May 21, 2026

Dental Creativ Management GmbH
% Patsy Trisler
Owner/Regulatory Consultant
Trisler Consulting (dba)
306 Turnberry Ct
Lebanon, Indiana 46052

Re: K253191
Trade/Device Name: DCMhotbond zircon
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: September 26, 2025
Received: September 26, 2025

Dear Patsy Trisler:

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,

Bobak Shirmohammadi -S

For 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.	K253191

Please provide the device trade name(s).

DCMhotbond zircon

Please provide your Indications for Use below.

DCMhotbond zircon is a glass-based ceramic material that is mixed with a modeling liquid. It is intended to be used to fuse together ceramic sections of dental restorations. DCMHotbond zircon liquid is a modeling liquid for mixing with the glassy ceramic solder DCMhotbond zircon.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

SUBMITTER Name:	Dental Creativ Management GmbH
Address:	Breite Strasse 16 18055 Rostock Germany
Contact Person: **Email:**	Mr. Milija Mitrovic info@dcm-hotbond.com
Date Prepared:	20 April 2026
DEVICE Trade Name:	DCMhotbond zircon
Common Name:	Porcelain powder for clinical use
Classification Name **Number** **Product Code &** **Regulatory Class**	Powder, Porcelain 21 CFR 872.6660 EIH, Class 2
Review Panel	Dental
PRIMARY PREDICATE:	K983453, Nobel Biocare Procera® AllCeram Fusing Material
DEVICE DESCRIPTION	DCMhotbond zircon is a glassy ceramic based on a powdered silicate material (DCMhotbond zircon) and a modeling liquid (DCMhotbond liquid). The powder and liquid are combined to form an emulsion (paste) by the dental professional to create the bonding material used to fuse zirconium to zirconium customized dental prosthetic parts. After fusing the parts, the resulting piece is fired as specified in the Intended Use statement. The zircon powder is offered in 3gm and 10gm glass jars and the zircon liquid comes in 20 ml plastic bottles.
INDICATIONS FOR USE STATEMENT	DCMhotbond zircon is a glass-based ceramic material that is mixed with a modeling liquid. It is intended to be used to fuse together ceramic sections of dental restorations. DCMHotbond zircon liquid is a modeling liquid for mixing with the glassy ceramic solder DCMhotbond zircon.
DEVICE TESTING: **Animal/Clinical**	In vivo Animal and Human Clinical performance testing are not required for this device category. Following are summaries of the non-clinical testing performed.
SAFETY TESTING	A biological risk evaluation was done according to ISO 10993, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system* to determine the testing needed for this product. Testing for *in vitro* Cytotoxicity (Part 5), Guinea Pig Maximization Sensitization (Part 10) and Oral Mucosa Irritation in Hamsters (Part 23) were performed by a GLP-certified contract research laboratory; all results met the requirements of the testing. Radioactivity levels also were measured and found to be well within acceptable limits.
DEVICE CHARACTERIZATION / PERFORMANCE TESTING	Physical and mechanical properties of the subject device were evaluated according to FDA-recognized standard, ISO 6872:1995, (*Dentistry – Ceramic materials*) and ISO 9693:1999 (*Dentistry — Compatibility testing for metal-ceramic and ceramic-ceramic systems*).

	Further, the bonding effectiveness was evaluated in reference to ISO 29022:2013(E) (*Dentistry–Adhesion–Noticed-Edge Shear Bond Strength Test* and ISO/TS 14569-2 (*Dental Materials—Guidance on Testing of Wear—Part 2: Wear by Two- and/or Three- Body Contact*).
COMPARISON TO THE PREDICATE DEVICE	The DCMhotbond zircon has the same intended use as the predicate device. The indications differ only in reference to the specified powder and liquid to be used for fusing the specified materials for the final dental prosthetics. Both are glass ceramics' powdered base materials and liquids, which are mixed to make an emulsion (or paste) to be applied by the dental professional to form the final dental prosthetic, which is then fired as specified and finished. These differences in the specific materials and the manufacturing processes to make the powders do not raise new questions of safety and effectiveness.
SUBSTANTIAL EQUIVALENCE CONCLUSION	The information and data provided in this 510(k) establish that DCMhotbond zircon device is substantially equivalent to the predicate device in the intended use, design, principle of operation and technology. See the following SE Comparison table.

Substantial Equivalence Comparison Table

510(k) Number	Proposed Device K253191	Primary Predicate K983453	Remarks
Device Name	DCMhotbond zircon	Procera All Ceram Fusing Material	N/A
Manufacturer	Dental Creativ Management GmbH	Nobel Biocare USA, Inc.	N/A
Classification Regulation Name Product Code Class	21 CFR 872.6660 Porcelain Powder for Clinical Use EIH 2	21 CFR 872.6660 Porcelain Powder for Clinical Use EIH 2	Same
Indications for Use	DCMhotbond zircon is a glass-based ceramic material that is mixed with a modeling liquid. It is intended to be used to fuse together ceramic sections of dental restorations. DCMHotbond zircon liquid is a modeling liquid for mixing with the glassy ceramic solder DCMhotbond zircon.	Nobel Biocare's Procera AllCeram Fusing Material is a glass based powder which is mixed with distilled water. It is intended to be used to fuse together sections of an aluminum oxide dental bridge.	Same intended use: both are glass-based powders to be mixed with a liquid to form a paste, which is used to fuse sections of dental appliances.
Prescription Use	Yes	Yes	SE
Manufacturing Material	Glass ceramics	Glass ceramics	SE
Materials	Glass-based powder and modeling/blending liquid (DCMhotbond zircon liquid), composed of primarily water:	Glass-based powder and modeling/blending liquid composed of distilled water.	SE
Conditions of Use	Used by trained professionals, trained in customized denture production. The two materials are mixed to make a paste that can be applied with a spatula for fusing the pieces.	Used by trained professionals, trained in customized denture production. The two materials are mixed to make a paste that can be applied with a spatula for fusing the pieces.	SE
Physico-chemical: Bonding characteristics:	Evaluated per requirements of ISO 6872: Evaluated per ISO 29022:2013(E) and ISO/TS 14569-2.	Unknown from public information; but presumably testing was performed that met the requirements of ISO 6872 for this product type.	SE
Categorization by body contact type & duration	Mucosal membrane surface-contact; long-term exposure contact time (>30 days)	Mucosal membrane surface-contact; long-term exposure contact time (>30 days)	SE
Biocompati-bility	Comply with ISO 10993-1:2018 and ISO 7405:2025	Comply with ISO 10993-1:2018 and ISO 7405:2016	SE
Applicable population	Suitable for clinical patients with denture defect or absence	Suitable for clinical patients with denture defect or absence	SE
Sterle	Non-sterile	Non-sterile	SE