



November 25, 2025

enCore Guards
Benjamin Li
CEO
1520 Brookhollow Dr
Unit 38
Santa Ana, California 92705

Re: K252004
Trade/Device Name: enCore Night Guard
Regulation Number: 21 CFR Unclassified
Regulation Name: Mouthguard, Over-The-Counter
Regulatory Class: Class II
Product Code: OBR
Dated: June 27, 2025
Received: June 27, 2025

Dear Benjamin Li:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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,

MICHAEL E. ADJODHA -S

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

Submission Number (if known)

K252004

Device Name

enCore Night Guard

Indications for Use (Describe)

The enCore 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary K252004

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

Submitter: enCore Guards, Inc.

Company Contact Person: Benjamin Li
Address: 1520 Brookhollow Dr, Santa Ana, CA 92705
Phone: 310-866-0323
Email: ben@encoreguards.com

Date Prepared: 11/19/25

Proprietary Name: enCore Night Guard

Common Name: Mouth Guard

Product Code: OBR

Device Classification: Unclassified

Predicate Device: FBCC Night Guard (K221369)

Reference Device: Thermoforming Sheet Materials (K200125)

Device Description:

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

Comparison to Predicate Devices:

<i>Specification</i>	<i>Subject Device: enCore Night Guard</i>	<i>Predicate Device: FBCC Night Guard (K221369)</i>	<i>Comparison Result</i>
Product Code	OBR	OBR	Same
Classification Panel	Dental	Dental	Same
Device Class	Unclassified	Unclassified	Same

Specification	Subject Device: <i>enCore Night Guard</i>	Predicate Device: <i>FBCC Night Guard (K221369)</i>	Comparison Result
OTC or Rx	OTC	OTC	Same
Anatomical Sites	Worn on maxillary or mandibular teeth	Worn on maxillary or mandibular teeth	Same
Sterile	Non-Sterile	Non-Sterile	Same
Patient Removable?	Yes	Yes	Same
Indication for Use	The enCore Night Guard is indicated for protection of teeth and restorations against grinding and clenching.	The FBCC Night Guard is indicated for protection of teeth and restorations against grinding and clenching.	Same as predicate

Indications for Use:

The indication for use is the same as the predicate device, the FBCC Night Guard; the devices are indicated for the protection of teeth against grinding and clenching.

Technological Features:

The enCore 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.

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 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>, ISO10993-1 “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

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 Night Guards are substantially equivalent to the predicate device.