	K170053	K153291	K113516	Same method
Manufacturer	Center for Craniofacial and Dental Sleep Medicine	SICAT GmbH & Co	Family Dental Service PC	NA
Primary Device Similarities to support Substantial Equivalence				
Classification #	872-5570	872-5570	872-5570	Same
Product Code	Primary LRK Secondary LQZ	Primary LRK Secondary LQZ	Primary LRK Secondary LQZ	Same
Indications for use	The Meridian PM is intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	In adult population • To reduce or alleviate snoring • To reduce or alleviate mild to moderate obstructive sleep apnea (OSA)	The TheraSom-CAST is used to reduce or alleviate the occurrence of snoring and/or for the treatment of mild to moderate obstructive sleep apnea (OSA) in patients 18 years of age or older	Similar to both predicates the Meridian PM Indications for use is aligned with product code LRK

Mode of Action	These devices function as a mandibular repositioner, which acts to increase the patient's pharyngeal space, improving their ability to exchange air during sleep.	This device functions as a mandibular repositioner, maintaining the lower jaw in a forward position during sleep. This mechanical protrusion acts to increase the patient's pharyngeal space, improving the ability to exchange air during sleep by reducing mechanical obstructions of the airway.	The device functions as a mandibular repositioner, which acts to improve the patient's ability to breathe without obstruction of the pharyngeal airway	Similar mode of action with slight technical deviations discussed below, not incurring additional patient risks
Material	**Acrylic** *The main parts of the device(s) are made of Acrylic Material, Stainless Steel, and Dental Alloy Material*	**Milled Acrylic** *The main parts of the device are made of Polymethylmeth acrylate. The exchangeable* *connectors are made of Polyamide*	**Cast Metal** Dental Alloy Material	The Meridian PM and OptiSleep devices are made of an acrylic material while the TheraSom is made of a dental metal alloy there is no significant difference between the Meridian PM and the OptiSleep regarding the acrylic base material used

Mode of Care	Adjustable by Dentist or Physician during the duration of use	Adjustable by Dentist or Physician during the duration of use	Adjustable by Dentist or Physician during the duration of use	Same
Insertion	the upper and lower appliance to be inserted at the same time	the upper and lower appliance to be inserted at the same time	the upper and lower appliance to be inserted at the same time	Same
Usage	Removable and Reusable by the same patient. Night Time Usage Only for Meridian PM device	Removable and Reusable by the same patient. Night Time Usage Only	Removable and Reusable by the same patient. Night Time Usage Only	Same
Biocompatible	Yes	Yes	Yes	Same
OTC or Rx	Rx	Rx	Rx	Same
Device Technological Differences Difference				
Fabrication	Hand made from acrylic and wire formation	Computer generated – milled from acrylic	Hand waxed and metal casted	Hand made component exists in the TheraSom device and a similar acrylic material is used in the OptiSleep device neither of these variations incur additional risk to the patients than are already present in the currently marketed devices.
Retention	Upper appliance has acrylic coverage on the occlusal and mid buccal and lingual	Upper and lower appliance has acrylic coverage on the	Upper appliance has metal casting that are formed around the	The Meridian PM and OptiSleep both have and acrylic coverage

	posterior teeth with retention clasp – Lower appliance has cast metal retention from the buccal of the posterior teeth wrapping to the lingual with acrylic anterior lingual coverage	buccal and lingual aspect of the teeth to the gum line	height of contour of the cuspid and bicuspid teeth – Lower appliance and metal casting covering the occlusal surface of the premolars and molar teeth	on commensurate dentition on the upper appliance the Meridian PM and the TheraSom device both utilize a metal casting in the lower appliance for retention incurring no additional risk the patient than are already present in currently marketed devices.

9. Non-Clinical Performance Data

As part of demonstrating the substantial equivalence of Meridian PM to the predicate devices that are subject to this 510(k) submission, The Center for Craniofacial and Dental Sleep Medicine completed a number of non-clinical performance tests, including:

- Determination Of Flexural Properties
  Test Method : ISO 178:2010/Amd.1:2013(E) Method A
- Plane-Strain Fracture Toughness and Strain Energy Release Rate of Plastic Materials
  Test Method : ASTM D5045 -14 (modified notch geometry)
- Tensile Properties
  Test Method : ASTM D638-14 - Modified specimen length, test speed and grip separation

The Meridian passed all the testing in accordance with internal requirements, applied national standards, and applied international standards shown below to support substantial equivalence of the subject device:

Biocompatibility - The biological compatibility of the Meridian PM was evaluated in accordance with ISO 10993-1:2009 and guidance document entitled *Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing within a Risk Management Process*" dated 16 June 2016. Under these, for the stated indications for use, each component of the device's biological compatibility was evaluated for in vitro cytotoxicity, skin sensitization, and irritation, and chemical characterization.

- Biocompatibility testing per ISO 10993-1: Passed
- Biocompatibility testing per ISO 10993-5 Cytotoxicity: Passed
- Biocompatibility testing per ISO 10993-10 Tests for irritation and skin sensitization: Passed
- Biocompatibility testing per ISO 10993-18 Chemical Characterization: Passed

Risk Analysis - Formal Risk Assessment of the Meridian PM was performed in accordance with ISO 14971. With respect to perceivable conditions in which the device would be subjected to a worst-case environmental or human error scenario, Center for Craniofacial and Dental Sleep Medicine believes the outcomes of these risks are considered acceptable within the context of ISO 14971, and that all potential risks have been mitigated to the lowest form.

10. **Performance Testing Summary**

As part of demonstrating the substantial equivalence of Meridian PM to the predicate devices that are subject to this 510(k) submission, Center for Craniofacial and Dental Sleep Medicine completed a number of tests. The Meridian PM meets all the requirements for overall design, biocompatibility, and performance testing confirm that the output meets the design inputs and specifications. The Meridian PM passed all testing stated above as shown by the acceptable results obtained.

The Meridian PM complies with the applicable voluntary standards for biocompatibility. The device passed all the testing in accordance with national and international standards.

11. Statement of Substantial Equivalence

It has been shown in this 510(k) submission that the differences between the Meridian PM and the predicate device do not raise any different questions. The performance testing provided demonstrates that the subject device is substantially equivalent to the predicate devices. The Enter for Craniofacial and Dental Sleep Medicine Meridian PM, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.