March 26, 2018

Insert Molding Solutions, Inc.
% Felicia Ruley
Principal Specialist
Regulatory and Quality Solutions, LLC
2790 Mosside Blvd #800
Monroeville, Pennsylvania 15146

Re: K172760
Trade/Device Name: REST EAZY 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: February 14, 2018
Received: February 22, 2018

Dear Felicia Ruley:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Division 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)*
K172760

Device Name
REST EAZY Appliance

Indications for Use *(Describe)*
The REST EAZY Appliance is intended for use in adult patients for the reduction of snoring and mild to moderate obstructive sleep apnea. The REST EAZY Appliance is worn while sleeping to support the lower jaw in a forward position as 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.

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 provided per the requirements of section 21 CFR 807.92 on March 20th 2018.

I. Submitter

Submitter's Name:	Insert Molding Solutions, Inc.
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II. Application Correspondent

Contact's Name:	Regulatory and Quality Solutions, LLC.
Contact Person:	Ms. Felicia Ruley, RAC Principal Specialist
Address:	2790 Mosside Blvd #800 Monroeville, PA 15146
Telephone:	(877) 652-0830 ext. 161
Email:	fruley@rqteam.com

III. Device

Trade Name:	REST EAZY Appliance
Common/Usual Name:	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Classification Name:	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Product Classification:	Class II, § 872.5570, Product Code LRK

IV. Predicate Device

- Specialty Appliance Works, Inc.'s Acrylic Splint Herbst Appliance
    - K083209 (Specialty Appliance Works, Inc), FDA cleared on 01/27/2009

V. Reference Devices

- Embassy Dental Laboratory's Acrylic Herbst Appliance
    - K111009 (Embassy Dental Laboratory), FDA cleared on 04/11/2011
- Selane Products Inc.'s SML-OSA2 Appliances
    - K162816 (Selane Products Inc.), FDA cleared on 0/27/2017
- Great Lakes Orthodontics' Variflex
    - K033632 (Great Lakes Orthodontics), FDA cleared on 11/19/2003

VI. Device Description

The proposed REST EAZY Appliance device consists of an upper and lower acrylic splint, custom fabricated to the patient's teeth. The splints are connected to each other via the REST EAZY adjustable Herbst style mechanism that orients the jaw in a predetermined relationship. These devices function as a mandibular repositioner, which increases the pharyngeal space. An enlarged pharyngeal space assists the patient with improved air exchange. The device is custom fit for each patient, as prescribed by the dentist.

Per 21 CFR 872.5570, intraoral devices for snoring and/or obstructive sleep apnea are worn during sleep to reduce the incidence of snoring and to treat obstructive sleep apnea. The devices are designed to increase the patency of the airway and to decrease air turbulence and airway obstruction. The classification includes palatal lifting devices, tongue retaining devices, and mandibular repositioning devices. The proposed REST EAZY Appliance is considered a mandibular repositioning device.

VII. Indications for Use

The REST EAZY Appliance is intended for use in adult patients for the reduction of snoring and mild to moderate obstructive sleep apnea. The REST EAZY Appliance is worn while sleeping to support the lower jaw in a forward position as prescribed by the dentist. The appliance is removable by the patient.

VIII. Comparison of Technological Characteristics with the Predicate Devices

The proposed REST EAZY Appliance has the same intended use, fundamental scientific technology and materials as the predicate device Specialty Appliance Works, Inc.'s Acrylic Splint Herbst Appliance.

The following table (**Table 7-1**) provides an overview of general technological characteristics in comparison to the predicate device.

