October 30, 2026

Zirconia Collective, Inc.
Gerard Giuliano Jr
CEO
10860 Dover St.
Suite 2500
Westminster, Colorado 80021

Re: K262685
Trade/Device Name: Zirconia Collective 4Y Dental Zirconia Blank
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: July 30, 2026
Received: July 31, 2026

Dear Gerard Giuliano Jr:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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

Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262685

Please provide the device trade name(s).

Zirconia Collective 4Y Dental Zirconia Blank

Please provide your Indications for Use below.

Zirconia Collective 4Y Dental Zirconia Blank is indicated for use in prosthetic dentistry for the fabrication of all-ceramic dental restorations, including crowns, bridges, veneers, inlays, and onlays. The blank is intended to be milled and fully sintered by a dental professional or dental laboratory prior to use. Prescription use only.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #: **K262685**

510(k) Summary

Prepared on: 2026-07-30

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Zirconia Collective, Inc.
Applicant Address	10860 Dover St. Suite 2500 Westminster CO 80021 United States
Applicant Contact Telephone	8472208311
Applicant Contact	Mr. Gerard Giuliano Jr
Applicant Contact Email	jerry@zirconiacollective.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Zirconia Collective 4Y Dental Zirconia Blank
Common Name	Dental Zirconia Blank
Classification Name	Porcelain Powder for Clinical Use
Regulation Number	21 CFR 872.6660
Product Code(s)	EIH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K152175	Dental Zirconia Blank for Aesthetic Restoration	EIH

Device Description Summary

21 CFR 807.92(a)(4)

Zirconia Collective is a partially sintered yttria-stabilized zirconia (Y-TZP) ceramic blank supplied in disc form for use in CAD/CAM fabrication of dental restorations. The device is intended for use by dental laboratories and dental professionals to manufacture crowns, bridges, veneers, inlays, onlays, and other fixed prosthetic restorations. The zirconia blank is milled to the desired restoration geometry and subsequently fully sintered prior to clinical use. The material consists primarily of zirconium oxide stabilized with yttrium oxide and conforms to ISO 6872 requirements for dental ceramic materials. Testing demonstrates acceptable flexural strength, density, thermal expansion characteristics, chemical solubility, and radiological safety for intended dental applications.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Zirconia Collective 4Y Dental Zirconia Blank is indicated for use in prosthetic dentistry for the fabrication of all-ceramic dental restorations, including crowns, bridges, veneers, inlays, and onlays. The blank is intended to be milled and fully sintered by a dental professional or dental laboratory prior to use. Prescription use only.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device and predicate device have the same general intended use. Both are zirconia dental blanks intended for fabrication of dental restorations by dental laboratories or dental professionals. Differences in indications wording do not change intended use.

Technological Comparison

21 CFR 807.92(a)(6)

Both devices are partially sintered Y-TZP zirconia ceramic blanks for CAD/CAM fabrication followed by final sintering. Differences in shade/pigment levels, dimensions, and processing parameters do not raise new questions of safety or effectiveness. Bench testing supports substantial equivalence.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Nonclinical bench testing was used to support substantial equivalence of Zirconia Collective 4Y Dental Zirconia Blank. Testing was performed in accordance with ISO 6872:2024 and included flexural strength, chemical solubility, radioactivity, sintered density, and thermal expansion coefficient evaluation. Results demonstrated performance consistent with the intended use of the device and comparable to legally marketed zirconia dental blanks. No animal testing or clinical evidence was relied upon for this submission.

Not Applicable. No clinical testing was performed or relied upon for this submission.

Nonclinical bench testing demonstrates that Zirconia Collective 4Y Dental Zirconia Blank performs as intended and is substantially equivalent to the predicate device. The subject device met applicable performance requirements for flexural strength, chemical solubility, radioactivity, sintered density, and thermal expansion coefficient. The testing supports the conclusion that the device is as safe and effective as the legally marketed predicate device for its intended use.