July 16, 2021

Ampower Dental Laboratories, LLC
% Parul Chansoria
CEO and Founder
Elexes Medical Consulting, LLC
30 N Gould St Ste R
Sheridan, Wyoming 82801

Re: K210011
Trade/Device Name: JS Dental Lab Mouth Guard
Regulatory Class: Unclassified
Product Code: MQC
Dated: June 3, 2021
Received: June 8, 2021

Dear Parul Chansoria:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210011

Device Name
JS Dental Lab Mouth Guard

Indications for Use *(Describe)*
The JS Dental Lab Mouth Guard is intended for protection against bruxism and teeth grinding. They create a barrier between the upper and lower dentition to protect the patient's overall occlusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary K210011

5.1. Submitter's Information

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Date Prepared: June 03, 2021.

5.2. Device Information

Common/Usual name: Mouthguard
Trade Name: JS Dental Lab Mouth Guard
Regulation Name: Mouthguard, Prescription
Regulatory Class: Class II
Review Panel: Dental
Product Code: MQC

5.3. Predicate Device Information

Table 1: Predicate Device Information

Company	Predicate Priority	Product	510(k) Number
Glidewell Laboratories - Sleep Devices Group	Primary	Thermoformed Mouthguards/Nightguards	K121365
Erkodent Erich Kopp GmbH	Reference	Thermoforming Sheet Materials	K200125

5.4. Device Description

The JS Dental Lab Mouth Guard (herein referred to as Subject Device) is a patient contact protective custom-fit mouth guard that covers the upper teeth and lower teeth to prevent premature tooth wear and noise caused due to bruxism and teeth grinding. It fits over upper teeth or lower teeth during sleep. The Subject Device

can offset the effects of bruxing or teeth grinding while protecting teeth from daily wear and tear. The Subject Device is created based on the user's teeth impression and manufactured using the biocompatible material, equivalent to the Thermoformed Mouthguards/Nightguards (herein referred to as Predicate Device, K121365).

The Subject Device contains biocompatible materials, namely, Erkodur or Splint Biocryl, Erkoloc-Pro, Erkoflex-95, EVA Based Clear Mouthguard Material and BIOPLAST and is available in four different variations. All the biocompatible materials used are ISO-certified, BPA-free, and are cleared for dental use in humans.

5.5. Indications for Use

The Subject Device (The JS Dental Mouth Guard) is intended for protection against bruxism and teeth grinding. They create a barrier between the upper and lower dentition to protect the patient's overall occlusion.

5.6. Comparison Of Technological Characteristics With The Predicate Device

A detailed comparison of the Subject Device with the predicate device is given in Table 2. The Indications for Use, key technological characteristics, and operating principle of the Subject Device is equivalent to the Predicate Device**,** K121365.

Table 2: Technological Characteristics Comparison

Parameters	**Subject Device: JS Dental Lab Mouth Guard**	**Predicate Device: Thermoformed Mouth Guards (K121365)**	**Reference Device: Thermoforming Sheet Materials (K200125)**	**Equivalence**
Manufacturer	Ampower Dental Laboratories LLC	Glidewell Laboratories-Sleep Devices Group	Erkodent Erich Kopp GmbH	--
Indications for Use	The JS Dental Lab Mouth Guard is intended for protection against bruxism and teeth grinding. They create a barrier between the upper and lower dentition to protect the patient's	The Thermoformed Mouthguards/Nightguards are customized devices fit over upper or lower teeth during sleep and can offset the effects of bruxing or clenching	Thermoforming Sheet Materials are indicated for the fabrication of orthodontic and dental appliances	Equivalent

