September 8, 2022

Greystone IP Ltd
Judy Purvis
Director
Unit 322, Moat House, 54 Bloomfield Avenue
Belfast, BT5 5AD
IRELAND

Re: K220330
Trade/Device Name: Soundly Anti Snoring Device
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: July 28, 2022
Received: August 4, 2022

Dear Judy Purvis:

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 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)*
K220330

Device Name
Soundly Mandibular Advancement Device

Indications for Use *(Describe)*
The Soundly Mandibular Advancement Device is intended to reduce or alleviate snoring and mild to moderate Obstructive Sleep Apnea (OSA) whilst sleeping, in adults

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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510K SUMMARY
K220330

1. SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON AND DATE PREPARED

Greystone IP Ltd
Unit 322, Moat House
54 Bloomfield Avenue
Belfast, BT5 5AD
Northern Ireland

Contact Person: Judy Purvis

Phone: +44 7515788487

Date Prepared: 28th July 2022

2. DEVICE

Name of Device

Soundly Mandibular Advancement Device

Common or Usual Name

Mandibular Advancement Device

Classification Name/Product Code/CFR Reference

Mandibular Advancement Device,
Product Code: LRK, LQZ
CFR Reference: 21 CFR 872.5570

3. PREDICATE DEVICE

Primary Predicate device: Slow Wave DS8, K191320. This predicate has not been the subject of a design-related recall.

Reference device: O2 Vent Optima, K190236

4. DEVICE DESCRIPTION

The Soundly Device is a mandibular advancement device to be worn by the patient in their own home at night whilst asleep. The advancement of the lower mandibular is an accepted method of reducing the incidence of light to moderate Obstructive Sleep Apnea (OSA). The Soundly Device consists of the following components:

- A single lower jaw splint that covers the lower teeth to the gum line. The lower splint has two wedge-shaped projections on its upper surface. These indentations are shaped to receive complementary wedges on the upper splint and so advance the lower jaw compared to the natural positioning.

- A set of three different upper jaw splints that cover the upper teeth to the gum line. Each upper jaw splint has a pair of wedges on its lower surface that interlock with the wedge indentation on the lower jaw. The set of three upper splints offer different amounts of mandibular advancement: They individually offer 40%, 60% or 70% of the maximum mandibular advancement that the patient's jaw can accommodate. The 70% value has an absolute maximum of 12 mm of mandibular advancement.

The dental impressions of the lower and upper jaw and a bite registration of the patient at maximum comfortable mandibular advancement are made by the prescribing dentist. The impressions are sent to the Soundly labs for processing. The impressions are turned into plaster models in the usual method and then the plaster models are subject to 3D scanning to make electronic 3D models of the mandibular arches. The 3D models are processed in 3D design software into the set of splints, which are then 3D printed in a biocompatible photopolymer. The finished set of splints are returned to the prescribing dentist for final fitting on the patient.

The perceived advantage of this digital method of production is that the splints should conform closely to the patient's actual teeth and gums as the edges have been positioned and shaped before printing, rather than having to be cut and filed after manufacture as is usual with thermoformed splints. Thus, the splints should be more comfortable than those produced by traditional methods.

The set of 3 upper splints allows the patient to self-titrate. The amount of mandibular advancement produced by the splints has been pre-scaled to the patient's comfortable range of jaw movement, and so the patient can choose which to wear to find the right balance of comfort and effectiveness. This would be more difficult or take longer with traditional fixed length tie bars or screw turnbuckles that require the dentist's intervention. The device could be worn all night and every night by the patient in order to reduce the incidence of OSA.

5. INTENDED USE / INDICATIONS FOR USE

The Soundly Mandibular Advancement Device is intended to reduce or alleviate snoring and mild to moderate Obstructive Sleep Apnea (OSA) whilst sleeping in adults.

