November 25, 2020

3D Diagnostix Inc.
Ehab Amin
Quality and Regulatory Consultant
24 Denby Road
Allston, Massachusetts 02134

Re: K202465
Trade/Device Name: Night Guard
Regulatory Class: Unclassified
Product Code: MQC
Dated: August 27, 2020
Received: August 27, 2020

Dear Ehab Amin:

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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 on last page

510(k) Number *(if known)*

K202465

Device Name

Night Guard

Indications for Use *(Describe)*

Night Guard is indicated for protection against bruxism or nighttime teeth grinding. It creates a barrier between upper and lower dentition to protect the patient's overall occlusion.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

3D Diagnostix Inc.'s Night Guard
510K Number: K202465

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

[COMPANY'S NAME AND ADDRESS]

3D Diagnostix Inc
24 Denby Road
Allston, MA 02134
USA

Phone: 1-617-820-5279
Fax: 1-617-904-1853

Contact Person: Ehab Mahmoud
Date Prepared: November 25, 2020

Name of Device and Name/Address of Sponsor

Name of Device:	Night Guard
Common or Usual Name:	Mouthguard, Prescription
Classification Name:	Not Applicable
Regulatory Class:	Unclassified
Product Code:	MQC

Primary Predicate Devices

Thermoformed Mouthguards/Nightguards	K121365	Prismatik Dentalcraft ,Inc. GLIDEWELL LABORATORIES-SLEEP DEVICES GROUP

Intended Use / Indications for Use

The **Night Guard** is indicated for protection against bruxism and nighttime teeth grinding. it creates a barrier between the upper and lower dentition to protect the patient's overall occlusion.

Technological Characteristics

Based on the comparative analysis of technological characteristics, the **Night Guard** has the same technological characteristics as the primary predicate device [**Thermoformed Mouthguards/Night**

Guards], in that all the devices are made from biocompatible material to create a customized- patient-specific Night Guard.

Night guard is substantially equivalent to the Primary Predicate Device [**Thermoformed Mouthguards/Night Guards**], the two devices are physically the same.

Night Guard is designated to alleviate the pain and damage caused by bruxing or clenching the teeth such as Severe tooth, jaw or facial muscle pains which are common side effects of bruxing or clenching the teeth. **Night Guard** creates a barrier between upper and lower dentition to protect the patient's overall occlusion the same as the primary Predicate Device [**Thermoformed Mouthguards/Night Guards**].

Performance Data

As part of demonstrating substantial equivalence of **Night Guard** to the primary predicate device that are subject to this 510(k) submission, 3D Diagnostix Inc. completed a number of non-clinical performance tests. **Night Guard** meets all the requirements for overall design, biocompatibility, and performance results confirming that the design output meets the design inputs and specifications for the device.

Night Guard passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility testing per ISO 10993-1 passed cytotoxicity, sensitization, irritation, acute systemic toxicity, Subacute/subchronic toxicity, Genotoxicity, and implantation.
- Process Flow validation was performed to ensure that the finished device matches the software output specifications. The output, work model and Night Guard were tested and compared. Night Guard met the specifications of this testing.
- Photopolymer (FormLabs Dental LT Clear V2) is flexible, resilient, tough, and show excellent resistance to environmental stress cracking. The following table summarizes the performed tests and their acceptance criteria and the results.

Test Performed	Objective of the Test	Reference Standard	Acceptance Criteria	Results
Rigidity	The printed device is rigid enough to stay on the patient's dentition	NA.	When fitting the splint onto the master dentition, does it feel sufficiently rigid to stay in place and immobilize the teeth?	Pass
Toughness	Printed device is tough enough to withstand breaking	ASTM D695 Compressive Properties of	Does the material survive 180 times of flexing cycles? (180 flex cycles is based on a daily insertion of a dry splint for 6 months).	Pass

