DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 11, 2014

Crane Dental Laboratory Inc.
Ms. Kate Young
Management Representative
200 Airpark Drive Suite 30
Rochester, New York 14624

Re: K140429
Trade/Device Name: Crane Acrylic Herbst Appliance
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral device for snoring and obstructive sleep apnea
Regulatory Class: II
Product Code: LRK
Dated: August 5, 2014
Received: August 14, 2014

Dear Ms. Young:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K140429

Device Name: *Crane Acrylic Herbst Appliance*

Indications for Use:

The Crane Acrylic Herbst Appliance is intended for use in patients 18 years of age or older for the reduction of night time snoring and mild to moderate obstructive sleep apnea.

Type of Use (Select one or both, as applicable)

Prescription Use ✓ (Part 21 CFR 801 Subpart 0) AND/OR Over-The Counter Use _____ (21 CER 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of Center for Devices and Radiologic Health (CDRH)

Revised 510(k) Summary

Submission Owner: Crane Dental Laboratory, Inc.
200 Airpark Drive, Suite 30
Rochester, New York 14624
Phone: (585) 730-5100
Fax: (585) 730-5095

Contact Person: Kate Young, Management Representative

Submission Date: February 17, 2014

Device Name: Trade Name-Crane Acrylic Herbst Appliance

Regulation Description: **Intraoral device for snoring and mild to moderate obstructive sleep apnea (OSA)**

Classification: **DEVICE, ANTI-SNORING**
Regulation- Number 21 CFR 872.5570, Intraoral devices for snoring and obstructive sleep apnea
Definition- Regulation Medical Specialty-Dental
Review Panel- Dental
Product Code- LRK
Device Class- II

Substantial Equivalence is claimed to this Predicate Device:

- Respire Medical LLC- Respire Pink Series (K131138)

Device Description:
The Crane Acrylic Herbst Appliance is comprised of upper and lower patient-specific acrylic splints connected bilaterally via a telescoping Herbst mechanism that orients the jaw in a predetermined relationship. The Herbst mechanism allows the patient vertical and lateral range of movement while the jaws are oriented in the biting relationship determined by the positioning of the mechanism as it connects to the respective arch splint.
The Appliance positions the lower jaw forward and open vertically from its normal location which causes a protrusion in the mandible in relation to the maxilla. The appliance aims through this repositioning (which is temporary while the appliance is being used) to increase air exchange, and to reduce snoring and apnea by increasing pharyngeal space.
The prescribing dentist determines the repositioning of the mandible through a patient-specific protrusive bite registration taken by the dentist. The dentist is also able to adjust the mandible's position by altering the Herbst mechanism, and/or adjusting the acrylic portion of the device.
The Acrylic Splint Herbst Appliance is removable by the patient, and is worn while sleeping to support the mandible in a forward position determined by the prescribing dentist.

Intended Use of the Device:
The Crane Acrylic Herbst Appliance is intended for use in patients 18 years of age or older for the reduction of night time snoring and mild to moderate obstructive sleep apnea.

Risks to Health:
As noted below the design of the Crane Acrylic Herbst Appliance addresses the risks outlined in the Guidance Document: *Class II Special Controls Guidance Document: Intraoral Device for Snoring and/or Sleep Apnea; Guidance for Industry and FDA* issued on November 12, 2002.

Intraoral gingival, palatal or dental soreness:
As similar to the predicate device, The Crane Acrylic Herbst Appliance is a patient-specific custom dental device fitted to the upper and lower arches, constructed of medical grade acrylic to contact the teeth on the lingual, occlusal and buccal surfaces, and a small area of the supporting tissue and dental-alveolar structures during sleep. The device design distributes the force of the repositioning of the mandibular arch throughout the appliance and the entire arch and supporting structures. Because the dvice is designed to eliminate single-point contact with individual teeth and these supporting structures, it reduces the opportunity for gingival, palatal, or dental soreness. Taking dental undercuts into consideration, the device is manufactured to reduce any possible soreness to the teeth and supporting structures.

Temporomandibular Joint (TMJ) Dysfuntion Syndrome:
The Crane Acrylic Herbst Applaince increases the patient's pharyngeal space by projecting the mandible down and forward to prevent the tongue and soft tissues from impeding the airway. The appliance is adjustable using a titration key and screw in the Herbst Mechanism, which enables the jaw to be brought forward in small increments by the prescribing dentist. It is recognized by the dental community that this type of repositioning can also affect the temporomanidibular joint. The prescribing dentist should evaluate the TMJ prior to prescribing the Crane Acrylic Herbst Appliance to be sure the patient does not possess risk factors to the TMJ that may be aggravated by using the appliance. Patients do sometimes report sensation in the TMJ the first few initial uses of the appliance, but usually resolve with continued wear. The prescribing dentist can also adjust the position of the mandible by changing either the length of the Herbst mechanism or the thickness of the acrylic interproximally. Patients who continue to have TMJ pain or discomfort that does not resolve through continued use should decide with their dentist to discontinue treatment with this modality.

Obstruction of Oral Breathing:
The design of the Crane Acrylic Herbst Appliance will not obstruct oral breathing.

Loosening or Flaring of Lower Anterior Teeth or General Tooth Movement:
Full arch coverage of the Crane Acrylic Herbst Appliance helps to minimize these issues. The full arch design helps to reduce localized forces and pressure on individual teeth, or sections of teeth such as the lower anterior segment. The dentist can easily modify the amount of mandibular repositioning. This also helps to reduce the forces on the teeth and supporting alveolar structures.

Material Composition:

- Medial Grade Acrylic-Polymethyl methacrylate Acrylic Splints. Methyl methacrylate has been used for decades in the dental industry and does not pose any known health hazards in its polymerized form.
- Stainless Steel-Herbst mechanism and ball clasps (if requested by the dentist). Stainles steel is and accepted material for dental products.

Sustantial Equivalence:

The Craen Acrylic Herbst Appliance is substantially equivalent to other legally marketed devices in the United States. The Crane Acrylic Herbst Appliance has the same intended use and technological characteristics as the following device:

- Respire Medical LLC-Respire Pink Series Herbst (K131138)

Substantially Equivalent Devices	***Crane Dental Laboratory, Inc. Crane Acrylic Herbst Appliance [510(k) TBD]***	***Respire Medical, LLC Respire Pink Series Herbst (K131138)***
Intended Use Indications for Use	To reduce or alleviate nighttime snoring and mild to moderate OSA	Same
Single or Multiple Use	Multiple	Same
Target Population	Adults age 18 and older	Same
Prescription usage	Prescription Only	Same
Basic Design	Upper and lower trays connected bilaterally via Telescopic Herbst Mechanisms	Same
Device Functionality	Increase patient's pharyngeal space to improve air exchange by repositioning the mandible thus reducing snoring and mild to moderate OSA	Same
Mandibular Advancement Range	Up to 8mm	Same
Device Components	Medical grade acrylic splints and stainless steel telescopic Herbst mechanisms	Same
Colorants	Red / Blue	Pink
Adjustability	By prescribing dentist or physician	Same
Method of Manufacture	Patient-specific Customization	Same
Sterility	Non-sterile	Same

Conclusion:

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and same technological characteristics as the previously cleared predicate device, and that the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device. The fundamental scientific technology and intended use of the Crane Acrylic Herbst appliance is the same as the above mentioned predicate device, and therefore raises no new safety and/or effectiveness issues.