July 30, 2026

Prismatik Dentalcraft, Inc.
So Hyun Park
Sr. Regulatory Affairs Manager
2144 Michelson Dr.
Irvine, California 92612

Re: K262239
Trade/Device Name: Obsidian® Press Over Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: June 30, 2026
Received: July 1, 2026

Dear So Hyun Park:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K262239

Device Name
Obsidian® Press Over Zirconia

Indications for Use *(Describe)*
Obsidian® Press Over Zirconia is used to fabricate press over zirconia dental prostheses in the nature of crowns and bridges for anterior and posterior applications.

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.

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PRISMATIK DENTALCRAFT, INC.

510(k) Summary

Date Prepared: July 28, 2026

CONTACT DETAILS (21 CFR 807.92(a)(1))

Applicant Name: Prismatik Dentalcraft, Inc.

Applicant Address: 2144 Michelson Drive, Irvine, CA 92612, USA

Applicant Contact Telephone: 949-535-3038

Applicant Contact: So Hyun Park, Sr. Regulatory Affairs Manager, MS

Applicant Contact Email: so.park@glidewelldental.com

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DEVICE NAME (21 CFR 807.92(a)(2))

Device Trade Name: Obsidian® Press Over Zirconia

Common Name: Ceramic Material for Dental Prosthesis

Classification Name: Porcelain powder for clinical use

Regulation Number: 872.6660

Regulatory Class: Class II

Product Code: EIH

LEGALLY MARKETED PREDICATE DEVICE (21 CFR 807.92(a)(3))

Predicate 510(k) #: K141887 (Primary Predicate)

Predicate Device Trade Name: Obsidian® Press (All-Ceramic and POM)

Product Code: EIH

DEVICE DESCRIPTION SUMMARY (21 CFR 807.92(a)(4))

Obsidian® Press Over Zirconia is a fully crystallized lithium disilicate glass-ceramic ingot for the fabrication of bi-layered dental restorations. It is intended to be hot-pressed over zirconia substructures to prepare full-contour single-unit crowns and bridges in the anterior and posterior region. After hot-pressing, the fabricated restorations are stained and glazed by dental technicians. The product is offered in four levels of translucency classified as low (LT), medium (MT), High (HT1), and Super High (HT2).

PRISMATIK DENTALCRAFT, INC.

INTENDED USE/INDICATIONS FOR USE (21 CFR 807.92(a)(5))

Obsidian® Press Over Zirconia is used to fabricate press over zirconia dental prostheses in the nature of crowns and bridges for anterior and posterior applications.

INDICATIONS FOR USE COMPARISON (21 CFR 807.92(a)(5))

Both the subject device, Obsidian® Press Over Zirconia, and the predicate device, Obsidian® Press (All-Ceramic and POM) (K141887), are ceramic materials intended for fabrication of dental prostheses over substructure in the form of crowns and bridges to restore chewing function. Both devices are indicated for use by dental technicians in the construction of custom-made ceramic restorations for anterior and posterior regions.

The subject device is pressed over zirconia substructure whereas the predicate device is pressed over metals and includes an additional indication for monolithic ceramic restorations, which is not applicable to the subject device. These differences reflect compatibility with different supporting substructures, but do not alter the fundamental intended use of the devices as ceramic materials for the fabrication of dental restorations. Therefore, the indications for use of the subject device are substantially equivalent to the predicate device.

TECHNOLOGICAL COMPARISON (21 CFR 807.92(a)(6))

The subject device, Obsidian® Press Over Zirconia, is substantially equivalent in technological characteristics to the predicate device, Obsidian® Press (All-Ceramic and POM) (K141887) in terms of overall design principles, material and performance.

The subject device, Obsidian® Press Over Zirconia, is similar in terms of overall design to the predicate device, Obsidian® Press (All-Ceramic and POM) (K141887). Both devices are ceramic ingots intended for use in the fabrication of dental restorations using a hot-press technique. The predicate device, Obsidian® Press (All-Ceramic and POM), is used in Press Over Metal (POM) applications in addition to the all-ceramic applications whereas the subject device, Obsidian® Press Over Zirconia, is used in Press Over Zirconia (POZ) applications. Although subject device, Obsidian® Press Over Zirconia, and the predicate device, Obsidian® Press (All-Ceramic and POM) (K141887), differ in material composition, with the predicate device consisting of a fully crystallized lithium silicate glass-ceramic and the subject device consisting of a fully crystallized lithium disilicate glass-ceramic, the fundamental principle of operation remains the same.

