February 14, 2024

Gelb Practice Solutions, Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K240427
Trade/Device Name: airVata™
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: September 29, 2023
Received: February 13, 2024

Dear Prithul Bom:

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 -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K240427

Device Name
airVata™

Indications for Use *(Describe)*

The airVata™ sleep appliance is indicated to reduce snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older. The airVata™ sleep appliance is worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The appliance is removable by the patient.

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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K240427

510(k) Summary
Gelb Practice Solutions, Inc.
airVata™
1/26/2024

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Gelb Practice Solutions, Inc. 52 Woodedge Drive Dix Hills, NY 33472 Telephone: +1 888-427-7671	Consultant:	Aclivi, LLC 3250 Brackley Drive Ann Arbor, Michigan 48105 Telephone: +1 810 360-9773
Official Contact:	Layne Martin – CEO		Chris Brown - Manager
Email:	lmartin@gpsfordental.com		acliviconsulting@gmail.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	airVata™
Device:	Device, Anti-Snoring
Regulation Name/Number:	21 CFR 872.5570
Device Class:	Class II
Product Code:	LRK, LQZ
Review Panel:	Dental
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

PREDICATE DEVICE INFORMATION

The Subject device in this submission is substantially equivalent in indications, use and design principles to the following Predicate device.

510(k)	Predicate Device Name	Company Name
K211069	EndSnorZ™ Sleep Appliance	Prismatik Dentalcraft, Inc.

INDICATIONS FOR USE

The airVata™ sleep appliance is indicated to reduce snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older. The airVata™ sleep appliance is worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The appliance is removable by the patient.

DEVICE DESCRIPTION

The airVata™ sleep appliance is a mandibular advancement device. It holds the mandible in a protrusive position as determined by a trained dentist. The device consists of upper and lower splints (trays), which are additive manufactured using a biocompatible light curable resin. Connectors, made of a biocompatible synthetic polymer with injection molding technology attach the upper and lower splints to maintain the forward position of the lower jaw. The device is adjustable in 1.0 mm increments by using different lower trays supplied with the device. The connectors are attached after the upper and lower splints (trays) are manufactured.

The Subject device is a single patient, non-sterile, prescription-only device. It is to be used only by the patient for whom it is custom designed. It is to be worn during sleep and may be removed by the patient at any time.

EQUIVALENCE TO MARKETED DEVICE

The Subject device is highly similar to the Predicate device with respect to Indications for Use and Technological Characteristics. The comparison tables below compare the Indications for Use and Technological Characteristics of the Subject and Predicate devices.

Indications For Use Statement Comparison

Device	Indications for Use Statement
Subject Device airVata™ Gelb Practice Solutions, Inc.	*The airVata™ sleep appliance is indicated to reduce snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older. The airVata™ sleep appliance is worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The appliance is removable by the patient.*
Predicate Device EndSnorZ™ Sleep Appliance (K211069) Prismatik Dentalcraft, Inc.	*EndSnorZ ™ Sleep Appliance is indicated to reduce snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older. EndSnorZ ™ Sleep Appliance is worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The appliance is removable by the patient.*

The Subject and Predicate Indications for Use Statement (IFUS) are highly similar differing in the specific device names. The slight differences in the wording related to the device name within Indications for Use Statements do not change the intended use of the Subject and Predicate devices to reduce snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older.

Technological Characteristics

Parameter	**Subject Device** airVata™ Gelb Practice Solutions, Inc.	**Predicate Device** EndSnorZ™ Sleep Appliance (K211069) Prismatik Dentalcraft, Inc.	Comparison
Reason for Predicate/Reference	n/a	IFUS, Technological Characteristics	n/a
Product Code	LRK, LQZ	LRK	Highly Similar
Device	Device, Anti-Snoring	Device, Anti-Snoring	**Same**
Regulation	21 CFR 872.5570	21 CFR 872.5570	**Same**
Regulatory Class	Class II	Class II	**Same**
Intended Use	Reduce snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older.	Reduce snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older.	**Same**
Method of Use:	Single patient user, removable and reusable appliance.	Single patient user, removable and reusable appliance.	**Same**
Method of Operation	Support the lower jaw in a forward position.	Support the lower jaw in a forward position.	**Same**
Biocompatible	Yes	Yes	**Same**
OTC or Rx	Rx	Rx	**Same**
Sterile	Non-sterile	Non-sterile	**Same**
Environment	During sleep at home or in sleep laboratory.	During sleep at home or in sleep laboratory.	**Same**
Design			
Rigid Trays	Upper and lower	Upper and lower	**Same**
Tray material	Methacrylate-based light cured polymer resin (additively manufactured)	Methacrylate-based light cured polymer resin (additively manufactured)	**Same**
Mode of Action	Mandibular advancement	Mandibular advancement	**Same**
Advancement mechanism (connector)	Synthetic polymer, three-point attachment	Synthetic polymer nylon, two-point attachment	Highly Similar
Adjustable / Titration of arch position	Yes, different trays	Yes, different connectors	Similar
Connector length range	19.9 mm	20.5mm to 26 mm	Similar
Maximum adjustment	3.0 mm, increments of 1.0 mm	5.5mm; increments of 0.5 mm	Similar
Maximum mandibular advancement	8 mm	Approximately 10 mm	Similar
Biocompatibility Testing	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	**Same**

The above table identifies the Technological Characteristic endpoints which are the **same**. Technological characteristic endpoints which are not the same are described below.

