February 27, 2024

Prismatik Dentalcraft, Inc.
Nina Chiang
Regulatory Affairs Specialist
2144 Michelson Dr.
Irvine, California 92612

Re: K234014
Trade/Device Name: Obsidian® NOW
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: December 19, 2023
Received: December 19, 2023

Dear Nina Chiang:

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.

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 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.

Submission Number *(if known)*

K234014

Device Name

Obsidian® NOW

Indications for Use *(Describe)*

Obsidian® NOW is used to fabricate ceramic dental prosthesis in the nature of crowns for posterior and anterior applications using CAD/CAM technology. The block is processed through dental laboratories or by dental professionals.

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

K234014

Date Prepared: February 20, 2024

I. Contact Details

Applicant Name: Prismatik Dentalcraft, Inc.

Applicant Address: 2144 Michelson Drive, Irvine, CA 92612 United States

Applicant Contact Telephone: 949-222-3516

Applicant Contact: Ms. Nina Chiang, Regulatory Affairs Specialist

Applicant Contact Email: nina.chiang@glidewelldental.com

Secondary Contact: So Hyun Park, Regulatory Affairs Manager

Secondary Contact Email: so.park@glidewelldental.com

Secondary Contact Phone: 949-863-5479

II. Device Name

Device Trade Name: Obsidian® NOW

Common Name: Glass Ceramic Milling Block or Dental CAD/CAM Block

Classification Name: Porcelain powder for clinical use

Regulation Number: 872.6660

Product Code: EIH

III. Legally Marketed Predicate Device

Predicate 510(k) #: K141788

Predicate Trade Name: Obsidian Milling Blocks

Product Code: EIH

IV. Device Description

Obsidian® NOW is a fully crystallized lithium disilicate glass-ceramic block that can be milled to produce dental restorations using CAD/CAM technology. The block is intended to be used for fabricating monolithic restorations such as full contour crowns without requiring any additional crystallization prior to placement. The milling block is offered in the commonly used VITA® Classical and Chromascop® Bleach shades.

PRISMATIK DENTALCRAFT, INC.

V. Intended Use/Indications for Use

Obsidian® NOW is used to fabricate ceramic dental prosthesis in the nature of crowns for posterior and anterior applications using CAD/CAM technology. The block is processed through dental laboratories or by dental professionals.

VI. Technological Comparison

The subject device, Obsidian® NOW, is substantially equivalent to the predicate device, Obsidian Milling Block (K141788) in intended use, material, design principles, and technological characteristics.

The subject device, Obsidian® NOW, has the same intended use as the predicate device, Obsidian Milling Block (K141788), as the material is used in fabrication of dental restorations such as crowns for the purpose of restoring chewing function. The subject device, Obsidian® NOW, has the same indication for use except for the device trade name and the addition of a chairside indication for use where the blocks are processed through dental laboratories or by dental professionals.

The subject device, Obsidian® NOW, is substantially equivalent to the predicate device, Obsidian Milling Block (K141788) in technological characteristics. The same mechanical property testing in terms of flexural strength that was conducted on the predicate device, Obsidian Milling Block (K141788), was also conducted on the subject device, Obsidian® NOW, according to ISO 6872:2015/Amd 1:2018. The flexural strength of the subject device, Obsidian® NOW, met performance criteria in ISO 6872 for Type II, Class 3.

The subject device, Obsidian® NOW, and the predicate device, Obsidian Milling Block (K141788) are similar in material composition. Both devices utilize glass components as the base material, colorants, and opacifiers that make up the lithium aluminosilicate glass matrix. Despite the differences in the colorants and opacifiers to achieve the desired shades, the slight differences in chemical formulation do not affect the safety and effectiveness of the device as verified by the biocompatibility and performance testing.

The subject device, Obsidian® NOW, is substantially equivalent to the predicate device, Obsidian Milling Block (K141788) in terms of design. Both devices are offered in a block form in different shades and are used to make final dental restorations based on the anatomical rendering of patient's teeth using CAD/CAM equipment.

