March 17, 2026

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

Re: K251926
Trade/Device Name: enCore Impression Material
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: SHI
Dated: June 23, 2025
Received: June 23, 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 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 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 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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
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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)*
K251926

Device Name
enCore Impression Material

Indications for Use *(Describe)*
The EnCore Impression Material is intended for dental impression techniques to reproduce the structure of a patient's dentition to fabricate patient matched night guards and mouthguards.

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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**K251926**

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

| | |
|---|---|
| **Submitter:** | enCore Guards, Inc. |
| **Company Contact Person:** | Benjamin Li<br>1520 Brookhollow Dr Ste 38, Santa Ana, CA 92705<br>310-866-0323<br>ben@encoreguards.com |
| **Date Prepared:** | 3/8/2025 |
| **Proprietary Name:** | enCore Impression Material Impression Material |
| **Common Name:** | SHI |
| **Product Code:** | Class II |
| **Device Classification:** | K213244, Accusil |
| **Predicate Device:** | enCore Impression Material Impression Material |
| **Reference Device:** | K092319 Star VPS, First, Half, First Quarter |

**Device Description:**

The EnCore Impression Material is an addition-cure impression material composed of vinyl polysiloxane impression and bite registration materials intended to allow dentists to take accurate impressions.

**Indications for Use:**

The EnCore Impression Material is intended for dental impression techniques to reproduce the structure of a patient's dentition to fabricate patient matched night guards and mouthguards.

**Comparison to Predicate Devices:**

Table 1. Predicate Comparison

| Name | *Subject Device:*<br>*EnCore Impression Material* | *Predicate Device:*<br>*K213244, Accusil* | *Reference Device:*<br>*K092319 Star VPS, First. Half, First Quarter* | *Comparison Result* |
|---|---|---|---|---|
| 510k Number | K251926 | K213244 | *K092319* | |
| Common Name | Impression material | Impression material | Impression material | Same |
| Classification Name | Impression material | Impression material | Impression material | Same |
| Class | II | II | II | Same |
| Product Code | SHI | ELW | ELW | Equivalent |
| CFR | 872.3660 | 872.3660 | 872.3660 | Same |
| Indications for Use | The EnCore Impression Material is intended for dental impression techniques to reproduce the structure of a patient's dentition to fabricate custom night guards and mouthguards. | Accusil dental impression material is intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums. | The device is an addition-cure vinyl-polysiloxane dental impression material that is used for all crown and bridges, edentulous and implant techniques. | Narrower Indication |
| Material | Vinyl Polysiloxane | Accusil light, heavy, mono, and bite registration: Mixture of vinyl terminated polydimethylsilox anes and filler materials with platinum catalyst and SIH capped polysiloxane<br><br>Accusil putty: Mixture of vinyl terminated polydimethylsilox anes and filler materials with platinum catalyst and SIH capped | Vinyl Polysiloxane | Same |

| | | | | |
|---|---|---|---|---|
| | | polysiloxane plus softener | | |
| Working/Processing Time | 40 - 140 sec | 40-150 sec | 0 to 30 sec | Same |
| Setting time/Time in the mouth | 180 - 275 sec | 60-300 sec | 50 to 300 sec | Same |
| Hardness | 70 to 81 Shore A | 63-70 Shore A | Not Available | Same |
| Working humidity | 50% | 50% | Not Available | Same |
| Dimensional accuracy | 99.0 % | 99.9%-99.2% | Not Available | Same |
| Stability (linear dimensional change) | <0.8% typical | <0.8% typical | Not available | Same |
| Consistency | Type 0-type 3 ISO 4823 | Type 0-type 3 ISO 4823 | Type 0-type 3 ISO 4823 | Same |
| Chemical Description | Room temperature vulcanizing 2-components silicone | Room temperature vulcanizing 2-components silicone | Room temperature vulcanizing 2-components silicone | Same |
| Package | Encore putty comes in plastic jars for both base and catalyst. | Accusil bite registration, heavy, light, and monophase come in 2 x 50 ml double cartridges Monophase regular also comes in a 5:1 380ml double cartridges. Accusil putty comes in plastic jars of 150ml and 300ml for both base and catalyst. | Two part plunger for easy of mixing base and catalyst. | Equivalent |
| Method of manipulation | Preformed impression tray | Preformed impression tray | Preformed impression tray | Same |
| Sterility | Non-sterile | Non-sterile | Non-sterile | Same |

# 510(k) Summary

**Technological Features:**

The EnCore Impression Material is technologically identical to the predicate device. As there is no difference between the subject and predicate device, they are substantial equivalent.

**Non-Clinical Testing**

Biocompatibility testing was performed on the product and all endpoints were met.

The standards used/referenced were:

- EN ISO 10993-1:2018, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- EN ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-10:2013, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization • BS EN ISO 10993-11:2018, Biological evaluation of medical devices – Tests for systemic

**Clinical Performance Testing**

Clinical studies were included to support changes relative to the subject device.

**Conclusion**

The EnCore Impression Material is substantially equivalent to the predicate device.