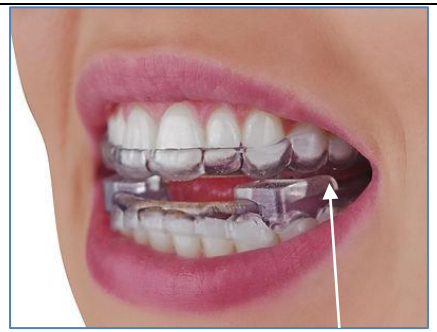
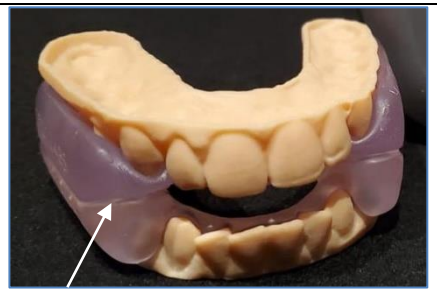
6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the Soundly Device and the Slow Wave DS8 are Mandibular Advancement Devices manufactured by a 3D printing process (an Additive Manufacture process). They both use the same 3D printing material, Dental LT Clear, which has an FDA clearance under the Master File process.

The reference device, O2 Vent Optima, is also made by Additive manufacture, but from a Polyamide material.

All 3 devices provide an airspace for oral breathing whilst wearing the device and all 3 devices provide the mandibular advancement to increase the patency of the airway, but they differ in the detail of the method of advancement.

A table to compare the technical characteristics is below:

#	Feature	Subject Device	Primary Predicate	Reference Device	Comparison
		Greystone IP Soundly MAD	Slow Wave DS8	O2 Vent Optima	
1	510(k) number	K220330	K191320	K190236	N/A
2	Product Classification	Class II, 21 CFR 872.5570, LQZ, LRK	Class II, 21 CFR 872.5570, LQZ, LRK	Class II, 21 CFR 872.5570, LRK	Same for all
3	Device Picture	 Note: the contact between the upper and lower splints are a pair of engaging wedges, not a pair of side arms	 Note that the contact between the upper and lower splints is a ramp, not a pair of side arms	 Note the pair of exchangeable arms linking the upper and lower splints and the breathing vent	All devices are trays/splints fitted to both upper and lower mandibles. All have an oral breathing gap at the front of the device. They use different methods to achieve the mandibular advancement to increase the airway patency
4	Common Name	Intraoral device for snoring and mild to moderate Obstructive Sleep Apnea	Intraoral device for snoring and mild to moderate Obstructive Sleep Apnea	Intraoral device for snoring and mild to moderate Obstructive Sleep Apnea	All same
5	Indication for Use	The Soundly Mandibular Advancement Device is intended to reduce or alleviate snoring and mild to moderate Obstructive Sleep Apnea (OSA) whilst sleeping in adults	Intended to reduce or alleviate snoring, mild to moderate Obstructive Sleep Apnea while sleeping in adults.	The O2Vent Optima is a removable medical device that is fitted in the patient's mouth and is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA). The device is indicated for use during sleep to aid in the treatment of these conditions	Effectively the same
6	Target Population	Adults	Adults	People over 18 years of age who snore and/or have sleep apnea	No significant difference
7	Principle of operation	Repositions the lower jaw forward to increase the patency of the airway.	Repositions the lower jaw forward and down to increase the patency of the airway	Repositions the lower jaw forward to increase the patency pf the airway	Substantially the same