Both devices are supplied as fully crystalized glass-ceramic ingots that are hot-pressed into an investment mold using conventional dental laboratory hot-pressing techniques to fabricate dental restorations. Following pressing, the restorations are finished, stained and glazed as needed prior to clinical use. The pressed ceramic provides the esthetic outer surface of the restoration, while the underlying substructure provides additional support. In both devices, clinical performance is achieved from the same mechanism: the glass-ceramic is hot-pressed over a substructure and is processed into a durable, tooth-colored restoration that is subsequently cemented for dental restoration applications. Therefore, the difference in the underlying framework material does not alter the device's fundamental scientific technology or principle of operation.

The subject device, Obsidian® Press Over Zirconia, is similar in terms of material composition to the predicate device, Obsidian® Press (All-Ceramic and POM) (K141887). Both devices contain lithium oxide and silicone dioxide as principal constituents of the crystalline phase. The subject device contains a lithium disilicate crystalline phase, whereas the predicate device contains a lithium silicate crystalline phase. Also, the subject device and the predicate device exhibit different Coefficient of Thermal Expansion (CTE). These thermal expansion characteristics are designed to be compatible with the corresponding restorative system and supporting framework. These differences in crystalline structure and thermal expansion properties are consistent with the intended design and performance requirements of the respective devices.

Comprehensive verification and validation testing were conducted to evaluate the safety and performance of the subject device, Obsidian® Press Over Zirconia. The testing results demonstrated that the subject device meets established performance requirements per ISO 6872:2024 for its intended use. A biological evaluation was conducted in accordance with ISO 10993-1:2025 considering the nature and duration of patient contact. Biocompatibility testing, including in vitro cytotoxicity testing performed in accordance with ISO 10993-5:2009, demonstrated that the subject device met the requirements of the testing and is substantially equivalent to the predicate in terms of biocompatibility. The results of the biological evaluation identified no new biocompatibility concerns.

The technological comparison table below outlines and provides the similarities between the subject device, Obsidian® Press Over Zirconia, and the predicate device, Obsidian® Press (All-Ceramic and POM) (K141887). Both the subject device and the predicate device have similar intended use, physical/mechanical and biocompatibility properties. Any differences between the subject device and the predicate device do not raise any new concerns of safety and effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.

Attributes	**Subject Device (K262239)**	**Predicate Device (K141887)**	**Comparison**
Device Name	Obsidian® Press Over Zirconia	Obsidian® Press (All-Ceramic and POM)	N/A
Manufacturer	Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	Same
Product Code	EIH	EIH	Same
Prescription Device	Yes	Yes	Same
Type and Class according to ISO 6872:2024	Type II, Class 1b Ceramic for coverage of a ceramic substructure	Type II, Class 3 Ceramic for coverage of a metal framework and monolithic ceramic	Similar; Both the subject device and the predicate device are Type II, Class 1b as ceramic for coverage of a metal framework or a ceramic substructure. The predicate device has an additional indication for use as a monolithic ceramic.

Attributes		Subject Device (K262239)	Predicate Device (K141887)	Comparison
Indications for Use		Obsidian® Press Over Zirconia is used to fabricate press over zirconia dental prostheses in the nature of crowns and bridges for anterior and posterior applications.	The Obsidian® Press ceramic is used to fabricate Press Over Metal dental prostheses in the nature of crowns and bridges as well as monolithic dental prostheses in the nature of crowns, partial crowns, veneers, inlays, and onlays for posterior and anterior applications, as well as 3-unit anterior bridges (including pre-molar region as terminal abutment) using pressing methods.	Similar; Both the subject device and the predicate device are used to fabricate ceramic dental prostheses over substructure in the nature of crowns and bridges. The subject device is pressed over zirconia substructure whereas the predicate device is pressed over metals. The predicate device has an additional indication for use as a monolithic ceramic.
Design Characteristics	Chemical Composition	SiO_2, Li_2O, K_2O, P_2O_5, Al_2O_3, and other oxides	SiO_2, Li_2O, K_2O, P_2O_5, Al_2O_3, and other oxides	Similar; The major components for both the subject device and the predicate device are the same with slight differences in the chemical composition.
	Design	Obsidian® Press Over Zirconia is a fully crystallized lithium disilicate glass ceramic to be supplied in the form of ingots to be hot-pressed over zirconia substructure.	Obsidian® Press (All-Ceramic and POM) is a fully crystallized lithium silicate glass ceramic to be supplied in the form of ingots to be hot-pressed over metal substructure, in addition to all ceramic applications.	Similar; Both the subject device and the predicate device are fully crystallized glass ceramic ingots for dental restorations but have different crystal structures and are intended for different substructures.

