DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Selane Products, Inc.
% Carolyn Primus
Consultant
Primus Consulting
7046 Owl's Nest Terrace
Bradenton, Florida 34203

July 27, 2017

Re: K162816
Trade/Device Name: Sml-osa2 Appliances
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: LQZ, LRK
Dated: June 25, 2017
Received: June 29, 2017

Dear Ms. Carolyn Primus:

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 contact the Division of Industry and Consumer Education 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. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

Mary S. Runner -S

for
Lori Wiggins
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162816

Device Name
SML-OSA2 Appliances

Indications for Use *(Describe)*
The SML-OSA2 Appliances are intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea in adults. The SML-OSA2 appliances are worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The customized appliance is inserted and removed by the patient and adjusted by the prescribing dentist.

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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K162816

510(k) Summary

Submitted by:	Space Maintainer Laboratory, Division of Selane products 9129 Lurline Ave. Chatsworth, CA 91311
Contact Person:	Mr. John Christian
Date Prepared:	July 25, 2017
Device Trade Name:	SML-OSA2 Appliances
Device Description:	Device, Jaw Repositioning
Device Class:	Class II
Regulation:	872.5570
Classification Panel:	Dental
Product Code:	LQZ, LRK
Predicate Device:	ATG/SM-OSA Appliances (K130130).

Device Description: The SML-OSA2 APPLIANCES include five device models: Adjustable Sleep Appliance (ASA), Clear Sleep Adjustable Dorsal, Clear Sleep Adjustable Anterior, Quiet Night Appliance (QNA) and V-force.

The SML-OSA2 Appliances are customized, intraoral dental devices designed to reduce snoring and mild to moderate obstructive sleep apnea in adults. The devices fit over the dentition and reposition the mandible in a slightly protrusive position. The SML-OSA2 APPLIANCES consist of 2 arch forms that are linked to advance the mandible, and are worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The customized appliance is inserted and removed by the patient and adjusted by the prescribing dentist.

The SML-OSA2 APPLIANCES are made by Appliance Therapy Group/Space Maintainer Laboratory, which is owned/operated by Selane Products, Inc. Appliance Therapy Group/Space Maintainer Laboratory will manufacture these customized, prescription devices. These reusable (repeated use by one patient) devices will be provided to the patient non-sterile.

Indications for Use: The SML-OSA2 Appliances are intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea in adults. The SML-OSA2 appliances are worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The customized

appliance is inserted and removed by the patient and adjusted by the prescribing dentist.

TECHNOLOGICAL CHARACTERISTICS:

Intended Use

The Indications for Use for the SML-OSA2A Appliances are identical to the ATG/SM-OSA Appliances' Indications for Use. Both the proposed and predicate devices are intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea in adults A more in-depth comparison of the materials of construction is provided in the Substantial Equivalence section.

Design

The SML-OSA2 APPLIANCES are made primarily of dental acrylic. Three modified designs (ASA, Clear Sleep Adjustable Dorsal, and Clear Sleep Adjustable Anterior) are a variation of the Dorsal design. Two modified designs (QNA and V-force) are a variation of the Herbst design. Stainless steel or elastomeric parts are incorporated to allow adjustment of the appliances. These designs may have dual-laminate dental polymers in place of the acrylic. Table S-1 summarizes the design characteristics of the five models of the proposed device.

The function, scientific concept and principle of operation are the same for each device design. The principle of operation is that two connected arch forms maneuver the mandible forward. The position of the mandible prevents the tongue from sliding backward or downward for a prone sleeping individual. Therefore, the airway will be more open, contributing to the reduction in snoring and mild to moderate sleep apnea.

Table S-1: Five Design Models of the Subject SML-OSA2

SML-OSA2 Appliance	Similarities to K130130	Differences from K130130
Adjustable Sleep Appliance (ASA)	Similar to the K130130 Dorsal.	Adjustable arch width with midline screw on maxillary arch; partial anterior coverage.
Clear Sleep Adjustable Dorsal	Similar to the K130130 Dorsal.	Acrylic wings are replaced with acrylic interlocking tabs.
Clear Sleep Adjustable Anterior	Similar to the K130130 Dorsal.	Adjustments in the anterior instead of the buccal corridor (area between the lateral margin of the lips and the outside of the posterior dental arches).
Quiet Night Appliance (QNA)	Similar to the K130130 Herbst.	Stainless steel connectors are replaced with polymer (POM) connectors.
V-force	Similar to the K130130 Herbst.	Stainless steel connecting hinges are replaced with orthodontic elastomers and acrylic tabs. Acrylic interlocking tabs are included to advance the mandible.