	overall occlusion.	while protecting teeth from daily wear and tear.		
Materials	Co-polyester, polyurethane, Ethyl Vinyl acetate (Erkodur or Splint Biocryl, Erkoloc-Pro, Erkoflex-95, EVA Based Clear Mouthguard Material and BIOPLAST)	Co-polyester, polyurethane, Ethyl Vinyl acetate (Erkoloc Pro, Erkoflex, Erkodur)	Erkoloc-pro (blue / green / pink), Erkodur (freeze / -0M1 /-A1 / -A2 / -A3), Erkoflex (color / freestyle / -95 / -bleach) Erkolign, Erkoplast PLA (-T/-W/-R), Erkolen, Playsafe triple (-light)	Different
Reusable device	Yes	Yes	Yes	Equivalent
Single patient use only	Yes	Yes	Yes	Equivalent
Variations of Mouthguard	Thermoformed Night Guards	Thermoformed Mouthguards/Night Guards	-	Equivalent
Design	Pre-formed Device	Pre-formed Device	-	Equivalent
Method of Manufacturing	Thermo-Molding Custom-Fit	Thermo-Molding Custom-Fit	Thermo-Molding Custom-Fit	Equivalent
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Equivalent

5.6.1. Similarities

- The Subject Device and the predicate have the same intended use.
- The design, intended user, and mouth guard materials of the Subject Device are the same w.r.t the Predicate Device.
- The Subject Device and the Predicate Device are reusable devices with an equivalent mode of disinfection method.
- Both the Subject Device and the Predicate Device are supplied non-sterile.

5.6.2. Differences

The differences are in the number of variants, addition of Splint Biocryl in the Subject Device and difference between Erkoflex - 95 and Erkoflex in the Predicate Device does not raise new questions of safety and efficacy.

5.7. Biocompatibility

The materials used by the JS Dental Lab Mouth Guard are equivalent to the Predicate Device and have the same manufacturing process and intended use. The Subject Device is manufactured from biocompatible materials using ISO-certified thermoforming materials from the Erkodent Company and Great Lakes Orthodontics. The materials are purchased from Erkodent Company and Great Lakes Orthodontics. These thermo-moulding materials are BPA-free and are cleared for dental use. The biocompatibility of the materials is confirmed according to ISO 10993-1:2018.

The materials used in the Subject Device have been tested for cytotoxicity, mucosa irritation, sensitization, acute systemic and subchronic toxicity, genotoxicity in compliance with ISO 10993-1 and FDA Guidance Document No. FDA-2013-D-0350 for the intended dental use.

The Material Safety Data Sheet (MSDS) and results of Biocompatibility evaluation report reflect that all the specifications of the materials have met the specified acceptance criteria and support the claim for substantial equivalence and safety and efficacy of the Subject Device.

The Subject Device is a non-sterile dental device available in four different variations as mentioned below.

- **JS Dental Lab Hybrid Mouth Guard**

  This Mouth Guard is made up of a material called Erkoloc-Pro. It is a Hard Night Guard with a hard outer surface and a smooth inner surface. The material Erkoloc-Pro is made up of two mixtures such as Polyethylene Terephthalate (PET-G) on the outside and Thermoplastic Polyurethane (TPU) on the inside. The Predicate Device also uses the same material and proved the biocompatibility in accordance with ISO 10993-1:2018.

- **JS Dental Lab Extra Durable Mouth Guard**

  This Mouth Guard is made up of a material called Erkodur. This one is the hardest Mouth Guard amongst all the ones supplied by Erkodent Company. It has the composition of Polyethylenterephthal (PET - G).

- **JS Dental Lab Soft Mouth Guard**

This Mouth Guard is made up of a material called Ethyl Vinyl Acetate (EVA) based clear mouthguard material and BIOPLAST.

- **JS Dental Lab Durable Mouth Guard**

  This Mouth Guard is made up of a material called Erkoflex-95. The material Erkoloc-95 is made up of Ethylenvinylacetat (EVA).

5.8. Bench Performance Testing

The physical properties for the materials for the Subject Device have been provided by the material manufacturer.

5.9. Conclusion

The Subject Device is substantially equivalent to the Predicate Device, Thermoformed Mouth Guards (K121365) in the indications for use and technological characteristics. The minor differences in technological characteristics do not raise any significant questions on the safety and efficacy of the Subject Device.