K102909

DEC 13 2011

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information: SomnoMed Inc. **Contact Persons:** Bradley Southworth

Address of Contact Person: 7460 Warren Parkway, Suite 190, Frisco, TX 75034, Phone 888-447-6673

Date Summary Prepared: October 28, 2011

Device Name: Various versions of SomnoBrux

Trade Name(s): SomnoBrux Splint(s) Classification Name: Mouthguard,Prescription

Panel: Dental; Product Code: MQC

Device Description: The SomnoBrux Splints are intraoral devices used for treating bruxism. They consist of a custom fitted tray that fits over the upper or lower teeth. There are four different designs for this application all with varying degrees of function and suitability depending on the patients needs. The Michigan and the SomnBrux "B" splints are fitted on the maxillary arch and ii) The Gelb and Tanner splints are fitted on the mandibular arch. These devices function as a protective barrier between upper and lower tooth surfaces which will prevent tooth damage caused by grinding, bruxing and will help alleviate jaw and muscle pain. The dentist prescribes the Michigan, Gelb, Tanner or SomnoBrux "B" design; whichever is best suited to the patient.

Intended Use: The SomnoBrux Splints are used for the protection of teeth and restorations from the forces of Bruxism.

Substantial Equivalence and Predicate Device Information:

Device Name	Manufacturer	510(k) Reference
MYOHEALTH CLENCHING INHIBITOR also know as Bite Soft	MCI-MYOHEALTH SYSTEMS	K040315
DSG Relaxer Spint	Dental Services Group Sentage Corporation, dba. Dental Services Group.	K022627

Conclusion: Based upon the comparative analysis of features, materials and design the SomnoBrux Splint, Myo Health Clenching Inhibitor, and the SomnoBrux Splints are all custom manufactured, all acrylic type devices that treat bruxism by relaxing the structure of the masticatory system. All of these splints cover posterior occlusal surfaces, whereby the Myo Health Clenching Inhibitor only covers the Maxiliary six anterior teeth. By having the dental arches discluded with these acrylic splints (anterior or posterior) prevents excessive wear of the hard dental tissue caused by the parafunctional movement known as bruxism. Any minor design differences between these various models do not affect safety and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Bradley Southworth
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SomnoMed Incorporated
7460 Warren Parkway, Suite 190
Frisco, Texas 75034

DEC 13 2011

Re: K102909
Trade/Device Name: SomnoBrux Splints
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MQC
Dated: December 5, 2011
Received: December 7, 2011

Dear Mr. Southworth:

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 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

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

Enclosure

Indications for Use

510(k) Number (if known): K102909

Device Name: SomnoBrux Splints

Indications for Use: The SomnoBrux Splints are used for the protection of teeth and restorations from the forces of Bruxism.

Prescription Use ___**Yes**___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____**No**___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K102909