September 6, 2024

Dental Direkt GmbH
Patrick Berz
Official Correspondent
Industriezentrum 106-108
Spenge, 32139
GERMANY

Re: K241579
Trade/Device Name: DD Hybridlayer (multicolored zirconia)
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: June 3, 2024
Received: June 3, 2024

Dear Patrick Berz:

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
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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)*

K241579

Device Name

DD Hybridlayer (multicolored zirconia)

Indications for Use *(Describe)*

Dental Direkt zirconium dioxide milling blanks are intended for the fabrication of fixed restorations for long-term use.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Prepared on: 2024-09-05

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Dental Direkt GmbH K241579
Applicant Address	Industriezentrum 106-108 Spenge 32139 Germany
Applicant Contact Telephone	+4952258631924
Applicant Contact	Mr. Patrick Berz
Applicant Contact Email	p.berz@dentaldirekt.de

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	DD Hybridlayer (multicolored zirconia)
Common Name	Porcelain powder for clinical use
Classification Name	Powder, Porcelain
Regulation Number	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
K142987	DD Bio Z, DD Bio ZX², DD Bio ZX² color	EIH

Device Description Summary

21 CFR 807.92(a)(4)

DD Hybridlayer (multicolored zirconia) includes the product Nacera® Pearl Natural. Nacera® Pearl Natural is a combination of 3Y-TZP (yttrium-stabilized tetragonal zirconia) and 5Y-TZP which is specially designed to produce fixed dentures such as crowns and bridges by the dental technican/dentist in the dental laboratory.
The product is not delivered sterile and cleaning, re-processing or sterilization by the user is not required.
The individual variants are available in six heights (12 mm, 14 mm, 16 mm, 20 mm, 25 mm and 30 mm) to meet customer requirements.
To achieve the appearance of natural tooth, the raw materials are partially mixed with oxides, which result in a coloring of the blank. The variants of the Nacera® Pearl Natural have a color gradient from light (occlusal) to dark (tooth neck) within the blank. In this way, the color gradient of the natural tooth is reproduced.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Dental Direkt zirconium dioxide milling blanks are intended for the fabrication of fixed restorations for long-term use.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the Subject Device is identical to the indications for use of the Predicate Device, even though the wording is not exactly the same. This is because the indications for use of the Predicate Device / Reference Device is more detailed compared to the general indications for use of the Subject Device. However, the indications for use of the Predicate Device / Reference Device is covered by the indications for use of the Subject Device.

Technological Comparison

21 CFR 807.92(a)(6)

Chemical composition and physical characteristics are comparable since the Subject Device is a combination of the Predicate Device and Reference Device.

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

Physical characteristics are comparable since the Subject Device is a combination of the Predicate Device and the Reference Device.