PRISMATIK
DENTALCRAFT, INC.

K121365

NOV 2 0 2012

005-510 (k) Summary-807.92(c)

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

A. SUBMITTER INFORMATION

Company Name:	Glidewell Laboratories-Sleep Devices Group
Company Address:	2181 Dupont Dr. Irvine, CA 92612
Company Phone:	949-399-1940
Company FAX:	949-553-0924
Contact Person:	Armin Zehtabchi, (949) 225-1234 Kathleen Dragovich, (949) 399-1940
Date Summary Prepared:	10/31/2012

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Thermoformed Mouthguards/Nightguards
21 CFR Reference:	Unclassified
21 CFR Common Name:	Mouthguard, Prescription
Classification:	Class II
Product Code:	MQC
Panel:	Dental

C. IDENTIFICATION OF PREDICATE DEVICE

Trade/Proprietary Name:	Doctor's® NightGuard™ (K053580), Ez Splint & Ez Splint PM (K022809) and Dr. Hays Bite Guard (K014079)

D. DEVICE DESCRIPTION

The Thermoformed Mouthguards/Nightguards are designed to alleviate the pain and damage caused by bruxing or clenching of the teeth. Severe tooth, jaw or facial muscle pains are common side effects of bruxing or clenching of the teeth.

These aches can be alleviated with a dentist-prescribed, custom-made Thermoformed Mouthguard/Nightguards.

These customized devices fit over upper or lower teeth during sleep and can offset the effects of bruxing or clenching while protecting teeth from daily wear and tear.

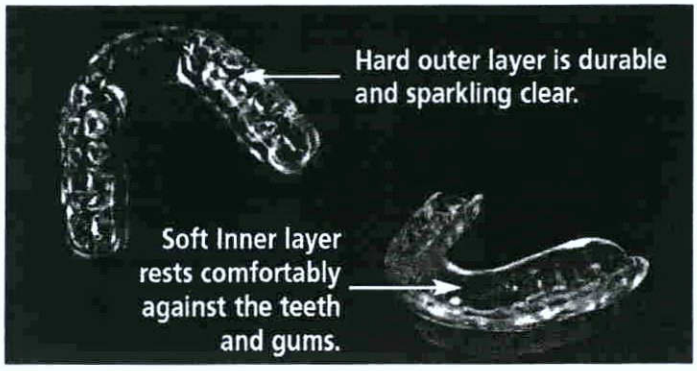
The design of Thermoforming Mouthguards/Nightguards is the same, and the only difference is the material in terms of hardness, softness or semi-softness. Each Mouthguard/Nightguard is made with a standard flat occulusal plane and slight opposing cusp indentation to each patient's specific bite plane needs that could be determined by a dentist after diagnosis of bruxism. The Comfort H/S™ Hard Soft Bite Splint is the most widely prescribed bite splint due to its comfort and fit. The soft internal surface rests comfortably against the teeth and gums, while the hard occlusal surface provides durability and bonds.

Thermoformed Mouthguards/Nightguards are manufactured from biocompatible materials. The materials are purchased from Erkodent Company that is DIN EN ISO 13485 certified. The ISO-certified thermoforming materials are BPA-free and are approved for dental use. The biocompatibility of the materials is confirmed according to DIN/EN 30993-1.

Glidewell has followed the FDA's Guidance's for Class II devices, and has met the following requirements:

(1) It conforms to the general controls of the Federal Food, Drug, and Cosmetic Act (the Act), including the premarket notification requirements described in 21 CFR 807, Subpart E.

(2) Has identified the predicate devices in lieu of performing biocompatibility testing, although the purchased materials are manufactured using medical grade material and precision extruding methods for the highest level of biocompatibility and tolerances. The biocompatibility of the materials is confirmed according to DIN/EN 30993-1 and a copy of the Safety Data Sheet for the purchased materials (Erkoflex, Erkodur, Erkolog-Pro) is included.



Glidewell Laboratories-Sleep Devices Group's Thermoformed Mouthguards/Nightguards are manufactured from biocompatible materials including Ethylene vinyl acetate (also known as EVA) which is similar to predicate devices' materials (Doctor's® NightGuard™, K053580) such as DuPont™ Elvax.

Elvax® resins are copolymers of ethylene and vinyl acetate and these specialty thermoplastic copolymers are inherently flexible, resilient, tough, and show excellent resistance to ozone and environmental stress cracking. Although Elvax® resins are available in various grade series; however, they all contain general properties. The following chart demonstrates the physical properties:

Product	Melting Point	Density	Hardness Shore	Tensile Strength
Glidewell Laboratories-Sleep Devices Group	>72 °C	> 0.92	> 82/	> 15
Elvax	>72 °C	> 0.92	> 82/	> 15

Glidewell Laboratories-Sleep Devices Group included a Technical Specifications sheet. This technical information sheet will help to find a good understanding of the physical properties of Materials that comply with the guidelines for European medical products 93/42/EEC or 2007/47/EC.