APPLIANCES' Materials

SML-OSA2 Appliances are manufactured of Stainless Steel 304, Stainless Steel 316, Polymethylmethacrylate, SBS/EVA laminate or Polyurethane/copolyester, Polyoxymethylene (POM), and intraoral latex rubber elastomers. Table S-2.1 through Table S-2.5 list the materials of each of the SML-OSA2 Appliances, and indicate that these materials have been used in the predicate device, in previously cleared dental devices, or have otherwise been proven safe for intraoral use.

Table S-2.1: Adjustable Sleep Appliance (ASA) Construction

MATERIAL	DEVICE PART	Predicate Device ATG/SM-OSA	Subject Device SML-OSA2	Acceptable Material for Medical Device Use
Stainless Steel 304/316	Connectors	Yes	Yes	K130130
Polymethyl Methacrylate (PMMA Acrylic)	Maxillary & Mandibular Arch Forms	Yes	Yes	K130130
SBS/EVA laminate or Polyurethane/ copolyester	Maxillary & Mandibular Arch Forms	Yes	Yes	K130130
Vitallium 2000 partial denture alloy	Maxillary	Yes	No	K130130

Table S-2.2: Clear Sleep Adjustable Dorsal Construction

MATERIAL	DEVICE PART	Predicate Device ATG/SM-OSA	Subject Device SML-OSA2	Acceptable Material for Medical Device Use
Stainless Steel 304/316	Connectors	Yes	No	K130130
Polymethyl Methacrylate (PMMA Acrylic)	Maxillary & Mandibular Arch Forms	Yes	Yes	K130130
	Connectors	No	Yes	K130130
SBS/EVA laminate or Polyurethane/ copolyester	Maxillary & Mandibular Arch Forms	Yes	Yes	K130130

Table S-2.3: Clear Sleep Adjustable Anterior Construction

MATERIAL	DEVICE PART	Predicate Device ATG/SM-OSA	Subject Device SML-OSA2	Acceptable Material for Medical Device Use
Stainless Steel 304/316	Connectors	Yes	No	K130130
Polymethyl Methacrylate (PMMA Acrylic)	Maxillary & Mandibular Arch Forms	Yes	Yes	K130130
SBS/EVA laminate or Polyurethane/ copolyester	Maxillary & Mandibular Arch Forms	Yes	Yes	K130130

Table S-2.4: Quiet Night Appliance (QNA) Construction

MATERIAL	DEVICE PART	Predicate Device ATG/SM-OSA	Subject Device SML-OSA2	Acceptable Material for Medical Device Use
Stainless Steel 304/316	Connectors	Yes	No	K130130
Polyoxymethylene (POM)	Connectors	No	Yes	FDA Biomaterials Compendium (1)
Polymethyl Methacrylate (PMMA Acrylic)	Maxillary & Mandibular Arch Forms	Yes	Yes	K130130
SBS/EVA laminate or Polyurethane/ copolyester	Maxillary & Mandibular Arch Forms	Yes	Yes	K130130

1 Polyoxymethylene (POM) is a recognized polymeric thermoplastic in the FDA Biomaterials Compendium.

Table S-2.5: V-force Construction

MATERIAL	DEVICE PART	Predicate Device ATG/SM-OSA	Subject Device SML-OSA2	Acceptable Material for Medical Device Use
Stainless Steel 304/316	Connectors	Yes	No	K130130
Latex Rubber Elastomers	Connectors	No	Yes	FDA Biomaterials Compendium(1), K935144 (2)
Polymethyl Methacrylate (PMMA Acrylic)	Maxillary & Mandibular Arch Forms	Yes	Yes	K130130
SBS/EVA laminate or Polyurethane/ copolyester	Maxillary & Mandibular Arch Forms	Yes	Yes	K130130

1 Natural latex is a recognized polymeric thermoset/elastomer in the FDA Biomaterials Compendium.

2 Latex rubber elastomers will be purchased from Dentaurum GmbH & Co. KG, Registration Number 9611458 or another FDA registered and listed establishment with FDA clearance for intraoral latex elastics.

