January 24, 2019

Always More Marketing
% Colette Cozean
Regulatory Consultant
EyeDeas Company
21581 Midcrest Drive
Lake Forest, California 92630

Re: K182312
Trade/Device Name: Zyppah 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
Dated: December 14, 2018
Received: December 26, 2018

Dear Colette Cozean:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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 -S3

Digitally signed by Mary S. Runner -S3
Date: 2019.01.24 14:05:59 -05'00'

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)*
K182312

Device Name
Zyppah(R) Anti-Snoring Device

Indications for Use *(Describe)*
Zyppah(R) is intended for use by adult patients (18 years or older) as an aid to reduce snoring.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K182312

Applicant:	Always More Marketing, Inc. 24981 Palmilla Drive Calabasas, CA 91302, USA Phone: 818-414-4817
Contact Person:	Colette Cozean, Ph.D. 21581 Midcrest Dr. Lake Forest, CA 92603 USA 949-855-2885 ccozean@cox.net
Date Prepared:	January 21, 2019
Proprietary Name:	Zyppah® Anti-Snoring Appliance
Common Name:	Intraoral Device for Snoring
Classification Name:	Device, anti-snoring (Class II, 21 CFR 872.5570, Product Code LRK)
Predicate Device:	Dr. Greenburg's Hybrid Zyppah (K111680) – Prescription Predicate
Reference Predicates:	ZQuiet (K180124) – Over the Counter Reference Predicate SnoreRX (K170825) – Over the Counter Reference Predicate

8. Description of the Device

The Zyppah Anti-Snoring Appliance is a single piece tray system for intraoral use. The 'boil-and-bite' device is customized to each patient. It features an elastic strap that spans the device that is designed to keep the tongue in place during sleep, instead of blocking the airway and contributing to snoring. The predicate The product is non-sterile and provided in a sealed box with directions for use.

9. Indications for Use

Zyppah® is intended for use by adult patients (18 years or older) as an aid to reduce snoring.

10. Technological Characteristics

The appliance is equivalent in design and functionality to the predicate, prescription Zyppah device (K111680). Both devices work by depressing the tongue during sleep to open the airway and reduce the incidence of snoring, in addition to advancing the mandible. Both are customized to the individual patient by a standard 'boil and bite' method. Both use the same materials and manufacturing process. Both devices are provided non-sterile. The sole difference between the subject and predicate device is the use of double-hole retention for the silicone strap, rather than the single-hole retention in the predicate device. This adds additional strength to the binding to prevent any breakage or loosening of the strap.

The appliance has similar labeling as the OTC reference predicate devices, SnoreRx and ZQuiet. It utilizes a validated questionnaire to assess the risk of sleep apnea, and contains appropriate warnings and labeling for the device to be used without a prescription.

	Subject	**Prescription Predicate**	**OTC Reference Predicate**	**OTC Reference Predicate**
Name	Zyppah® Anti-Snoring Appliance	Dr. Greenburg's Hybrid	SnoreRx	ZQuiet
Classification Name	Device, anti-snoring	Device, anti-snoring	Device, anti-snoring	Device, anti-snoring
510(k) Number	K182312	K111680	K170825	K180124
Class	II	II	II	II
Product Code	LRK	LRK	LRK	LRK
21 CFR	872.5570	872.5570	872.5570	872.5570
Technology & Mechanism of Action	Repositioning the tongue, mandibular advancement	Repositioning the tongue, mandibular advancement	Mandibular advancement	Mandibular advancement
Indications for use	Zyppah® is intended for use by adult patients (18 years or older) as an aid to reduce snoring.	This appliance is indicated for persons 18 years or older, who wish to reduce the incidence of snoring and/or mild to moderate sleep apnea.	"SnoreRx is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring"	"ZQuiet is intended as an aid in the reduction of snoring for adults at least 18 years old."
Prescription Status	OTC	Prescription	OTC	OTC

Provided Sterile	No	No	No	No
Materials	Hard outer shell with thermoplastic filling material and elastic band	Hard outer shell with thermoplastic filling material and elastic band		Thermoplastic Elastomer with Colorant

10.1 Technology – Mechanism of Action

The subject device and prescription predicate device (K111680) are identical in mechanism of action. They both work by utilizing an intraoral mouthpiece to reposition the tongue in conjunction with a slight advancement of the mandible.

