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Attachment 6

510(k) SUMMARY
Dental Crafter's IST Device

Submitter's Name, Address, Telephone Number, Contact Person

Robert Slominski
Co-Owner
1000 Corporate Drive
PO Box 770
Marshfield, WI 54449
715/387-2642
800/472-8302
715/387-4100 (fax)
bobs@dentalcrafters.net

Date Prepared:

Name of Device: IST Snoring Appliance

Name/Address of Sponsor

Common or Usual Name: Apnea and Anti-Snoring Device

Classification Name: Anti-Snoring Device

Predicate Devices:

Endsnor (K072731)

Removable Arylic Herbst Allesee Snore (K070327)

TAP® III (K062951)

Intended Use: The IST Snoring Appliance is a dentist prescribed intraoral device for repositioning the upper and lower jaw into a prescribed relationship in single patient for multi-use at home or sleep laboratories.

Indications for Use: The IST Snoring Appliance is indicated for persons 18 years or older, who wish to reduce the incidence of snoring and/or mild to moderate obstructive sleep apnea.

Technological Characteristics and Substantial Equivalence:

The **Dental Crafters' IST Snoring Appliance** is a dentist prescribed intraoral device for repositioning the upper and lower jaw into a prescribed relationship in single patient for multi-use at home or sleep laboratories.

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The Dental Crafters' IST Snoring Appliance is a 2 piece upper and lower arch system designed to posture the lower jaw forward which increases the lower airway passage and alleviates snoring. It is custom-fit to a patient's teeth by a professional dentist. The upper and lower appliances are connected by means of a telescoping male and female stainless steel tube (upper) and rod (lower) ISTplus mechanism produced by Dr Hinz Dental. The acrylic arches of the appliance are secured to the occlusal surface. 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 dentist determines the position in which the lower jaw is supported in an anterior position.

The Company's anti-snoring device covered by this submission is substantially equivalent to other legally marketed Anti-Snoring Devices. Specifically, the Dental Crafters' IST Snoring Appliance is substantially equivalent to Endsnor (K072731), Removable Arylic Herbst Allesee Snore (K070327), and TAP® III (K062951). IST has the same general intended use, similar principles of operation, and similar technological characteristics as the previously cleared predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 11 2009

Ms. Amy Nystrom
Chief Financial Officer
Dental Crafters
1000 Corporate Drive
PO Box 770
Marshfield, Wisconsin 54449

Re: K090911
Trade/Device Name: IST Snore Appliance
Regulation Number: 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LQZ
Dated: September 2, 2009
Received: September 4, 2009

Dear Ms. Nystrom:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K090911

Attachment 8

510(k) Number (if known):

Device Name: IST Snore Appliance

Indications for Use:

The IST Snoring Appliance is a dentist prescribed intraoral device for repositioning the upper and lower jaw into a prescribed relationship in single patient for multi-use at home or sleep laboratories. It is indicated for persons 18 years or older, who wish to reduce the incidence of snoring and/or mild to moderate obstructive sleep apnea.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER LINE IF NECESSARY0

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic & ENT Devices

510(k) Number_____

Prescription Use__*__ or Over-The-Counter Use_____
(Optional Format 1-2-96)

Susan Runge

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

510(k) Number: K090911