K070327

SYBRON DENTAL SPECIALTIES
Submitter:

MAY 25 2007

Allesee Orthodontic Appliances, Inc.
13931 Spring Street
Sturtevant, WI 53177

Contact:
Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
(714) 516-7488 - Facsimile
Colleen Boswell - Contact Person
Date Summary Prepared: May 2007

Device Name:

- Trade Name – *Removable Acrylic Herbst*
- Common Name – Intraoral Device for Snoring and/or Sleep Apnea
- Classification Name – Intraoral Device for Snoring and Intraoral Device for Snoring and Obstructive Sleep Apnea, per 21 CFR § 872.5570

Devices for Which Substantial Equivalence is Claimed:

- State University of New York at Buffalo, School of Dental Medicine, *Removable Herbst Appliance*

Device Description:

The *Removable Acrylic Herbst* appliance is an upper and lower arch system designed to hold the lower jaw forward which increases the lower airway passage and reduces the tendency to snore. The upper and lower appliances are connected by means of a telescoping male and female stainless steel tube (upper) and rod (lower) Herbst mechanism. The system is bilateral, left and right. While the patient can open and close their mouth, the lower jaw arcs as predetermined by the construction of the appliance. The degree to which the patient's lower jaw is supported in an anterior position is determined by the dentist.

Intended Use of the Device:

The intended use of the *Removable Acrylic Herbst* is for the reduction of snoring and mild to moderate obstructive sleep apnea (OSA) by moving the lower jaw into a prescribed relationship to the upper jaw.

Substantial Equivalence:

The *Removable Acrylic Herbst* is substantially equivalent to another legally marketed device in the United States. The *Removable Acrylic Herbst* is used in a manner similar to the *Removable Herbst Appliance* developed by the State University of NY at Buffalo, School of Dental Medicine.

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Colleen Boswell - Contact Person
Date Summary Prepared: May 2007

Device Name:

- Trade Name – *Enoch Snorinator*
- Common Name – Intraoral Device for Snoring and/or Sleep Apnea
- Classification Name – Intraoral Device for Snoring and Intraoral Device for Snoring and Obstructive Sleep Apnea, per 21 CFR § 872.5570

Devices for Which Substantial Equivalence is Claimed:

- Hays & Meade Inc., *Snore Guard*

Device Description:

The *Enoch Snorinator* is a one-piece appliance designed for the upper arch only. It is a pressure-formed anterior repositioning splint which postures the lower jaw forward to alleviate snoring. The anterior portion is formed into a "ramp" shape to engage the lower incisors. This ramp postures the lower jaw into the prescribed position as determined by the dentist.

Intended Use of the Device:

The intended use of the *Enoch Snorinator* is for the reduction of snoring and mild to moderate obstructive sleep apnea (OSA) by moving the lower jaw into a prescribed relationship to the upper jaw.

Substantial Equivalence:

The *Enoch Snorinator* is substantially equivalent to another legally marketed device in the United States. The *Enoch Snorinator* is used in a manner similar to the *Snore Guard* appliance developed by Hays & Meade Inc.

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Colleen Boswell - Contact Person
Date Summary Prepared: May 2007

Device Name:

- Trade Name – *Allesee Snore Appliance (ASA)*
- Common Name – Intraoral Device for Snoring and/or Sleep Apnea
- Classification Name – Intraoral Device for Snoring and Intraoral Device for Snoring and Obstructive Sleep Apnea, per 21 CFR § 872.5570

Devices for Which Substantial Equivalence is Claimed:

- Great Lakes Orthodontic Laboratory, *NAPA Appliance*

Device Description:

The *Allesee Snore Appliance (ASA)* is a one-piece upper and lower, pressure-formed splint. The upper and lower jaw plastic appliances are joined together with orthodontic acrylic. The appliance postures the patient's lower jaw in a forward or anterior position. The amount of advancement is patient specific and determined by the dentist. The appliance has a rectangular airway between the upper and lower anterior teeth.

Intended Use of the Device:

The intended use of the *Allesee Snore Appliance (ASA)* is for the reduction of snoring and mild to moderate obstructive sleep apnea (OSA) by moving the lower jaw into a prescribed relationship to the upper jaw.

Substantial Equivalence:

The *Allesee Snore Appliance (ASA)* is substantially equivalent to another legally marketed device in the United States. The *Allesee Snore Appliance (ASA)* is used in a manner similar to the *NAPA Appliance* produced by Great Lakes Orthodontic Laboratory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Colleen Boswell
Vice President, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

MAY 25 2007

Re: K070327
Trade/Device Name: Removable Acrylic Herbst, Allesee Snore Appliance (ASA), and Enoch Snorinator
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: May 11, 2007
Received: May 14, 2007

Dear Ms. Boswell:

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.

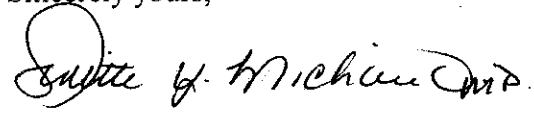
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070327

Indications for Use

510(k) Number (if known): K070327

Device Name: *Removable Acrylic Herbst*

Indications for Use:

The *Removable Acrylic Herbst* is intended to be used for the reduction of snoring and mild to moderate obstructive sleep apnea (OSA) by repositioning the lower jaw into a prescribed relationship to the upper jaw.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

R S Bethel DDS for Dr. Susan Runner

ospital

K070327

K070327

Indications for Use

510(k) Number (if known): K070327

Device Name: *Allesee Snore Appliance (ASA)*

Indications for Use:

The *Allesee Snore Appliance (ASA)* is intended to be used for the reduction of snoring and mild to moderate obstructive sleep apnea (OSA) by repositioning the lower jaw into a prescribed relationship to the upper jaw.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert S Betz DDS for Dr Susan Runner

Hospital

K070327

K070327

Indications for Use

510(k) Number (if known): K070327

Device Name: *Enoch Snorinator*

Indications for Use:

The *Enoch Snorinator* is intended to be used for the reduction of snoring and mild to moderate obstructive sleep apnea (OSA) by repositioning the lower jaw into a prescribed relationship to the upper jaw.

Prescription Use __X__ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert Betz DDS for Dr. Susan Runner

Hospital

510(k) K070327