May 10, 2023

Island Dental Lab, Inc dba Emerald Dental
% Colette Cozean, Phd
Regulatory Consultant
The EyeDeas Company
21581 Midcrest Dr.
Lake Forest, California 92630

Re: K223624
Trade/Device Name: Emerald Herbst
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: November 30, 2022
Received: December 5, 2022

Dear Colette Cozean, Phd:

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, 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)*
K223624

Device Name
Emerald Herbst

Indications for Use *(Describe)*
The Emerald Herbst appliance is intended to treat snoring and mild to moderate Obstructive Sleep Apnea (OSA) in adults 18 years of age 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.

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5. 510(k) Summary

Applicant:	Island Dental Lab, Inc dba Emerald Dental Lab 76 S. Central Ave., # 1D Valley Stream, NY, 11580 516-327-0810 347-522-9800
Contact Person:	Colette Cozean, PhD 21581 Midcrest Drive Lake Forest, CA 92630 (949) 855-2885 colettecozean@gmail.com
Date Prepared	August 15, 2022
Proprietary Name	Emerald Herbst Appliance (Hard and Hard/Soft)
Common Name	Device, Snoring and Mild to Moderate Obstructive Sleep Apnea
Classification Name	Intraoral devices for snoring; intraoral devices for snoring and obstructive sleep apnea (Class II, 21 CFR872.5570, Product Code LRK and LQZ)
Primary Predicate Device	Respire Pink Series with DentiTrac(K170692) refers to Herbst ((K131138), Respire Pink Series – Herbst EF (K150572)
Reference Device	Dent-O-Cryl Orthodontic Acrylic (K942667) is used to justify the use of a different color. Emerald Dental certifies that the Herbst Emerald Device uses the following identical materials found in the Respire Pink Series:

Description: The Emerald Herbst appliance is a customized oral device featuring both lower and upper trays and interlocking system. The product is non-sterile, biocompatible, and provided in a sealed box with instructions for use and an adjustment screw. The upper and lower trays are connected by an adjustable hinge allowing the patient to open and close the mouth while wearing the appliance. The Herbst Telescopic Hardware on the side of the device allows the patient to move forward and left and right but not backwards. This freedom of movement is important for comfort and overall success of the device.

The Emerald Herbst appliance is intended to treat snoring and mild to moderate sleep apnea (OSA) in adults 18 years of age or older by guiding the mandible forward during sleep, preventing the tongue and soft tissues of the throat from collapsing into the airway.

The Emerald Herbst is offered in two options:

1. Hard devices which are all acrylic and retained with ball clasps that allow the device to be tightened if it becomes loose.
2. Hard /Soft which has a laminate layer that provides a soft layer on the tooth surface.

These two options are also available in the predicate, Respire Pink Series.

Indications for Use: The Emerald Herbst appliance is intended to treat snoring and mild to moderate obstructive sleep apnea (OSA) in adult patients 18 years of age or older. This indication for use is identical to that of the predicate device(s).

Technological Characteristics: The Emerald Herbst appliance consists of upper and lower interlocking, customized trays. The Emerald Herbst appliance is customized on models of the patient's teeth, using standard orthodontic acrylics and standard orthodontic ball clasps for retention. The Emerald Herbst appliance allows for inter1ocking of the upper and lower trays to adjust the mandibular position of the user. The technical characteristics are identical to the predicate devices.

Mechanism of Action: All predicate devices (Respire Pink Series) also function as mandibular advancement devices to increase the patient's pharyngeal space and improve the ability to exchange air during sleep. They each have customized upper and lower trays that interlock to advance the mandible. The mechanism of action of the subject device is substantially equivalent to the predicate devices.

Substantial Equivalence Table:

		Subject Device Emerald Dental	Primary Predicate Device Respire Pink Series K170692	Included in Primary Predicate Device Respire Pink Series - Herbst K131138	Included in Primary Predicate Device Respire Pink Series - Herbst EF K150572
Intended Use					
	Indication for Use	Intended to treat snoring and mild to moderate obstructive sleep apnea (OSA) in adult patients 18 years of age or older	Intended to treat snoring and mild to moderate Obstructive Sleep Apnea (OSA) in adult patients 18 years of age or older	Intended to treat mild to moderate OSA	Intended to treat mild to moderate OSA
	Class	II	II	II	II
	Intended as Intraoral Device	Yes	Yes	Yes	Yes
	Intended to reduce snoring	Yes	Yes	Yes	Yes
	Intended to treat mild to moderate OSA	Yes	Yes	Yes	Yes
	Intended for nighttime use	Yes	Yes	Yes	Yes
	Intended for single patient multiuse	Yes	Yes	Yes	Yes
	Intended for use at home or sleep labs	Yes	Yes	Yes	Yes
	Intended for adults, 18 years or older	Yes	Yes	Yes	Yes
Design					
	Customized fit for each patient	Yes	Yes	Yes	Yes
	Mechanism of action: Mandibular Advancement	Yes	Yes	Yes	Yes

	Can be adjusted or refit	Yes	Yes	Yes	Yes
	Range of forward movement of mandible	Yes	Yes	Yes	Yes
	Upper & lower trays disengage for easy removal	Yes	Yes	Yes	Yes
	Permits patient to breathe through the mouth	Yes	Yes	Yes	Yes
	Has tracking device	No	Yes	No	No
	Cleaned and inspected daily by patient	Yes	Yes	Yes	Yes
Materials					
	Hard surface material	Yes	Yes	Yes	Yes
	Soft lining material	No Hard, Yes Hard/Soft	No Herbst, Yes Herbst EF	No	Yes
	Advancement mechanism	Yes	Yes	Yes	Yes
	Advancement mechanism - Herbst telescoping hinge, stainless steel	Yes	Yes	Yes	Yes
	Cobalt Chrome Mesh inside Acrylic	Yes	Yes	Yes	Yes
Mechanism					
	Mechanism of Action	Mandibular Advancement	Mandibular Advancement	Mandibular Advancement	Mandibular Advancement
	Method of Positioning the Mandible	Herbst Telescoping Hinge	Herbst Telescoping Hinge	Herbst Telescoping Hinge	Herbst Telescoping Hinge
	Maximum Amount of Mandible Protrusion	6 mm	6 mm	6 mm	6 mm
Labeling					
	Prescription Only	Yes	Yes	Yes	Yes

Clinical and Non-Clinical Data: A biocompatibility and physical properties assessment was completed based on the material composition of the primary predicate, which concluded that the subject device was substantially equivalent to the primary predicate device. A risk assessment has also been conducted with the subject device, which concluded there are no additional risks as compared to the predicate device(s).

Performance Testing: The Emerald Herbst is equivalent to the predicate device, Pink Series, as it uses all the same materials, same manufacturing procedure and same manufacturer. Therefore, no mechanical testing was conducted to establish equivalence. The Emerald Herbst was subjected to pre and post accelerated aging test measured by deflection strength. Aging did not decrease the strength of the device.

Differences: The Emerald Herbst is green unlike the Pink Series, which is pink. Both colors have received premarket approval in K942667 for the reference device, Dent-O-Cryl. This reference device justifies the use of all colors submitted by Dentauraum for Dent-O-Cryl, including the Emerald Herbst green and the Pink Series pink color additives. This 510(k) contains all the information considered by the FDA to determine substantial equivalence, including physical parameters and biocompatibility.

Summary: Based on the intended use, technical characteristics, biocompatibility assessment, labeling and other data provided in this submission, the Emerald Herbst appliance demonstrates substantial equivalence to the predicate devices in both safety and efficacy.