Product Code – Both the Subject and Predicate devices have the same Primary Product code. Both the Subject and Predicate devices operate as Jaw Repositioning Devices (Mandibular Advancement Devices), where the LQZ product code is applicable. The lack of use of the LQZ Product code in the Predicate device premarket does not change the same Mode of Operation or Mode of Action of both devices.

Advancement mechanism (connector) – Both the Subject and Predicate devices advancement mechanism are connectors fabricated of a synthetic polymer material and are therefore highly similar. Slight differences of material composition and the two-point vs three-point design do not impact the intended use of the device. No specific performance claims are made related to differences in the number of points of attachment. Any differences in material composition and number of connector attachments for the Subject device and the impact on Subject device performance have been mitigated by means of clinical product validation performance testing.

Adjustable / Titration of arch position – Both the Subject and Predicate devices support similarly adjustable advancement or titration of the lower tray and arch position relative to the position of the upper tray and arch. The Subject device accomplishes titration by means of different lower trays with connector attachments positioned to result in 1 mm incremental advancement of the lower tray position. The Predicate device accomplishes titration by means of different connector lengths. To increase the advancement of the lower arch, a shorter length connector is attached to the device. The ability to titrate arch position in the Subject and Predicate devices is similar but accomplished by different means. Slight differences of method of titration does not impact the intended use of the device. Any differences in titration method and performance of the Subject device have been mitigated by means of clinical product validation performance testing.

Connector length range – Both the Subject and Predicate devices have similar defined connector lengths. The Subject device has a fixed connector length of 19.9 mm and accomplishes titration by means of different lower trays with connector attachments positioned to result in 1 mm incremental advancement of the lower tray position. The Predicate device accomplishes titration by means of different connector lengths ranging from 20.5 mm to 26 mm. The different approach to titration results in different approach to connector length and device design. Slight differences of method of titration and connector lengths does not impact the intended use of the device. Any differences in titration method and performance of the Subject device using the different approach to titration have been mitigated by means of clinical product validation performance testing.

Maximum adjustment – Both the Subject and Predicate devices support similarly adjustable advancement or titration of the lower tray and arch position relative to the position of the upper tray and arch. The Subject device offers a maximum 3 mm adjustment while the Predicate device offers a maximum adjustment of 5.5 mm. Slight differences in the maximum titration adjustment does not impact the intended use of the device. Any differences in titration method and performance of the Subject device using the different approach to titration have been mitigated by means of clinical product validation performance testing.

Maximum mandibular advancement – Both the Subject and Predicate devices similarly support mandibular advancement or titration of the lower tray and arch position relative to the position of the upper tray and arch. The Subject device accomplishes titration by means of different lower trays with connector attachments positioned to result in a maximum 2 mm advancement of the lower tray position for typical cases (0-, 1- and 2-mm advancement). The Predicate device accomplishes titration by means of different connector lengths. Based on position of connectors and attachments, the Predicate device offers a maximum mandibular advancement of approximately 10 mm. The Subject device allows for a maximum mandibular advancement of 8 mm (one of three different lower trays with sequential one mm titration positions) when directed by the prescribing doctor. Differences of maximum mandibular advancement and approach they are implemented does not impact the intended use of the device. Any differences in performance of the Subject device have been mitigated by means of clinical product validation performance testing.

Biocompatibility - The Subject and Predicate devices are the same in the standards and biological endpoints the devices were evaluated to.

Overall, the Technological Characteristics of the Subject and Predicate devices are the Same, Highly Similar or Similar. Technological differences between the Subject and Predicate devices have been evaluated through validation performance testing of the Subject device. The results of the tests performed show that the Subject device is suitable for its intended use and confirms that the Subject device performs similarly to Predicate which has the same intended use.

CLINICAL AND ANIMAL TESTING

No clinical or animal testing data is included in this submission.

NON-CLINICAL PERFORMANCE TESTING

Validation of the manufacturing process and compatible equipment was performed demonstrating consistency of the process output with that of the process input.

Physical property testing according to ISO 20795-2, *Dentistry — Base polymers — Part 2: Orthodontic base polymers* was leveraged from the sponsor's material supplier.

Biocompatibility testing for the Subject device, was conducted in accordance with ISO 10993-1, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*. Consideration was given to the Subject device materials, manufacturing process and packaging. Testing was performed according to ISO 10993-5 and ISO 10993-10.

An MRI safety assessment was performed on the Subject device to support MR Safety labeling as required by the FDA guidance "*Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*".

Non-clinical performance testing of the Subject device met the acceptance criteria for each validation and test described above. This non-clinical performance testing demonstrates that the Subject device is suitable for intended use.

CONCLUSION

Overall, the Indications for Use statements for the Subject and Predicate devices are highly similar differing only in device name. Overall, the Technological Characteristics of the Subject device is the same, highly similar, or similar to the Predicate device with any differences mitigated through non-clinical performance testing.

Overall, these similarities between the Subject and Predicate devices support a determination of substantial equivalence.