DaSoft Partners
% Kimberly Lane
President and Principal Regulatory Consultant
J Blane, LLC
980 N Sinagua Heights Dr
Flagstaff, Arizona 86004

Re: K203462
Trade/Device Name: Advanced Dental Appliance
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: November 20, 2020
Received: November 24, 2020

Dear Kimberly Lane:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*

K203462

Device Name
Advanced Dental Appliance

Indications for Use *(Describe)*
The DaSoft Advanced Dental Appliance is indicated to reduce snoring in adult patients age 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

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR Part 807.92.

1 SPONSOR INFORMATION

Sponsor/Manufacturer:

Name: DaSoft Partners
Address: 4079 Governor Drive, #111
San Diego, CA 92122 USA
Phone: **(**619) 405-1530
Contact: Dante Togliatti
Email: dtogliatti@gmail.com

Official Correspondent:

Name: Kimberly Lane
Address: J Blane, LLC
980 N Sinagua Heights Dr.
Flagstaff, AZ 86004
Phone: (928) 707-2852

Establishment Reg. No.: 10061658

Date Prepared: November 20, 2020

2 DEVICE NAME

Trade Name:	Advanced Dental Appliance
Common Name:	Anti-snoring Device
Classification Name:	Intraoral device for snoring
Classification Number:	21 CFR 872.5570 (Class II)
Product Code:	LRK
Classification Panel:	Dental

3 PREDICATE DEVICES

Primary Predicate: Zyppah Anti-Snoring device (K182312)

Reference Predicates: DaSoft Partners Advanced Dental Appliance (K172991)
SnoreRx® device (K170825)

4 INTENDED USE

The DaSoft Advanced Dental Appliance is indicated to reduce snoring in adult patients age 18 years or older.

5 DEVICE DESCRIPTION

The DaSoft Advanced Dental Appliance, previously cleared under K172991, 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; a causative factor in snoring. The device is manufactured using medical grade ethylene vinyl acetate (EVA) polymer, which is a material that has a "generally recognized as safe" (GRAS) designation from FDA.

6 TECHNOLOGICAL CHARACTERISTICS

The subject device is equivalent in basic technology to the primary predicate Zyppah device (K181212). Both the subject device and the primary predicate devices work by mandibular advancement and tongue displacement.

The subject device is equivalent in design, materials and functionality to the reference predicate, DaSoft Advanced Dental Appliance (K172991) and has similar labeling as the reference predicate devices, DaSoft device (K172991) and SnoreRx (K170825). All devices are non-sterile and are customized to the individual patient by a standard 'boil and bite' method. A comparison table of the subject and predicate technological characteristics is provided below in **Table 1**.

Table 1: Substantial Equivalence Comparison

Feature	DaSoft Advanced Dental Appliance (THIS SUBMISSION)	PRIMARY PREDICATE: Zyppah® Anti-Snoring Device	REFERENCE PREDICATE 1: DaSoft Advanced Dental Appliance	REFERENCE PREDICATE 2: SnoreRx
510(k) Number	**TBD**	**K182312**	**K172991**	**K170825**
Manufacturer	DaSoft Partners	Always More Marketing, Inc.	Same as subject device	Apnea Sciences Corporation
Classification Name	Device, anti-snoring	Same as subject device	Same as subject device	Same as subject device
Classification # & Product Code	21 CFR 872.5570 (Class II) LRK	Same as subject device	Same as subject device	Same as subject device
Intended Use	Indicated to reduce snoring in adult patients aged 18 years or older.	Same as subject device	Same as subject device	Same as subject device
Type of Use (Rx or OTC)	Over the counter (OTC)	Same as subject device	Prescription Only	Same as subject device
Mechanism 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.	Repositions the tongue in conjunction with a slight advancement of the mandible.	Same as subject device	Repositions the jaw anteriorly in order to increase the patient's pharyngeal space, which improves the ability to exchange air and decreases air turbulence.
Design	Single tray unit fits in mouth over teeth, with single-sized protruding aperture (tongue sleeve) for holding the tongue by suction.	Single tray unit with tongue strap that spans across tray.	Same as subject device	The device consists of two custom fabricated trays that fit separately over the upper and lower dental arches and engage each other in the anterior area of the mouth.
Materials	100% Medical grade Ethylene vinyl acetate (EVA) polymer.	Hard outer shell with thermoplastic filling material and silicone tongue strap.	Same as subject device	- Polycarbonate resin - Ethylene vinyl acetate copolymer
Biocompatibility	ISO 10993	Same as subject device	Same as subject device	Same as subject device

6.1 Mechanism of Action

The maintenance of the tongue in a forward position creates an increase in cross-sectional area in the oropharynx, hypopharynx, and velopharynx, reducing resistance and therefore the chance for turbulent air flow.

The subject device and its primary and reference predicates, Zyppah device (K181212) and DaSoft Advanced Dental Appliance (K172991) and respectively, are identical in mechanism of action. They work by positioning the tongue in a forward position while sleeping, which provides a snoring reduction mechanism.

7 DEVICE TESTING

7.1 Nonclinical Testing

Device materials were previously tested for various physical properties. The tray material was tested for flexural modulus and strength (ISO 178), stress and strain at break (ISO 527), and water absorption (ISO 62). All materials met device specifications.

7.2 Biocompatibility Testing

Cytotoxicity, irritation, and sensitization were previously completed and results showed the DaSoft Advanced Dental Appliance to be biocompatible, in accordance with ISO 10993.

8 USABILITY TESING

To evaluate the consumer's understanding of the Over-the-Counter (OTC) device labeling and instructions for use, a usability study was conducted following FDA Guidance, *"Applying Human Factors and Usability Engineering to Medical Devices"*, issued February 3, 2016. Results demonstrated that the OTC consumer can appropriately prepare, fit, and adjust the DaSoft Advanced Dental Appliance.

9 CONCLUSION

The DaSoft Advanced Dental Appliance and its predicates are technologically identical. Use in an OTC environment does not raise any new questions of safety or effectiveness. Therefore, the subject device (Advanced Dental Appliance) is determined to be substantially equivalent to the predicate devices.