



February 26, 2026

Owl Dental Lab, Inc.
% Jennifer Day
Regulatory Correspondent
Prime Path Medtech
539 W Commerce St.
5446
Dallas, Texas 75208

Re: K253641

Trade/Device Name: Owl Night Guard
Regulatory Class: Unclassified
Product Code: OBR, MQC, OCO
Dated: January 28, 2026
Received: January 28, 2026

Dear Jennifer Day:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, MChE, RAC, CQIA
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K253641

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Please provide the device trade name(s).

?

Owl Night Guard

Please provide your Indications for Use below.

?

The Owl Night Guard is Indicated for protection of teeth and restorations against grinding and clenching, and as an aid in the reduction of medically diagnosed migraine pain associated with jaw clenching and bruxing.

Please select the types of uses (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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510(k) Summary K253641

A summary of 510(k) substantial equivalence information in accordance with the requirements of 21 CFR 807.92.

Submitter:	Owl Dental Lab Inc
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Email:	owldentallab@hotmail.com
Submission Correspondent:	Jennifer Day, Regulatory Affairs
Address:	539 W Commerce St, #5446 Dallas, TX 75208
Phone:	314-809-1818
Email:	jday@primepathmedtech.com
Date Prepared:	10/21/2025
Proprietary Name:	Owl Night Guard
Common Name:	Mouth Guard
Product Code:	OBR, MQC, OCO
Device Classification:	Unclassified
Primary Predicate Device:	Remi Custom Night Guard (K251778)
Secondary Predicate Device:	NTI Clench Guard (K211158)
Reference Device:	Thermoforming Sheet Materials (K200125)

Device Description:

The Owl 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 Owl Custom Night Guard is Indicated for protection of teeth and restorations against grinding and clenching, and as an aid in the reduction of medically diagnosed migraine pain associated with jaw clenching and bruxing.

510(k) Summary K253641

Comparison to Predicate Devices:

Table 1. Predicate Comparison

Specification	Subject Device: <i>Owl Night Guard</i>	Predicate Device: <i>Remi Night Guard</i>	Predicate Device: <i>NTI Clench Guard</i>
510(k)	K253641	K251778	K211158
Product Code	OBR, MQC, OCO	OBR, OCO	OBR, MQC, OCO
Panel	Dental	Dental	Dental
Class	Unclassified	Unclassified	Unclassified
OTC or Rx	OTC & Rx	OTC	OTC & Rx
Anatomical Sites	Worn on maxillary or mandibular teeth	Worn on maxillary or mandibular teeth	Worn on maxillary teeth
Sterile	Non-Sterile	Non-Sterile	Non-Sterile
Removable?	Yes	Yes	Yes
Indication for Use	The Owl Night Guard is Indicated for protection of teeth and restorations against grinding and clenching, and as an aid in the reduction of medically diagnosed migraine pain associated with jaw clenching and bruxing.	The Remi Custom Night Guard is Indicated for protection of teeth and restorations against grinding and clenching, and as an aid in the reduction of medically diagnosed migraine pain associated with jaw clenching and bruxing.	<ol style="list-style-type: none"> 1. As an aid in the reduction of medically diagnosed migraine pain associated with jaw clenching and bruxing; 2. Protection against bruxism or nighttime teeth grinding and reduce damage and the noise associated with bruxing and/or grinding.

Indications for Use:

The indication for use is aligned with the Primary Predicate and Secondary Predicate devices. Both devices are indicated for protection of teeth and restorations against grinding and clenching, and the Secondary Predicate is indicated for the reduction of medically diagnosed migraine pain associated with jaw clenching and bruxing.

Technological Features:

The Owl Night Guard uses the same mechanism of action as the Primary Predicate product and Secondary Predicate product. It is intended to be worn on the teeth to protect teeth and restorations against grinding and clenching. It also aids in the reduction of medically diagnosed migraine pain associated with jaw clenching and bruxing. Owl Night Guards are manufactured using impressions and/or scans.

Non-Clinical Performance Testing

Durability testing was completed on these night guards.

An internal manufacturing validation was performed to test the dimensional accuracy of the manufacturing process for the Owl Night Guards.

Biocompatibility assessment testing was performed on the subject device in accordance with FDA Guidance Document, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and> , ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", and ISO 7405 "Dentistry – Evaluation of biocompatibility of medical devices used in dentistry".

Clinical Performance Testing

No new clinical studies were required to establish substantial equivalence for the Owl Night Guard.

Conclusion

Based on comparison of indications for use, user population (adults 18 years and older), mechanical and technological features, the Owl Night Guard is substantially equivalent to the Primary Predicate device (Remi Night Guard, K251778) and the Secondary Predicate device (NTI Clench Guard, K211158).