November 18, 2022

FBCC Inc
% Elisabeth Miller
Regulatory Affairs Consultant
Prime Path Medtech
1321 Upland Dr. Suite 6792
Houston, Texas 77043

Re: K221369
Trade/Device Name: FBCC Night Guard
Regulatory Class: Unclassified
Product Code: OBR
Dated: September 19, 2022
Received: September 19, 2022

Dear Elisabeth Miller:

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,

Bobak Shirmohammadi -S

For 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)*

K221369

Device Name
FBCC Night Guard

Indications for Use *(Describe)*

The FBCC Night Guard is indicated for protection of teeth and restorations against grinding and clenching.

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.

Section 5. 510(k) Summary K221369

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter: FBCC Inc

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Date Prepared: November 2022

Proprietary Name: FBCC Night Guard

Common Name: Mouth Guard

Product Code: OBR

Device Classification: Unclassified

Predicate Device: Bright Guard

Reference Device: JS Dental Lab Mouth Guard

Device Description:

The FBCC Night Guard is a mouth guard used as a barrier between teeth for nighttime teeth grinding by creating physical separation between upper and lower tooth surfaces preventing tooth damage caused by bruxism (e.g., grinding and clenching).

Indications for Use:

The FBCC Night Guard is indicated for protection of teeth and restorations against grinding and clenching.

Comparison to Predicate Devices:

Table 1. Predicate and Reference Device Comparison

Specification	***Subject Device:*** *FBCC Night Guard*	***Predicate Device:*** *Bright Guard (K181099)*	***Reference Device:*** *JS Dental Lab Mouth Guard (K210011)*	***Comparison Result***
Product Code	OBR	OBR	MQC	Same as predicate
Classification Panel	Dental	Dental	Dental	Same
Device Class	Unclassified	Unclassified	Unclassified	Same
OTC or Rx	OTC	OTC	RX	Same as predicate
Material	Thermoplastic Polyurethane or Ethylene-Vinylacetate	Thermoplastic resin Propylene Elastomer: ethylene-vinylacetate [Elvax] No Flavor; No Color Additives	Thermoplastic Polyurethane, Ethyl Vinyl acetate (Erkodur or Splint Biocryl, Erkoloc-Pro, Erkoflex-95, EVA Based Clear Mouthguard Material and BIOPLAST)	Similar
Method of Manufacturing	Thermoforming	Injection Molding	Thermoforming	Same as reference
Anatomical Sites	Worn on maxillary or mandibular teeth	Worn on maxillary teeth	Worn on maxillary or mandibular teeth	Same as reference
Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Same
Device Description	The FBCC Night Guard is a mouth guard used as a barrier between teeth for nighttime teeth grinding by creating physical separation between upper	Flexible, moldable mouth guard used as a barrier between teeth for nighttime teeth grinding.	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	Similar

	and lower tooth surfaces preventing tooth damage caused by bruxism (e.g., grinding and clenching).		grinding. It fits over upper teeth or lower teeth during sleep. The Subject Device 510(k) Summary K210011Ampower Dental Laboratories LLC Confidential Page 3 of 6 AI response for K210011 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.	
Patient Removable?	Yes	Yes	Yes	Same
Indication for Use	The FBCC Night Guard is indicated for protection of teeth and restorations against	Bright Guard is a mouth guard intended to protect against grinding and clenching.	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	Similar

	grinding and clenching.		protect the patient's overall occlusion.	
Mechanism of Action	Disocclusion	Disocclusion	Disocclusion	Same

Comparison of Indications for Use to Predicate Device:

The indications for use are similar for the subject and reference devices. The subject and predicate devices are indicated for the protection of teeth against grinding and clenching.

Comparison of Technological Features to Predicate Devices:

The FBCC Night Guard uses the same mechanism of action as the predicate product. It is intended to be worn on the teeth to protect teeth against grinding and clenching.

As summarized above, the main differences between the subject device (FBCC Night Guard) and predicate device (Bright Guard):

- Material
- Method of Manufacturing

Overall, the differences are minor and do not impact risk to the patient or user of the product.

Material

The subject device is manufactured using thermoplastic polyurethane, whereas the predicate device is manufactured using a thermoplastic resin. While these are not identical polymers, each material is a known dental thermoplastic polymer with similar characteristics. The use of thermoplastic polyurethane does not introduce or reduce any risks when compared to the other.

Method of Manufacturing

The subject device is thermoformed while the predicate device is injection molded. While these are not identical processes, both are commonly used to create mouth guards and other dental devices. The subject and reference device (*JS Dental Lab Mouth Guard)* both use thermoforming as the method of manufacturing. The use of thermoforming does not increase the risk associated with manufacturing.

Non-Clinical Performance Testing

The use of thermoplastic materials Night Guards indicated for protection of teeth against grinding and bruxing has been well documented in scientific literature. However, durability testing was completed on these night guards. Real world use was simulated to ensure that the Night Guard material and manufacturing process produced Night Guards that were suitable for the intended period of use.

An internal manufacturing validation was performed to test the dimensional accuracy of the manufacturing process for the FBCC Night Guards. The robustness of the process was demonstrated from 3D printing through thermoforming.

Clinical Performance Testing

The technological characteristics, indications for use, material, and manufacturing and processes are the same or similar to the predicate device and therefore, no clinical studies were deemed necessary to demonstrate the safety and effectiveness of the subject device.

Conclusion

Based on the similarities in indications for use, technological characteristics, and non-clinical performance testing the FBCC Night Guards are substantially equivalent to the predicate device Bright Guard *(K181099).*