Table 7-1: General Technological Characteristics Comparison

Product Features	Proposed Device Insert Molding Solutions, Inc. REST EAZY Appliance	Predicate Device Specialty Appliances Acrylic Splint Herbst Appliance (K083209)
Device Description	The proposed device consists of 2 customized maxillary and mandibular form-fitting arches (splints). These splints are produced in a lab using industry standard dental acrylic material. The splints are formed with stainless steel nut flanges to permit the attachment of the advancement connectors. The advancement connectors each consist of a threaded portion with an eyelet and a receptacle (nut) portion with an eyelet. Vertical adjustment stops may also be placed on the occlusal aspect of the maxillary base.	The Acrylic Splint Herbst Appliance consists of an upper and lower acrylic splint custom fabricated to the teeth. These full arch splints are connected to each other by the Herbst mechanism, which is a rod and tube type assembly that orientates the jaws in a predetermined relationship. The Herbst mechanism allows the patient vertical and lateral range of motion while the jaws are orientated in the biting relationship dictated by the positioning of the Herbst mechanism as it connects to the respective arch splints.
Indications for Use	The REST EAZY Appliance is intended for use in adult patients for the reduction of snoring and mild to moderate obstructive apnea. The REST EAZY Appliance is worn while sleeping to support the lower jaw in a forward position as prescribed by the dentist. The appliance is removable by the patient.	The Acrylic Splint Herbst Appliance is intended for use in patients 18 years of age or older for the reduction of snoring and mild to moderate obstructive sleep apnea. The Acrylic Splint Herbst 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.
Class	II	II
Product Code	LRK	LRK
Regulation Number	872.5570	872.5570
Regulation Name	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Design	Herbst Upper and lower arches to support jaw	Herbst Upper and lower arches to support jaw
Patient Contact	External communicating (>30 days) Surface-contacting (mucosa)	External communicating (>30 days) Surface-contacting (mucosa)
Sterility	Non-sterile Device is cleaned between uses by the patient following instructions provided by its manufacturer	Non-sterile Device is cleaned between uses by the patient following instructions provided by its manufacturer
Type of Device	Prescription use only.	Prescription use only.
Usage	Removable intraoral device. Single patient multiple use.	Removable intraoral device. Single patient multiple use.
Scientific Principle	Supports forward movement of lower mandible during sleep	Supports forward movement of lower mandible during sleep
Principle of Operation	Positions the lower jaw forward and open vertically causing the mandible to protrude from the position of the maxilla. Temporarily repositions the mandible to increase the pharyngeal space which allows for improved air exchange.	Positions the lower jaw forward and open vertically from its normal location which causes a protrusion of the mandible in relation to the maxilla. This forward repositioning, which is temporary while the appliance is being used, increases the pharyngeal space which assists the patient with improved air exchange.
Materials	Stainless Steel (304 or 316) and Dental Acrylic (Variflex®)	Stainless Steel (304 or 316) and Dental Acrylic (methyl methacrylate or Variflex®)

IX. Performance Data

The following performance data was considered in support of the substantial equivalence determination.

Performance Guidelines

The special control for these devices is the FDA guidance document entitled "Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA." [67 FR 68512, Nov. 12, 2002]

Biocompatibility

The predicate and subject devices are considered to be external communicating devices of permanent exposure (>30 days) per ISO 7405 and surface-contacting devices (mucosa) of permanent contact (>30 days) per ISO 10993-1. There are no new materials being used in the proposed device. Materials utilized for the REST EAZY Appliance are identical to the primary materials used in the predicate device for the same intended use. Both the predicate and REST EAZY Appliance are made from stainless steel and dental acrylic. Biocompatibility testing has been previously established through biocompatibility testing for the Variflex (K033632) material.

Non-Clinical Testing

The following physical properties testing was conducted on the Variflex (K033632) material.

- Ultimate Tensile Strength
- Young's Modulus
- Hardness (Shore D)
- Water Sorption
- Water Solubility

Risk Analysis

A risk analysis including an evaluation of the materials of construction and design was performed. The prescribing dentist must recognize the potential for TMJ soreness, soft tissue soreness, and dentition complications (soreness, motion, loosening) when using a mandibular advancement device. The contraindications, warnings, precautions, storage directions, prescription preparation instructions, fitting and adjustment directions are provided to avoid potential problems from arising or persisting with the dentition, tissue, or joints. No significant new risks were identified.

X. Conclusion

The proposed REST EAZY Appliance has the same intended use, fundamental scientific technology and materials as the predicate device Specialty Appliance Works, Inc.'s Acrylic Splint Herbst Appliance; therefore, the REST EAZY Appliance is substantially equivalent to the predicate device.