Test Performed	Objective of the Test	Reference Standard	Acceptance Criteria	Results
		Rigid Plastics	Was the maximum compressive stress of the material over 77MPa before break? The material is expected to survive 77MPa of compression stress	Pass Avg: 159.6 MPa Std Dev: 1.698
Fit	Ensure the device will fit snugly to a patient's dentition and not move.	NA.	• By visual examination through the splint itself, does the splint seat all the way down onto the occlusal table and/or incisal edge of the metal simulated dentition? • Does the splint stay on metal dentition when turned upside down? • After applying light pressure to each quadrant of the splint after it is seated on the metal simulated dentition. Does the splint stay in place without another section of the splint separating from the occlusal surfaces or incisal edges of the teeth? • Does the splint stay in place without shifting after attempting to rotate the splint back and forth	Pass
Wear Resistance	Devices are sufficiently wear-resistant to withstand teeth wear against the patient's opposing dentition.	ISO 14569	After 10,000 cycles of abrasion in a 37 C water bath samples must not show signs of cracking or wear to a degree that would jeopardize the efficacy or safety of the device	Pass

In all instances, the **Night Guard** functioned as intended and **Biocompatibility Testing, Process Flow Validation, and Material Testing** observed was as expected.

Substantial Equivalence

Feature	Proposed Device Night Guard	Predicate Device Thermoformed Mouthguards/Nightguards
K Number	**K202465**	**K121365**
Manufacturer	3D Diganostix Inc.	Prismatik Dentalcraft ,Inc. GLIDEWELL LABORATORIES-SLEEP DEVICES GROUP
Regulation Number	Not Applicable	21 CFR 807.92
Device Classification Name	Mouthguard, Prescription	Mouthguard, Prescription
Product Code	MQC	MQC
Device Class	Unclassified	Class II
Indications for Use	Night Guard is indicated for the protection against bruxism and nighttime teeth grinding. It creates a barrier between upper and lower dentition to protect the patient's overall occlusion.	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.
Device Description	Night Guards are designated to alleviate the pain and damage caused by bruxing or clenching the teeth. Severe tooth, jaw or facial muscle pains are common side effects of bruxing or clenching the teeth. These patients specific 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. Night Guard is shipped non-sterile.	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 patients specific 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. Night Guard is shipped non-sterile.
Mode of Action	They create a barrier between the upper and lower dentition to protect the patient's overall occlusion.	They create a barrier between the upper and lower dentition to protect the patient's overall occlusion.
Anatomy Location	Mouth; mucosal	Mouth; mucosal
Size	Patient specific	Patient specific
Manufacturing Method	3D Printing	Thermoforming

Feature	Proposed Device Night Guard	Predicate Device Thermoformed Mouthguards/Nightguards
K Number	**K202465**	**K121365**
Material	Photopolymer Resin	Thermoplastic Polymer
Material Properties	Dental LT Clear V2 (Biocompatible Photopolymer Resin)	Approved Biocompatible material Co-polyester (Erkoflex) Polyurethane (Erkodur) Ethyl vinyl acetate (EVA)(Erkolog-Pro)
Design	Pre-formed Device	Pre-formed Device
OTC/Prescription Device	Prescription use	Prescription use
Reusable Device	Yes/Single consumer /Patient	Yes/Single consumer /Patient
Sterility	Non-Sterile	Non-Sterile

The **Night Guard** and **Thermoformed Mouthguards/Nightguards** have the same intended use and similar indications, technological characteristics and principles of operation. The technological differences between the **3D Diagnostix's Night Guard** and **Thermoformed Mouthguards/Nightguards** are:

1. **Night Guard** manufactured by **3D Printing** method.

2. Material used for **Night Guard** manufacturing by using **3D Printing Method**.

These differences do not present any new issues because they do not impact on intended uses, indications, and principles of operation. Thus, the **Night Guard** is substantially equivalent to the **Thermoformed Mouthguards/Nightguards**.

3D Diagnostix Inc. has relied on the existing predicated devices for substantial equivalence of its **Night Guard** device. In addition, the biocompatibility of the materials is confirmed according to ISO 10993-1. Therefore, the Night Guard is substantial equivalent for its intended use.

Conclusions

As demonstrated in this application, the proposed device **Night Guard**, has the same intended use as the identified predicate device, **Thermoformed Mouthguards/Nightguards** originally cleared under premarket notification **K121365**, and employs the same basic technological characteristics; any differences between the proposed device and the predicate are minor and do not constitute different technological characteristics. The relevant information on biocompatibility and the performance testing confirm the **Night Guard** fulfills its intended use as substantially equivalent to a legally marketed predicate device. The **Night Guard** is therefore substantially equivalent to the cited predicate.