August 25, 2025

DenMat Holding, LLC
Kimberly Maynes
Sr. Supervisor, Regulatory Affairs
1017 W. Central Avenue
Lompoc, California 93436

Re: K251593
Trade/Device Name: DenMat Multilayered Zirconia Disc
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: May 23, 2025
Received: May 27, 2025

Dear Kimberly Maynes:

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

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)*

K251593

Device Name

DenMat Multilayered Zirconia Disc

Indications for Use *(Describe)*

The Multilayered Zirconia Disc is indicated for fabrication of anterior and posterior dental restorations using different CAD/CAM or manual machines.
All discs are 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.

510(k) Summary - K251593

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information — 21 CFR 807.92(a)(1)

Submitter: Den-Mat Holdings, LLC
1017 W. Central Ave.
Lompoc, CA, 93436, USA
Phone: 805-346-3700
Establishment Registration Number: 2018957

Contact Person: Kim Maynes
Sr. Supervisor, Regulatory Affairs
Phone: 805-346-3700
Email: regulatory@denmat.com

Date Prepared: August 25, 2025

Device Information — 21 CFR 807.92(a)(2)

Trade Name:	DenMat Multilayered Zirconia Disc
Common Name:	Powder, Porcelain
Regulation Number:	21 CFR 872.6660
Regulation Name:	Porcelain powder for clinical use
Classification:	Class II
Product Code:	EIH
Review Panel:	Dental

Legally Marketed Predicate Device(s) — 21 CFR 807.92(a)(3)

Device Trade Name:	Gradual Dental Zirconia Blank
510(k) Number:	K231687
Product Code:	EIH

Device Description — 21 CFR 807.92(a)(4)

DenMat Multilayered Zirconia Discs are made of Zirconium Oxide (Y-TZP ZrO_2). For dental applications in accordance with ISO 6872, (DIN EN ISO 6872), this material is specially made for manufacturing of permanent and removable dental prosthetics. After completion of the final sintering, all DenMat Multilayered Zirconia meets the requirements of ISO 6872, Type II, Class 5. It is necessary to mill the disc with an appropriate enlargement factor to account for the shrinkage that occurs during full sintering. DenMat Zirconia Multilayered (ML) discs can be used with any compatible CAD/CAM machine.

Material Used:
DenMat Multilayered Zirconia Discs are composed of zirconia ceramics (ZrO_2) based on yttria-stabilized tetragonal zirconia (Y-TZP). The material is biocompatible according to ISO 10993-1: 2018 “Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”

Intended Use / Indications for Use	21 CFR 807.92(a)(5)

The Multilayered Zirconia Disc is indicated for fabrication of anterior and posterior dental restorations using different CAD/CAM or manual machines. All discs are processed through dental laboratories or by dental professionals.

Comparison of Technological Characteristics	21 CFR 807.92(a)(6)

DenMat Multilayered Zirconia Disc comparison to the predicate device, UPCERA Gradual Dental Zirconia Blank (K231687), is based upon similar characteristics such as intended use, indications, contra-indications, material properties, chemical composition, processing/fabrication and testing to recognized standards and guidelines. DenMat Multilayered Zirconia Disc utilizes a substantially equivalent composition ($ZrO_2+HfO_2+Y_2O_3$: > 99), which results in a flexural strength of >800MPa and a fracture toughness of >5.0 MPa $\sqrt{m}$, therefore allowing for a classification of Class 5 in the ISO 6872:2024 standard. Thus, the product meets the standards for "Monolithic-ceramic for prostheses involving four or more units or fully covered substructure for prostheses involving four or more units."

The predicate device's Indications for Use provide for "the production of full contour and substructure restorations up to a full arch" and the subject device also meets the standards for this same indication based upon the specification with ISO 6872:2024, Section 4 and Annex A.

Additionally, while Indication for Use statements now note prescription requirements on the form, we have still indicated the device is for use by dental technicians. We have also noted the prescription requirements in the Instructions for Use and on the device labeling. Both the subject device and predicate device are provided in disc shapes of various sizes. The subject and predicate device have similar physical/mechanical properties that meet the requirements of ISO 6872:2024.

DenMat Multilayered Zirconia Disc biocompatibility was addressed using FDA' Biocompatibility Guidance "Use of International Standard 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.

Zirconia Multilayered Zirconia Disc dental porcelain zirconium oxide blanks for use by dental professionals to construct custom dental restorations are substantially similar to the UPCERA (K231687) in general composition, safety and effectiveness.

Subject and Predicate comparison table below.

Device(s) Similarities

	DenMat Zirconia Multilayered Disc (K251593)	**UPCERA Gradual Dental Zirconia Blank (K231687)**
Indications for use	The Multilayered Zirconia Disc is indicated for fabrication of anterior and posterior dental restorations using different CAD/CAM or manual machines. All discs are processed through dental laboratories or by dental professionals.	The device is indicated for fabrication of anterior and posterior dental restorations using different CAD/CAM or manual machines. All blanks are processed through dental laboratories or by dental professionals.
Contra- Indications*	DenMat Multilayered Zirconia Disc blanks are milled, the dental technician should take appropriate safety methods such as face mask and eye protection when removing the finished dental prostheses from the holder to preclude inhaling dust particles upon removal with power tools. • Insufficient tooth structure reduction. • Insufficient tooth structure for proper adhesion and force distribution. • Insufficient oral hygiene. • Insufficient interproximal space for sufficient joints in bridges. • Known allergies. • Known incompatibilities to product composition. • Heavy discoloration of prepped tooth structure.	There are no specific precautions, warnings or contra- indications that are required for the safe and effective use of the device by the dental professional or patient.
Technical Data (performance testing included)		

