K083209

JAN 27 2009

5. 510(k) Summary of Safety and Effectiveness

Submitter:

Scott Huge
Specialty Appliances Works, Inc.
4905 Hammond Industrial Drive
Cumming, GA 30041

Contact:

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Date prepared:

September 2008
Amended: January 09

Guidance Documents used:

The 510 K Submittal for the Acrylic Splint Herbst manufactured by Specialty Appliances was prepared in accordance with the Guidance Document listed below:

> *Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Sleep Apnea; Guidance for Industry and FDA, dated November 12, 2002*

Device Name:

- Trade Name – Acrylic Splint Herbst Appliance
- Classification name – Device, Anti-Snoring Device
- Regulation Description – Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.
- Definition –Regulation Medical Specialty – Dental
- Review Panel – Dental
- Product Code – LRK
- Regulation Number 21 CFR 872.5570
- Device Class - II

Devices for Which Substantial Equivalence is claimed:

- Allesee Orthodontic Appliances, Inc. – Removable Acrylic Herbst (K070327)

Device Description:

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.

The functional relationship built into the appliance 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.

The prescribing dentist determines the exact repositioning of the lower bite via a wax construction bite obtained from the patient in the clinic. The dentist is also able to fine tune the jaw positioning clinically as needed by altering the Herbst mechanism and/or adjusting the acrylic portions of the appliance.

Intended use of the Device:

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.

Substantial Equivalence:

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

The Removable Acrylic Herbst by Allesee Orthodontic Appliances (K070327).

Risks to Health

As noted below, the design of the Acrylic Splint Herbst Appliance addresses the risks identified in the Guidance Document: *Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Sleep Apnea; Guidance for Industry and FDA, dated November 12, 2002.* Specialty Appliance has not identified any other risks with the Acrylic Splint Herbst Appliance.

Intraoral gingival, palatal or dental soreness

The Acrylic Splint Herbst Appliance is custom fitted to the dental arches and designed to contact the teeth on the lingual, occlusal and labial/buccal, plus a small portion of the supporting dental-alveolar structures. This design distributes the mandibular repositioning forces throughout the appliance and therefore the entire dental arch and supporting structures. Eliminating single point contact with specific teeth or supporting structures reduces the opportunity for dental and gingival soreness. Some patients using The Acrylic Splint Herbst Appliance present with dental undercuts on certain teeth. The appliance is manufactured taking this into consideration to reduce soreness to the teeth and supporting structures. One appliance design option is to use a thermal setting resin for the acrylic portions contacting the teeth. This material softens slightly in the mouth to better accommodate teeth with undercut anatomy.

TMD Concerns

The Acrylic Splint Herbst Appliance accomplishes the goal of increasing the lower airway by repositioning the lower jaw down and forward. It is recognized by the dental community that this altered jaw relationship can also affect the temporomandibular joints. The prescribing dentist should perform a TMJ examination prior to using The Acrylic Splint Herbst Appliance to make sure the patient is not predisposed to TMJ risks that may be aggravated by using appliance. Some patients do report sensations in the TMJ area in the early stages of appliance wear but these are usually transitory with continued wear. The prescribing dentist can also alter the position of the lower jaw by changing the length of the Herbst mechanism and/or by adjusting the thickness of the interproximal acrylic. Patients that do not tolerate the appliance in terms of TMJ discomfort can decide with their dentist to discontinue treatment with this modality.

Obstruction of Oral Breathing

The design of the Acrylic Splint Herbst will not obstruct oral breathing.

Loosening or flaring of the lower teeth or general tooth movement

The Acrylic Splint Herbst Appliance is fabricated to minimize these issues by designing full arch coverage of all the teeth. This reduces local forces and pressure on individual teeth or segments of teeth like the lower anteriors. The dentist is also able to easily control and modify the amount of lower jaw repositioning (decrease as needed) which can reduce the forces directed to the teeth and supporting alveolar structures.

Material Composition

The Acrylic Splint Herbst Appliance is fabricated from known dental materials used for decades throughout the industry. The Acrylic Splint Herbst Appliance contains or uses the following materials:

Stainless Steel (304 or 316) - Stainless steel is a commonly accepted material for dental products. All wire and Herbst Mechanism components are manufactured with 304 or 316 Stainless Steel.

Dental Acrylic - The Acrylic Splint Herbst Appliance is typically made with a methyl methacrylate formulation for the acrylic portions of the appliance. Methyl methacrylate has been used in the dental industry for well over 50 years and does not pose any known health hazards to the patient in its polymerized form.

Variflex® - If prescribed by the doctor, the Acrylic Splint Herbst may be constructed using Variflex® a heat softening acrylic manufactured by Great Lakes Orthodontics (reference KO33632).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2009

Ms. Carolyn Thomas
Business Manager
Specialty Appliance Works, Incorporated
4905 Hammond Industrial Drive
Cumming, Georgia 30041

Re: K083209
Trade/Device Name: Acrylic Splint Herbst Appliance
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: January 8, 2009
Received: January 12, 2009

Dear Ms. Thomas:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4. Indications for Use

510(k) Number: K083209

Device Name: Acrylic Splint Herbst Appliance

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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