Substantial Equivalence

Table S-3 has a comparison of the predicate and the subject devices with regard to their substantial equivalence.

Table S-3: Substantial Equivalence Comparison of Devices

	Predicate Device ATG/SM-OSA Appliances	Subject Device SML-OSA2 Appliances
510(k) #	K130130	K162816
Class	II	II
Pro Code	LQZ, LRK	LQZ, LRK
Regulation #	872.5570	872.5570
Regulation Name	Intraoral Devices for Snoring and Obstructive Sleep Apnea	Intraoral Devices for Snoring and Obstructive Sleep Apnea
Indications for Use	The ATG/SM-OSA appliances are intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea in adults. The ATG/SM-OSA appliances are worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The customized appliance is inserted and removed by the patient and adjusted by the prescribing dentist.	The SML-OSA2 appliances are intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea in adults. The SML-OSA2 appliances are worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The customized appliance is inserted and removed by the patient and adjusted by the prescribing dentist.
Models	Dorsal Herbst	1. Adjustable Sleep Appliance (ASA) 2. Clear Sleep Adjustable Dorsal 3. Clear Sleep Adjustable Anterior 4. Quiet Night Appliance (QNA) 5. V-force
Patient Contact	Acrylic, polymers, and stainless steel	Acrylic, polymers, elastomers, and stainless steel
Biocompatibility per ISO 7405 & 10993-1	External communicating (>30 days) Surface-contacting (mucosa)	External communicating (>30 days) Surface-contacting (mucosa)
Sterility	Non-sterile	Non-sterile
Type of Device	Customized, prescription	Customized, prescription
Scientific Principle	Moves lower mandible forward during sleep	Moves lower mandible forward during sleep
Design	Upper and lower arches to support jaw	Upper and lower arches to support jaw
Adjustable or Fixed	Adjustable	Adjustable
Connection Parts	Stainless steel connectors	Polyoxymethylene (POM) connectors, acrylic spacers, and orthodontic elastomers

The indications for use are identical for the predicate K130130 and subject K162816 devices. No significant differences exist in technology, intended use, or design between the subject devices and the predicates selected.

Performance Standards:

- *ISO 7405 Second edition 2008-12-15, dentistry - evaluation of biocompatibility of medical devices used in dentistry* as published in the Federal Register (Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 036; 07/09/2014).
- The special control for these devices is the FDA guidance document entitled "Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA." [Nov. 12, 2002]

Biocompatibility:

The predicate and subject devices are considered to be external communicating devices of permanent exposure (>30 days) per ISO 7405 and surface-contacting devices (mucosa) of permanent contact (>30 days) per ISO 10993-1. No changes have been made in the primary materials of construction from the sponsor's own predicate device. In some models, stainless steel connecting parts have been substituted with Polyoxymethylene (POM) or intraoral latex rubber elastomers.

No biocompatibility tests have been performed for the modified devices; the new materials have also been used in other cleared intraoral devices and implantable devices.

Clinical Testing:

No clinical testing is required for these devices.

Risk Analysis:

A risk analysis including an evaluation of the materials of construction and design was performed. The function of mandibular advancement devices requires that the prescribing dentist be cognizant of the potential for TMJ soreness, soft tissue soreness, and dentition complications (soreness, motion, loosening) by mandibular advancement. The contraindications, warnings, precautions, storage directions, prescription preparation instructions, fitting and adjustment directions are provided to avoid potential problems from arising or persisting with the dentition, tissue, or joints. A risk related to the polymer spacers was addressed. No significant new risks were identified.

Conclusions:

The subject devices have identical indications for use to the predicate devices. The intended use, materials of construction, technology, principle of operation, and designs of the SML-OSA2 Appliances are comparable to the legally marketed predicate. Therefore, the proposed SML-OSA2 Appliances are substantially equivalent to the predicate.