DaSoft Partners
% Alyssa Schwartz
Principal, Regulatory Affairs Consultant
ASchwartz Consulting
1225 Hall Road
West Chester, Pennsylvania 19380

July 10, 2018

Re: K172991
Trade/Device Name: Advanced Dental Applicance
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
Dated: May 30, 2018
Received: May 31, 2018

Dear Alyssa Schwartz:

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 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)*

Device Name
DaSoft Advanced Dental Appliance

Indications for Use *(Describe)*
The DaSoft Advanced Dental Appliance is indicated to reduce snoring in adult patients aged 18 years or older.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitted By:	DaSoft Partners 4079 Governer Drive, #111 San Diego, CA 92122 619-405-1530
Contact Person:	Alyssa Schwartz Regulatory Affairs Consultant 1225 Hall Road West Chester, PA 19380 610-806-6895
Date Prepared:	July 9, 2018
Trade Name:	DaSoft Advanced Dental Appliance
Common Name:	Anti-snoring device
Classification Name:	Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Device Class:	Class II
Product Code:	LRK
Regulation No.:	21 CFR 872.5570
Predicate Device:	MPowRx K081965
Reference Device:	SnoreRx K112205
Device Description:	The DaSoft Advanced Dental Appliance is an intraoral device designed to be worn during sleep to reduce snoring. The device includes a manually adjustable tongue sleeve to position the tongue and surrounding tissues forward in order to increase the patient's pharyngeal space, improving the ability to exchange air and decreases air turbulence. The device is manufactured using only medical grade ethylene vinyl acetate (EVA) polymer.
Intended Use:	Intraoral device for reduction in snoring.
Indications for Use:	The DaSoft Advanced Dental Appliance is indicated to reduce snoring in adult patients age 18 years or older.
Technology Comparison:	The subject and predicate devices are nearly identical in design and functionality. Both the DaSoft Advanced Dental Appliance and its predicates are intraoral mouth pieces that are molded to the patient's teeth using a boil and bite method. The DaSoft Advanced Dental Appliance includes the tongue sleeve which gently positioning the tongue in a forward position while sleeping, which provides a snoring reduction mechanism, which is substantially equivalent to the mode of action of the predicates. The subject and predicate device are provided non-sterile and use similar packaging systems. Table 1 below summaries the comparison.

Table 1: Substantial Equivalence Summary

Attribute	Subject Device DaSoft Dental Appliance for Anti-Snoring	Predicate MPowRx Snoring Solution K081965	Reference SnoreRx K112205	Differences and Justification
Classification and Product Code	Class II 21 CFR 872.5570 LRK	Class II 21 CFR 872.5570 LRK	Class II 21 CFR 872.5570 LRK	No Differences
Intended Use	Intraoral device for snoring	Intraoral device for snoring	Intraoral device for snoring	No Differences
Indications for Use	Intended to reduce snoring in adult patients aged 18 years or older.	Intended for the treatment of mild to moderate snoring.	Intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.	No Differences
Mode of Action	Repositions the tongue and related tissues anteriorly in order to increase the patient's pharyngeal space, which improves the ability to exchange air and decreases air turbulence.	Tongue retention within the protrusion of the device, forward retention of the tongue keeps the upper respiratory air passages open to relieve snoring.	Mandibular repositioning device that advances the lower jaw to increase pharyngeal space.	Mechanism of action for snoring reduction is equivalent.
Materials	Medical grade Ethylene vinyl acetate polymer, heat sensitive impressible material	Common oral appliance material, specifics not available.	Polycarbonate resin Ethylene vinyl acetate (EVA) copolymer, heat sensitive impressible material in addition to Eastar Copolyester MN058	EVA is commonly used in dental and consumer products intended for use in the mouth.
Design	Custom fitted intraoral device.	Single-sized, tongue positioner, fits between lips and teeth with protruding aperture for holding the tongue by suction.	Custom fitted intraoral device Repositions mandible anteriorly up to 6mm	The positioning and placement of the subject device is known to be efficacious for reducing snoring, and the materials are characterized to be substantially equivalent to predicates.
Sterility	Non-sterile	Non-sterile	Non-sterile	No Differences
Biocompatibility	Tested per ISO 10993	Not available	Tested per ISO 10993	No Differences

Non-Clinical Testing:	The DaSoft Advanced Dental Appliance material (EVA) was tested for cytotoxicity, irritation, and sensitization and it was concluded the material is biocompatible per ISO 10993. Biocompatibility test reports are submitted as part of the filing. In addition, the DaSoft Advanced Dental Appliance was tested for tensile properties (ISO 527-1,2:2012), flexural properties (ISO 178:2010/Amd.1:2013), and water absorption properties for plastics (ISO 62:2008). Performance testing reports are submitted as part of the filing.
Conclusion of Comparison:	DaSoft has demonstrated that the DaSoft Advanced Dental Appliance is substantially equivalent to the predicate devices.