#	Feature	Subject Device Greystone IP Soundly MAD	Primary Predicate Slow Wave DS8	Reference Device O2 Vent Optima	Comparison
8	Method of operation	The mandibular advancement is achieved by the interlocking of opposing wedge faces on the upper and lower splints, which determines the lower jaw position. There are no locking side arms, so the splints can be disengaged by a small forward and downward movement of the lower jaw. The upper splint is supplied with 3 sizes of mandibular advancement, tied to the patient's maximum mandibular advancement, see next row.	The mandibular advancement is achieved by the lower jaw splint resting on a ramp on the upper jaw splint. The user finds the most comfortable position for themselves. The ramp means that under small amounts of mandibular advancement, the lower jaw is forced apart from the upper jaw. Under larger amounts of mandibular advancement, the lower jaw can move upwards, closer to the upper jaw. Either way, the airway is opened by the combination of pushing the jaws apart and advancing the lower jaw.	The lower jaw is advanced by the side arms between the upper and lower splints. There is a specific oral breathing vent in the front of the upper splint.	Different ways of achieving the same end, see discussion at the end of the table.
9	Mandibular Advancement	3 positions at 40%, 60% & 70% of the patient's maximum comfortable mandibular advancement Maximum advancement is 12mm	Up to 15 mm	Up to 8mm	Each has a range of adjustment to titrate the balance of effectiveness and comfort
10	Adjustment method	User chooses which of the 3 lower splints to wear – self titration	No fixed adjustment, the upper and lower splints rest on each other on angled wedges. The wearer adopts the most comfortable position between small advancement and mouth open to jaws clenched but jaw advanced	Changing the connectors between upper and lower splints. This can be done by either the dentist or the user	The amount of mandibular advancement can be adjusted by the patient, it does not depend upon a fixed setting made by the dentist
11	Supplemental Oral Breathing	Yes, the front of the mouth is opened to allow oral breathing, see picture above. There is no physical connection between upper and lower splints so the mouth can be opened as wide as desired, or one	Yes, the front of the mouth is opened to allow oral breathing. There is no physical connection between upper and lower splints so the mouth can be opened as wide as desired, or one part easily	Yes, through a breathing duct in the front of the splint. The upper and lower splints are physically connected so the splint would have to be removed to open the mouth wider	All provide a route for oral breathing. The Soundly MAD and Slow Wave DS8 give the user simpler removal in

#	Feature	Subject Device	Primary Predicate	Reference Device	Comparison
		Greystone IP Soundly MAD	Slow Wave DS8	O2 Vent Optima	
		part easily removed during any coughing/sneezing or discomfort	removed during any coughing/sneezing or discomfort		the event that the user is sneezing or coughing
12	Method of manufacture	Dental impressions made by the prescribing dentist are scanned at the Soundly Dental Lab to create the 3D file for additive manufacture by 3D printing on Formlabs equipment	3D intraoral scan is made by the prescribing dentist. The Slow Wave Dental Lab produces the splints by additive manufacture by 3D printing on Formlabs equipment	Customized for each patient in a dental laboratory located at the manufacturing site based on the dentist prescription Use of computer aided design (CAD) and computer aided manufacturing (CAM) and is made through additive manufacturing using laser sintering	All 3 devices are made by additive manufacturing from 3D scans of the teeth/models of the teeth
13	Material	Formlabs Dental LT Clear V2	Formlabs Dental LT Clear V2	PA2200 Polyamide 12 nylon material	All 3 made from a setting material built up in layers from a 3D scan. The materials are FDA approved for additive manufacturing
14	Single use/Reusable	Reusable	Reusable	Reusable	All same
15	Sterile/Non Sterile	Non-sterile	Non-sterile	Non-sterile	All same
16	Prescription/ OTC	Prescription only	Prescription only	Prescription only	All same
17	Cleaning & Maintenance	Routine cleaning with water, instructions in patient IFU	Routine cleaning with water or mild bleach, instructions in patient IFU	Routine cleaning with water or mild bleach, instructions in patient IFU	All similar

Detailed comparison of the mandibular advancement methods (Rows #8, 9 and 10):

- The O2 Vent Optima (Reference Device) has the traditional method of mandibular advancement – a pair of links between the upper and lower splints that sets the amount of the lower jaw advancement. These links are available as a series of lengths that can be changed to titrate the advancement to the optimal balance between effectiveness in reducing snoring/OSA and comfort in wearing the device. The side links can be easily changed by the patient and do not depend upon a visit to the dentist to change the amount of advancement. The maximum opening of the mouth whilst wearing the device is limited by the side links and it takes a few steps to remove the device from the mouth.

- The Slow Wave DS8 (Primary Predicate) has no fixed link between the upper and lower splints. The interface between the two splints is an angled ramp that moves the lower jaw downwards as it is retracted (see image at row#3). In that way, the wearer can find the most comfortable position of the lower jaw for them. Wherever the lower jaw position is, the airway is opened up over the natural lying position without the device by the combination of advancement and dropping of the lower jaw, even when clenched. The mouth can be opened wider than the natural position of the device if the wearer needs to rapidly open their mouth or remove part of the device.