Attributes		Subject Device (K262239)	Predicate Device (K141887)	Comparison
	Principle of Operation	The device is hot-pressed over zirconia substructures to fabricate dental restorations. After hot pressing, the fabricated restorations are stained and glazed by dental technicians.	The device is hot-pressed over metal substructures to fabricate dental restorations. After hot pressing, the fabricated restorations are stained and glazed by dental technicians.	Similar; Both the subject device and the predicate device use hot-press technique over different substructures. The pressed restorations are then finished with staining and glazing by dental technicians.
	Shades	Four levels of translucency – Low (LT), Medium (MT), High (HT1), and Super High (HT2)	A1, A2, A3, A3.5, B1, B2, B3, C1, C2, C3, D2, D3, BL1, and BL4	Different; There are no shades available for the subject device.
	Flexural Strength	>400 MPa	>300 MPa	Similar; The subject device has greater flexural strength than the predicate device although the minimum flexural strength per ISO 6872:2024 for Class Ib is 50MPa.
	Coefficient of Thermal Expansion (CTE/25-500°C)	$8.7 \pm 0.5 \times 10^{-6}$ /℃	$12.2 \pm 0.5 \times 10^{-6}$ /℃	Different; The subject device exhibits a lower CTE than the predicate device, as it is pressed over zirconia whereas the predicate device is pressed over metal.
	Chemical Solubility	<100 µg/cm^2	<100 µg/cm^2	Same
	Radioactivity	The activity concentration of Uranium-238 is no more than 1.0 Bq/g^{-1}.	The activity concentration of Uranium-238 is no more than 1.0 Bq/g^{-1}.	Same
	Freedom from Extraneous Material	Free from extraneous materials when assessed by visual inspection	Free from extraneous materials when assessed by visual inspection	Same
	Biocompatibility	Biocompatible and non-toxic	Biocompatible and non-toxic	Same
	Sterility	Non-sterile	Non-sterile	Same
	Manufacturing Process	Glass melting and crystallization process	Glass melting and crystallization process	Same

PRISMATIK DENTALCRAFT, INC.

NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY & CONCLUSIONS (21 CFR 807.92(b))

Design verification and validation were conducted by Prismatik Dentalcraft, Inc. The tests conducted are listed below.

- Glass Transition Temperature (T_g) and Peak Crystallization Temperatures (T_{p1} and T_{p2})
- Chemical Solubility according to ISO 6872:2024
- Radioactivity according to ISO 6872:2024
- Biaxial Flexural Strength according to ISO 6872:2024
- Coefficient of Thermal Expansion according to ISO 6872:2024
- % Opacity
- Freedom from Extraneous Materials and Uniformity by Visual Inspection according to ISO 6872:2024
- Pressing and Glazing Test

No clinical data is included in this submission.

The test samples were manufactured using the standard, validated manufacturing and quality control processes for Obsidian® Press Over Zirconia to ensure that the final finished devices met the following specified acceptance criteria.

- The glass transition temperature (T_g) and the peak crystallization temperatures (T_{p1} and T_{p2}) of the Obsidian® Press Over Zirconia precursor glass ingot shall not deviate by more than ± 20 °C (for a particular translucency) from the mean T_g, T_{p1}, and T_{p2}.
- The chemical solubility must be lower than 100 µg/cm^2 per ISO 6872:2024.
- The activity concentration of ^{238}U must not exceed 1.0 Bq·g^{-1} per ISO 6872:2024.
- Minimum mean Biaxial Flexural Strength must be 50 MPa, as measured per ISO 6872:2024, Type II Class 1b.
- The Coefficient of Thermal Expansion measured between 25°C and 500°C must be less than 10.5 x 10^{-6} /°C and the standard deviation of CTE must not deviate by more than 0.5 x 10^{-6}/°C per ISO 6872:2024.
- The % Opacity must be consistent between different ingots in a batch and between different batches of the same translucency.
- The crystalized ingots must be free from extraneous materials and should be uniform in appearance when assessed by visual inspection in accordance with ISO 6872:2024.
- The pressed and glazed dental crowns fabricated by hot-pressing crystalized ingots over zirconia substructures, followed by glazing must be free of bubbles and must not exhibit fractures.

The results of the verification and validation activities demonstrated that the design of the subject device, Obsidian® Press Over Zirconia, met all the predetermined design and performance specifications. The testing results were used to support substantial equivalence by addressing differences in technological characteristics between the subject device, Obsidian® Press Over Zirconia, and the predicate device, Obsidian® Press (All-Ceramic and POM) (K141887). Testing

also confirmed that the design modifications were implemented successfully without introducing any new risks or impacting safety or performance of the device.

The subject device, Obsidian® Press Over Zirconia, is substantially equivalent to the predicate device, Obsidian® Press (All-Ceramic and POM) (K141887), with respect to intended use, indications for use, fundamental technological characteristics, including design, materials and principles of operation. The identified technological differences do not raise new questions of safety and effectiveness. Therefore, the subject device is as safe and effective as the predicate device and supports a determination of substantial equivalence.