K130130

(21 CFR 801 Subpart C)

510(k) Summary- REVISED

per 21CFR807.92

CONTACT:

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AUG 2 6 2013

DATE PREPARED: June 9, 2013

TRADE OR PROPRIETARY NAME: ATG/SM-OSA APPLIANCES

CLASSIFICATION NAME: Intraoral devices for snoring and obstructive sleep apnea: CFR 872.5570, Product Code LQZ & LRK

PREDICATE DEVICE: K103076

DEVICE DESCRIPTION: The ATG/SM-OSA APPLIANCES are primarily polymer trays that are used intraorally over the dentition to make the mandible protrude. Three designs are included: Adjustable Herbst, Adjustable Dorsal, and MIRS. The mandible protrusion is controlled by stainless steel tubes & rods or screws for the Herbst and Dorsal designs. The MIRS single-piece construction has a lingual rest to set the mandibular protrusion. Each device is fabricated to the prescription of a dentist.

INTENDED 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.

TECHNOLOGICAL CHARACTERISTICS vs. the predicate device: The ATG/SM-OSA APPLIANCES are essentially identical in indications for use to the predicate devices of DynaFlex® Anti-snoring and Sleep Apnea Devices: LISA, DORSAL and HERBST ADJUSTABLE Appliances. Both the present and predicate devices are customized for the patient using a prescription from the dentist. The scientific principle for the device is mandibular advancement determined by the design of the device.

Three designs of the ATG-/SM-OSA designs are included which are denoted as MIRS, Adjustable Dorsal and Adjustable Herbst, which we believe are the same as the predicate DynaFlex® Anti-snoring and Sleep Apnea Devices: LISA, DORSAL and

HERBST ADJUSTABLE Appliances, respectively. Both the ATG/SM-OSA APPLIANCES and the predicate DynaFlex® Anti-Snoring & Sleep Apnea Devices are composed primarily of dental polymers. Dental acrylic and dual-laminate polymers are used in the predicate and new designs.

The Herbst and Dorsal designs of both the new and predicate devices include stainless steel fixation attachments that unite the upper and lower mandible trays, to allow for adjustments in the mandibular advancement. Stainless steel attachments are used in the Herbst and Dorsal designs of both the predicate and new devices. The linkage of the upper and lower trays and the trays themselves seem identical for both the predicate and new devices.

A metallic palate design is included for the adjustable Herbst design of the new OSA appliance. The material of the metal palate is a dental alloy that is used for partial dentures, which is unlike the predicate Herbst device. However, the metal palate is identical to partial denture designs for the palate, and uses the same materials as partial dentures, with the addition of acrylic and stainless steel attachments on the maxillary posterior buccal area. The designs are completed in the laboratory such that the metal palate does not contact the opposing dentition or polymer tray.

The Lisa design of the predicate and the new MIRS design are essentially the same, using a lingual rest protruding from a polymer tray formed to cover the maxillary dentition. This lingual rest creates mandibular protrusion, designed to meet the prescription of the dentist.

RISKS: Selane Products Inc. performed no clinical or non-clinical testing. However, an FMEA risk analysis, and evaluation of the materials of construction and design were 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. Management of these risks is achieved by advising the patient and dentist in the directions for use that early and repeated examination of the fit of the device, and its performance, must be performed in the dental office by the prescribing dentist. The contraindications, warnings, precautions, storage directions, prescription preparation instructions, fitting and adjustment directions are written to avoid potential problems from arising or persisting with the dentition, tissue, or joints, caused by the OSA devices. No new materials are being used in the devices; all materials are already used in dental laboratories for other devices of a related nature. No new risks are introduced with the new devices that are not present in the predicate devices.

CONCLUSIONS: By comparison and analysis of the new and predicate devices, we note herein that the intended use, the designs, the functions, and the polymeric and stainless steel materials for the acrylic and the dual-laminate polymer models of the devices are the same as the predicate. The metal palate design of the adjustable Herbst device requires the fabrication technology, material, and palate design that

are used for removable dentures; these characteristics are suitable for the ATG/SM-OSA devices, because they do not change the function of the Herbst adjustable device, and do not affect safety or efficacy for mandibular advancement and treatment of mild to moderate OSA.

We believe that the analysis provided herein supports the substantial equivalence in safety and effectiveness to the predicate device, and we believe the new devices are as safe, as effective, and perform as well as the legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 26, 2013

Selane Products, Incorporated
C/O Carolyn M. Primus, PhD
Consultant
Primus Consulting
7046 Owl's Nest Terrace
BRADENTON FL 34203

Re: K130130
Trade/Device Name: ATG/SM-OSA APPLIANCES
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: LQZ, LRK
Dated: August 2, 2013
Received: August 7, 2013

Dear Dr. 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 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. 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 Ulmer M.S.
Acting Division 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):K130130

Device Name: ATG/SM-OSA APPLIANCES

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.

Susan Runner DDS, MA Mary S. Runner -S 2013.08.26 12:35:53 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and
Dental Devices
510(k) Number: _K130130_____

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