Biocompatibility

Thermoformed Mouthguards/Nightguards are manufactured from biocompatible materials. The ISO-certified thermoforming materials are BPA-free and are approved for dental use. The biocompatibility of the materials is confirmed according to DIN/EN 30993-1.

Glidewell Laboratories-Sleep Devices Group included two test reports for Cytotoxicity. The summary of the test results indicate that thermoformed materials do not release substances in cytotoxic concentrations during a permanent 24 h contact of 4.5 cm^2 surface area to 1 ml physiological fluid.

In addition, a copy of the MSDS for Elvax material that is manufactured by DuPont is included.

E. INDICATIONS FOR USE

The Thermoformed Mouthguards/Nightguards are intended for protection against bruxism and nighttime teeth grinding. They create a barrier between the upper and lower dentition to protect the patient's overall occlusion.

F. SUBSTANTIAL EQUIVALENCE

The Thermoformed Mouthguards/Nightguards are substantially equivalent to the Doctor's® NightGuard™ (K053580), Ez Splint & Ez Splint PM (K022809) and Dr. Hays Bite Guard (K014079). These mouthguards/nightguards are substantially equivalent in intended use, indication for use, material, design and performance.

Comparison of Predicate Devices

Elements of Comparison	Thermoformed Mouthguards	Doctor's® NightGuard™ (K053580)	Dr. Hays Bite Guard (K014079)	Ez Splint & Ez Splint PM (K022809)
Indications	Thermoformed Mouthguards/Nightguards are intended for protection against bruxism and nighttime teeth grinding. They create a barrier between the upper and lower dentition to protect the patient's overall occlusion.	The Doctor's® NightGuard™ is indicated for 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. Short-term pain relief from muscle spasm due to occlusal interference.	Protection against teeth grinding, bruxism and jaw clenching. Short-term pain relief from muscle spasm due to occlusal interference.
Material	Approved Biocompatible Materials: Co-Polyester, Polyurethane, Ethyl Vinyl Acetate (Erkoflex, Erkodur, Erkolog-Pro)	Elvax Resin (a copolymer of ethylene and vinyl acetate)	Lexan & Elvax	Elvax Resin and Polyurethane
Design	Pre-formed Device	Pre-formed Device	Pre-formed Device	Pre-formed Device
Prescription Device	Yes	No	Yes	Yes
Re-Usable Device	Yes, Single Consumer/Patient	Yes Single Consumer/Patient	Yes, Single Consumer/ Patient	Yes, Single Consumer/Patient
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile
Method of Manufacturing	Thermo-Molding Custom-Fit	Thermo-Molding Custom-Fit	Thermo-Molding Custom-Fit	Injection Molding

G. NON-CLINICAL TESTING

Glidewell Laboratories-Sleep Devices Group has relied on the existing predicated devices for the safety and the effectiveness of its Thermoformed Mouthguard/Nightguards devices. In addition, the ISO-certified Erkodent thermoforming materials are BPA-free and are approved for dental use. The biocompatibility of the materials is confirmed according to DIN/EN 30993-1. Therefore, the Thermoformed Mouthguards/Nightguards are safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 20, 2012

Mr. Armin Zehtabchi
Senior Regulatory Affairs / Quality Assurance Coordinator
Glidewell Laboratories-Sleep Devices Group
2181 Dupont Drive
Irvine, California 92612

Re: K121365
Trade/Device Name: Thermoformed Mouthguards
Regulation Number: Unclassified
Regulation Name: Mouthguard, prescription
Regulatory Class: Unclassified
Product Code: MQC
Dated: October 31, 2012
Received: November 2, 2012

Dear Mr. Zehtabchi:

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,

Kwame O. Ulmer

Digitally signed by Kwame O. Ulmer
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Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

GLIDEWELL LABORATORIES
Sleep Devices Group
2181 Dupont Dr., Irvine, CA 92612

004-Indications for Use Statement

K121365

510 (K) Number (if known): ~~To be determined~~

Device Name: Thermoformed Mouthguards

Indications for Use: The Thermoformed Mouthguards are intended for protection against bruxism and nighttime teeth grinding. They create a barrier between the upper and lower dentition to protect the patient's overall occlusion.

Prescription Use: Yes ☒ No ☐ (Part 21 CFR 801 Subpart D)

Over-the-Counter Use: Yes ☐ No ☒ (Part 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)

Kwame O. Ulmer

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

510(k) Number: K121365