<table>
<tr>
<td>Material Composition
% wt.</td>
<td>
<table>
<tr><td>ZrO_2</td><td>91.958-92.570%</td></tr>
<tr><td>Y_2O_3</td><td>7.250-7.800%</td></tr>
<tr><td>SiO_2</td><td>≤0.010%</td></tr>
<tr><td>Fe_2O_3</td><td>0.017-0.114%</td></tr>
<tr><td>CaO</td><td>≤0.007%</td></tr>
<tr><td>Na_2O</td><td>≤0.004%</td></tr>
<tr><td>Mn_2O_3</td><td>≤0.003%</td></tr>
<tr><td>Er_2O_3</td><td>≤0.263%</td></tr>
</table>
</td>
<td>Zirconia (ZrO_2+HfO_2+Y_2O_3: ≥ 98%)
Inorganic pigments</td>
</tr>
<tr>
<td>Radioactivity(Freedom from extraneous materials per ISO 6872:2024 Section
5.2 active conc. of not more than 1.0 Bq g-1 of Uranium238)</td>
<td>< 0.0174 $Bq \cdot g^{-1}$ of ^{238}U</td>
<td>Not supplied</td>
</tr>
<tr>
<td>Blank sizes (mm)</td>
<td>
<table>
<tr><th>Disc</th><th>Diameter (mm)</th><th>Thickness (mm)</th></tr>
<tr><td>1</td><td>98.5</td><td>14</td></tr>
<tr><td>2</td><td>98.5</td><td>18</td></tr>
<tr><td>3</td><td>98.5</td><td>22</td></tr>
<tr><td>4</td><td>98.5</td><td>25</td></tr>
</table>
</td>
<td>Not supplied</td>
</tr>
<tr>
<td>Sintered Density g cm-3
ISO 13356: 2015
Section 4.1 Req't.
of ≥ 6.0</td>
<td>6.04 ± 0.03 g/cm^3</td>
<td>Not supplied</td>
</tr>
<tr>
<td>Coefficient of thermal expansion (CTE) ISO 6872:
2024, No req't.</td>
<td>10.39 ± 0.34 ($x10^{-6}$ K^{-1})</td>
<td>Not supplied</td>
</tr>
<tr>
<td>Fracture toughness KIC
ISO 6872:2024 Annex A; minimum for class 5, 4.0 MPa
m1/2</td>
<td>4.90 ± 0.94 MPa√m</td>
<td>Not supplied</td>
</tr>
</table>

Average Flexural strength per ISO 6872: 2024, Limit >800MPa	1085.51 ± 265.06 MPa	Not supplied
Chemical solubility per ISO 6872:2024 Limit 100 µg/cm2	< 100 µg/cm2	Not supplied
Biocompatibility per ISO 10993-1: Part 1 - 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."	Biocompatibility was addressed using FDA' Biocompatibility Guidance "Use of International Standard 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.	Tested for Cytotoxicity, Irritation Oral Mucosa, Irritation, Sensitization, Subacute and subchronic toxicity and genotoxicity on shaded material, no adverse reactions identified.
Safety and Efficacy of the Device	The device functions in a similar manner to other comparative devices and the intended use is the same. The differences between comparatives devices are minor and do not raise new safety concerns. The effectiveness and suitability of the device for the intended purpose is assured through wide, general use of similar other predicate devices that demonstrate the safe use of the device to construct dental restorations.	Not supplied

Performance Data	21 CFR 807.92(b)

Physical Properties:
Tabulated chart of finished product DenMat Multilayered Zirconia Disc below:

Summary of The Performance Testing Report:

Single Crown

Test Performed	**Test Results**	**Acceptance Criteria**	**Applied Standard**	**Results**
Biaxial Flexural strength	568.72 ± 168.22 MPa	> 100 MPa	ISO 6872: 2024	Pass
Coefficient of Thermal Expansion	10.40 ± 0.02 ($x10^{-6}$ K^{-1})	10.40 ± 0.34 ($x10^{-6}$ K^{-1})	ISO 6872: 2024 ASTM E831	Pass
Chemical solubility	< 100 µg/cm^2	< 100 µg/cm^2	ISO 6872: 2024	Pass
Fracture toughness	4.14 ± 0.43 MPa√m	> 1.0 MPa√m	ISO 6872: 2024 (ISO 18756/ASTM C1421)	Pass
Sintered Density	6.11 ± 0.05 g/cm^3	≥ 6.0	ISO 13356: 2015	Pass

Single Crown Units & 3 Unit Bridges

Test Performed	Test Results	Acceptance Criteria	Applied Standard	Results
Biaxial Flexural strength	740.45 ± 252.32 MPa	> 500 MPa	ISO 6872: 2024	Pass
Coefficient of Thermal Expansion	10.43 ± 0.05 ($x10^{-6}$ K^{-1})	10.40 ± 0.34 ($x10^{-6}$ K^{-1})	ISO 6872: 2024 ASTM E831	Pass
Chemical solubility	< 100 µg/cm^2	< 100 µg/cm^2	ISO 6872: 2024	Pass
Fracture toughness	4.21 ± 0.48 MPa√m	> 3.5 MPa√m	ISO 6872: 2024 (ISO 18756/ASTM C1421)	Pass
Sintered Density	6.05 ± 0.03 g/cm^3	≥ 6.0	ISO 13356: 2015	Pass

Conclusion

Based on the indications for use, technological characteristics, and the summary of data submitted, Den-Mat Holdings, LLC has determined that the subject device does not raise different questions of safety and effectiveness compared to the predicate devices. Therefore, the proposed subject device is substantially equivalent to the legally marketed predicate devices.