The mechanism of action for the other two OTC predicate devices, the SnoreRx and ZQuiet, is solely advancing the mandible. With any intraoral device that alters the mandible position, mandibular changes can lead to pain or discomfort in the temporomandibular joint (TMJ). The subject device has no new risks in regards to mandibular advancement.

Utilizing the same mechanism of action as the prescription predicate the subject device raises no new concerns regarding effectiveness or safety as compared to predicate devices.

10.2 Technology – Indication for Use

The subject device uses language for the indication for use that is identical in substance to previously-approved OTC devices for the reduction of snoring. The subject device is "intended for use by adult patients (18 years or older) as an aid to reduce snoring."

This is almost identical to the indications for use for the two OTC predicate devices, the SnoreRx and ZQuiet, whose indications for use are "SnoreRx is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring" and "ZQuiet is intended as an aid in the reduction of snoring for adults at least 18 years old," respectively.

As the indications for use are identical, there is no new concerns regarding effectiveness or safety as compared to predicate devices.

10.4 Technology - Prescription Status

The subject device is intended to be sold over-the-counter. Product labeling has therefore eliminated prescribing information. Two of the predicate devices, SnoreRx and ZQuiet, have clearance for over-the-counter use.

Warnings and contraindications are substantially equivalent to those of over-the-counter predicate devices. The labeling specifically states that the device does not treat obstructive sleep apnea, and includes the validated STOP-BANG questionnaire is included in the labeling to help mitigate the risk of undiagnosed OSA among potential Zyppah patients.

The similar predicate prescription device (Dr. Greenburg's Hybrid, K111680) has been on the market for more than seven years. Due to its postmarket record of substantially equivalent performance to other devices of this type and substantially equivalent labeling and instructions for use to that of the over-the-counter predicate devices, there are no new concerns regarding effectiveness or safety as compared to predicate devices.

10.5 Technology - Materials

To support this application, the sponsor has included Biocompatibility testing results demonstrating the subject device is biocompatible under ISO 10993, including cytotoxicity, sensitization, and irritation testing. The device was shown to meet the requirements of the ISO 10993 guidelines for each of these tests. Other biocompatibility tests recommended for permanent mucosal contact were not conducted because all materials used in the device are certified USP Class VI and used in many other currently marketed medical devices.

Because the same materials and manufacturing processes are used as the currently marketed predicate device, there are no new concerns regarding effectiveness or safety as compared to the predicate device.

11. Non-Clinical Testing

The tensile strength of the proposed OTC device was compared to the single-hole design of the cleared predicate in bench testing. It was found that using a two-hole design to hold the silicone strap in place increased the force the strap could withstand by 14% over that of a single-hole design used in the predicate device.

The sponsor conducted a risk analysis on the device in accordance with ISO 14971:2007, taking into account the issues raised in the FDA Guidance Document "Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea – Guidance for Industry and FDA." All identified risks have been addressed through device design or with communication with the user through the instructions for use.

12. Biocompatibility

The materials and manufacturing process are similar to the currently marketed materials in the prescription predicate device.

Testing results that have been included include cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10) and irritation (ISO 10993-10). As all materials used in the device are certified USP Class VI and used in many other currently marketed medical devices, no additional biocompatibility testing was conducted.

Class VI certification is less stringent than 10993

13. Clinical Testing

No clinical testing was performed in association with this submission.

14. Conclusions

The results of the comparison of design, materials, intended use, labeling, and technological characteristics demonstrate the subject device is substantially equivalent in safety and efficacy the legally marketed predicate devices. Therefore, the sponsor concludes the proposed Zyppah® device is substantially equivalent to the identified predicate devices.