- The Soundly MAD (Subject Device) also has no fixed link between upper and lower splints. The interface between the two splints is a pair of interlocking wedges that hooks the lower jaw in a lowered and advanced position. The patient is supplied with 3 upper splints to give them a range of 3 different advancement positions that are linked to their personal maximum mandibular advancement ability. The mouth can be opened wider than the natural position of the device if the wearer needs to rapidly open their mouth or remove part of the device.

  Thus, the 3 devices achieve their mandibular advancement and increased airway patency by methods that are different in detail but have the same overall effect: the lower jaw is advanced; the airway is opened and there is provision for oral breathing. Also, all 3 devices give the patient the opportunity to self-titrate the amount of mandibular advancement to arrive at the suitable balance, for them, of comfort and effectiveness.

7. SPECIAL CONTROLS/GUIDANCE USE

The Soundly MAD application has followed the specific FDA Guidance:

For Mandibular Advancement Devices:

“Intraoral Devices for Snoring and/or Obstructive Sleep Apnea – Class II Special Controls Guidance Document for Industry and FDA”, published November 12, 2002.

For 3D Printing Methods of Manufacture

Technical Considerations for Additive Manufactured Medical Devices - Guidance for Industry and Food and Drug Administration Staff, issued December 5, 2017

For Biocompatibility

Biological evaluation of medical devices--Part 1: Evaluation and testing within a risk management process", Issued June 2016. Updated September 2020

There are no deviations from these guidance documents in the preparation of this Abbreviated 510k

8. BRIEF SUMMARY OF NON-CLINICAL TESTS

Additive Manufacture Consistency:

The consistency of the additive manufacture process was confirmed by:

- The accuracy of the manufactured splints with the source 3D CAD file when printed with aged printing resin. This was conducted by a comparison of the splint dimensional accuracy when printed with new resin and resin that had been subjected to extreme heat and freezing and the aged to 2 years old. All splints printed were within the acceptable dimensional accuracy target of >80% of the splint dimensions being within 150 micron of the CAD file dimension.

- The consistency of the printed splints with varied location on the print bed and across three different print runs was tested. The splints produced were confirmed as being fit for use by being fitted to the source Plaster of Paris models and being inspected by an independent practicing Orthodontist. All of the splints were free from air bubbles and inclusions. There was no interference or free space in the fit of the splints on the source models.

Physical Properties Testing:

The physical properties of the printed material were tested by the manufacturer for:

- Ultimate tensile strength

- Elongation
- Flexural modulus
- Flexural strength
- Shore hardness

In addition, Soundly MAD devices were tested for expected mis-handling by being dropped onto a tiled floor from increasing heights. This was to simulate being dropped whilst being handled or cleaned in a bathroom. The splints survived being dropped from 4 feet, 5 feet and 6 feet in different orientations. These drop tests were cumulative as the same splints were used for all of the tests. It was only when the splints were dropped from 7 feet (from above head height) did one of the splints break in half. This test proved that:

- The splints are resistant to the expected accidental dropping or misuse.
- When a splint is damaged by dropping, it is not by minor and perhaps unnoticed chipping, but by complete breakage and so the splint would not be used in a damaged state.

Biocompatibility:

The evidence of the 3D printing material biocompatibility was provided under a separate cover to FDA by the material manufacturer. The material was tested for the following biocompatibility parameters, as required by ISO 10993 and ISO 7405 for the cumulative use of “permanent”:

- Cytotoxicity
- Sensitization
- Irritation
- Acute systemic toxicity
- Material mediated pyrogenicity
- Subacute/Subchronic toxicity
- Genotoxicity
- Implantation

The material passed each and all of the test requirements.

9. CONCLUSIONS

The conclusions drawn from the use of the specific guidance documents and comparison with the predicate and reference devices demonstrate that the subject device, the Soundly MAD device, conforms to the requirements of a Mandibular Advancement Device and is Substantially Equivalent to legally marketed devices, the Slow Wave DS8 [K191320] and the O2 Vent Optima [K190236].