K110468

RANDMARK DENTAL PRODUCTS LLC

284 Elkins Ln, Lusby, MD 20657

(410) 326-6235

AUG - 5 2011

SECTION 5.0

SUMMARY OF SAFETY & EFFECTIVENESS

This summary of 510 (k) safety and effectiveness information is being supplied in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92.

5.1 ADMINISTRATIVE INFORMATION

5.1.1 Sponsor Identification

Randmark Dental Products LLC
284 Elkins Ln
Lusby, MD 20657
Tel: 410-326-6235
Fax: 501-637-7204

5.1.2 Sponsor/Manufacturer Establishment Registration Number: NA

5.13 Submission Correspondent

Norman F. Estrin, Ph.D.
Managing Partner
ESTRIN CONSULTING GROUP LLC
9109 Copenhaver Drive
Potomac, MD 20854
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5.2 Date Prepared: July 27, 2011

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5.3 Device Trade Names

Freeway Comfort™ Bite Guard

5.3.1 Model Numbers

Not currently available

5.3.2 Common Name: Dental Guard

5.3.3 Classification Name: None

5.3.4 Regulation Numbers: None

5.3.5 Proposed Regulation Class: unclassified

5.3.6 Device Product Code: OBR, MQC

5.3.7 Medical Specialties: Dental

5.4 Device Description

The **Freeway Comfort™ Bite Guard** dental guard is composed of a moldable thermoplastic inner lining that adapts to the teeth, and a hard outer shell. The shell is composed of a hard polycarbonate material. When heated, the moldable thermoplastic material is molded to fit the user's upper anterior teeth. The hard outer shell contacts the lower anterior teeth and prevents contact of the user's posterior teeth.

5.5 INDICATIONS FOR USE

OTC:
Protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

Protection against teeth grinding, bruxism and jaw clenching.

Rx:
Short-term pain relief from muscle spasm due to occlusal interference.

For the prevention of chronic tension and temporomandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the mandibular and maxillary teeth by the temporalis muscle.

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5.6 PREDICATE DEVICES

5.61 **Predicate Devices**: SleepRight® Products listed below (K071404) (**Applicant:** Power Products, Inc. – Splintek)

5.62 NTI Tension Suppression System (K010876)(**Applicant:** NTI-TSS, Inc.)

5.6.3

Product Code	Predicate Device Names:
OBR	SleepRight® -Select
OBR	SleepRight®-Low Profile
OBR	SleepRight®-Advance
OCO	NTI Tension Suppression System
MQC	SleepRight® - Low Profile Rx
MQC	SleepRight® - Advance Rx
OCO	NTI Tension Suppression System

5.7 SUBSTANTIAL EQUIVALENCE

OTC: The Freeway Comfort™ Bite Guard mouth guard is substantially equivalent to the three above listed SleepRight® products under Product code OBR. **The Freeway Comfort™ Bite Guard** mouth guard has the same intended uses, indications and similar technological characteristics as its predicate devices. The minor technological differences between the **Freeway Comfort™ Bite Guard** mouth guard and the predicate devices raise no new questions of safety or effectiveness. Thus, **the Freeway Comfort™ Bite Guard** mouth guard is substantially equivalent to the three SleepRight® products and the NTI product noted above.

Rx: The Freeway Comfort™ Bite Guard mouth guard is substantially equivalent to the two SleepRight® products shown above with the Product Code MQC. **The Freeway Comfort™ Bite Guard** mouth guard has the same intended uses, indications and similar technological characteristics as its predicate devices. The minor technological differences between the **Freeway Comfort™ Bite Guard mouth** guard and the predicate devices raises no new questions of safety or effectiveness. Thus, the **Freeway Comfort™ Bite Guard** mouth guard is substantially equivalent to the above noted two SleepRight® products with the Product Code MQC and the NTI Tension Suppression System with the Product Code OCO. Note that the **Freeway Comfort™ Bite Guard** mouth guard is not claiming substantial equivalence to the NTI Tension Suppression System for either OTC or Rx uses for the NTI migraine treatment claims.

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

Randmark Dental Products, LLC
C/O Norman F. Estrin, Ph.D.
Managing Partner
Estrin Consulting Group, LLC
9109 Copenhaver Drive
Potomac, Maryland 20854

AUG - 5 2011

Re: K110468
Trade/Device Name: Freeway Comfort™ Bite Guard
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: MQC, OBR
Dated: July 28, 2011
Received: July 29, 2011

Dear Dr. Estrin:

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

4.0 Indications for Use

510(k) Number (if known): K110468

Device Name: Freeway Comfort™ Bite Guard

Indications for Use:

OTC:
Protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

Protection against teeth grinding, bruxism and jaw clenching.

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Prescription Use ___X__ (Part 21 CFR 801 Subpart D)

AND/
OR

Over-The-Counter Use __ X___ (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)

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

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