Attributes	Subject Device (K234014)	Predicate Device (K141788)	Comparison
Device Name	Obsidian® NOW	Obsidian Milling Block	N/A
Manufacturer	Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	Same

Attributes		Subject Device (K234014)	Predicate Device (K141788)	Comparison
Product Code		EIH	EIH	Same
Prescription Device		Yes	Yes	Same
Intended Use		Obsidian® NOW is intended to be used in fabrication of dental restorations for the purpose of restoring chewing function.	Obsidian Milling Block is intended to be used in fabrication of dental restorations for the purpose of restoring chewing function.	Same; except for the device trade name.
Indications for Use		Obsidian® NOW is used to fabricate ceramic dental prosthesis in the nature of crowns for posterior and anterior applications using CAD/CAM technology. The block is processed through dental laboratories or by dental professionals.	The Obsidian Milling Blocks are used to fabricate ceramic dental prostheses in the nature of crowns and bridges for posterior and anterior applications using CAD/CAM methods.	Similar; except for the device trade name and the subject device has the addition of a chairside indication for use.
Prescription Device		Yes	Yes	Same
Design Characteristics	Material Composition	The device is composed of lithium aluminosilicate glass matrix embedded with lithium disilicate crystals, colorants, and opacifiers to achieve the desired shade.	The device is composed of lithium aluminosilicate glass matrix embedded with lithium silicate crystals, colorants, and opacifiers to achieve the desired shade.	Similar; the subject device is made of lithium disilicate glass, fewer colorants, and opacifiers as opposed to the predicate device.
	Design	Fully crystallized lithium disilicate glass ceramic available in milling block form for single-unit restorations.	Partially crystallized lithium silicate glass ceramic available in milling block form for single-unit restorations.	Similar; the subject device does not require additional crystallization prior to placement.
	Shades	A1, A2, A3, A3.5, B1	A1, A2, A3, A3.5, B1, B2, B3, C1, C2, C3, D2, D3, BL1, and BL4	Similar; no bleach shades and fewer VITA shades are offered for the subject device.

Attributes		Subject Device (K234014)	Predicate Device (K141788)	Comparison
	Flexural Strength	≥300 MPa Type II Class 3 per ISO 6872:2015/Amd 1:2018	>300 MPa Type II Class 3 per ISO 6872:2015/Amd 1:2018	Same
	Chemical Solubility	<100 μg/cm^2	<100 μg/cm^2	Same
	Biocompatibility	Biocompatible per ISO 10993-1	Biocompatible per ISO 10993-1	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 Materials	Shall be free from extraneous materials when assessed by visual inspection	Shall be free from extraneous materials when assessed by visual inspection	Same
	Glass Transition Temperature	Shall not deviate by more than ±20°C	Shall not deviate by more than ±20°C	Same
	Sterility	Non-sterile	Non-sterile	Same

VII. Non-Clinical and/or Clinical Tests Summary & Conclusions

Non-clinical data submitted to demonstrate substantial equivalence include:

- Flexural Strength according to ISO 6872:2015/Amd 1:2018
- Visual Shade Evaluation
- Color Consistency
- Cementation Testing
- Printing & Gluing
- Uniformity of Color according to ISO 6872:2015/Amd 1:2018
- Chemical Solubility according to ISO 6872:2015/Amd 1:2018
- Radioactivity according to ISO 6872:2015/Amd 1:2018
- Freedom from Extraneous Materials according to ISO 6872:2015/Amd 1:2018
- Glass Transition Temperature according to ISO 6872:2015/Amd 1:2018
- Biocompatibility assessment per the FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."
- Packaging Validation according to ASTM D4169-22

No clinical data is included in this submission.

Flexural Strength

Flexural strength was tested on all shades offered for Obsidian® NOW. The average flexural strength met the acceptance criteria of 300 MPa, which is the value to be achieved for Type II, Class 3 ceramic product according to ISO 6872:2015/Amd 1:2018. The results of the testing were used to address questions related to substantial equivalence based on differences in technical specifications between the subject device, Obsidian® NOW, and predicate device, Obsidian Milling Blocks (K141788).

Visual Shade Evaluation

All shades offered for Obsidian® NOW were evaluated by qualified evaluators using the sample dental restorations milled from the final crystallized products against corresponding VITA® Classical shade guide. Evaluations concluded that Obsidian® NOW meets visual shade match requirements and works as intended. The results of the testing were used to address questions related to substantial equivalence based on differences in technical specifications between the subject device, Obsidian® NOW, and predicate device, Obsidian Milling Blocks (K141788).

Color Consistency

Color consistency within a batch was tested on all shades offered for Obsidian® NOW. A ΔE of less than 2.0 between two coordinates in the CEILAB color space is considered indicative that different samples within a batch being perceptibly identical to one another. Obsidian® NOW meets the color consistency requirement since the ΔE calculation between the samples measured was less than 2.00. The results of the testing were used to address questions related to substantial equivalence based on differences in technical specifications between the subject device, Obsidian® NOW, and predicate device, Obsidian Milling Blocks (K141788).

Uniformity of Color

Uniformity of color was tested on all shades offered for Obsidian® NOW to meet the requirement of ISO 6872:2015/Amd 1:2018. Obsidian® NOW meets the uniformity of color requirement since all samples milled into restorations from a representative final finished block were uniform in color when assessed by visual inspection. The results of the testing were used to address questions related to substantial equivalence based on differences in technical specifications between the subject device, Obsidian® NOW, and predicate device, Obsidian Milling Blocks (K141788).

Chemical Solubility

The worst cases were tested for solubility and the measured value was <100 µg/cm^2, meeting the ISO 6872:2015/Amd 1:2018 requirement. The results of the testing were used to address questions related to substantial equivalence based on differences in technical specifications between the subject device, Obsidian® NOW, and predicate device, Obsidian Milling Blocks (K141788).

Radioactivity

Obsidian® NOW was tested on the worst cases to meet the radioactivity requirement of ISO 6872:2015/Amd 1:2018. Obsidian® NOW meets the radioactivity requirement since the sample measured below the Uranium-238 activity threshold of 1.0 $Bq \cdot g^{-1}$ per ISO 6872:2015/Amd 1:2018. The results of the testing were used to address questions related to substantial equivalence based on differences in technical specifications between the subject device, Obsidian® NOW, and predicate device, Obsidian Milling Blocks (K141788).

Freedom from Extraneous Materials

All shades offered for Obsidian® NOW were tested to meet the freedom from extraneous materials requirement of ISO 6872:2015/Amd 1:2018. Obsidian® NOW meets the freedom from extraneous materials requirement since the samples were all free from extraneous materials when assessed by visual inspection. The results of the testing were used to address questions related to substantial equivalence based on differences in technical specifications between the subject device, Obsidian® NOW, and predicate device, Obsidian Milling Blocks (K141788).

Glass Transition Temperature

All shades offered for Obsidian® NOW were tested to meet the glass transition temperature requirement of ISO 6872:2015/Amd 1:2018. Obsidian® NOW meets the glass transition temperature requirement since the samples did not deviate by more than ±20°C of the average T_g obtained across all lots. The results of the testing were used to address questions related to substantial equivalence based on differences in technical specifications between the subject device, Obsidian® NOW, and predicate device, Obsidian Milling Blocks (K141788).

Coefficient of Thermal Expansion (CTE)

Coefficient of thermal expansion was not tested on the subject device, Obsidian® NOW, as it is not applicable. Coefficient of Thermal Expansion (CTE) is an important property if staining and glazing were required, for which the subject device, Obsidian® NOW, is not. This difference in technical specification does not raise any issues related to substantial equivalence between the subject device, Obsidian® NOW, and predicate device, Obsidian Milling Block (K141788).

Biocompatibility

Biological evaluation within a risk management process was performed in accordance with ISO 10993-1:2018 and ISO 14971:2019. Based on the cytotoxicity testing results from the subject device, Obsidian® NOW, it was determined that there is no biocompatibility concern regarding dental glass material, colorants, or other elements. The results of the testing were used to address questions related to substantial equivalence based on

differences in chemical composition between the subject device, Obsidian® NOW, and predicate device, Obsidian Milling Blocks (K141788).

Packaging Validation

Packaging validation was conducted to ensure that the packaging configurations for Obsidian® NOW are suitable to withstand the distribution environment. Per ASTM D4169-22, Obsidian® NOW was tested to check resistance against manual handling, vehicle stacking, loose load vibration, low pressure (high altitude) hazard, vehicle vibration, and concentrated impact. After the test, the shipping containers were visually inspected for any damage. It was determined that the respective packaging for Obsidian® NOW is suitable for use. The results of the testing were used to address questions related to substantial equivalence based on differences in product packaging between the subject device, Obsidian® NOW, and the predicate device, Obsidian Milling Block (K141788).

VIII. Conclusion

Based on the technological characteristics and non-clinical test data included in this submission, the subject device, Obsidian® NOW, has been shown to be substantially equivalent to the predicate device, Obsidian Milling Block (K141788).