October 18, 2024

Edelweiss Dentistry Products GmbH
% Leonie Zeller
QA/RA Engineer
Medagent GmbH
Griesweg 47
Mühlheim an der Donau, 78570
GERMANY

Re: K241131
Trade/Device Name: edelweiss CAD/CAM T-BLOCK; edelweiss CAD/CAM C-BLOCK; edelweiss CAD/CAM i-BLOCK; Ceramir CAD/CAM T-BLOCK; Ceramir CAD/CAM C-BLOCK; Ceramir CAD/CAM i-BLOCK
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: October 1, 2024
Received: October 1, 2024

Dear Leonie Zeller:

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
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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)*

K241131

Device Name

edelweiss CAD/CAM T-BLOCK;
edelweiss CAD/CAM C-BLOCK;
edelweiss CAD/CAM i-BLOCK;
Ceramir CAD/CAM T-BLOCK;
Ceramir CAD/CAM C-BLOCK;
Ceramir CAD/CAM i-BLOCK

Indications for Use *(Describe)*

T-BLOCK and C-BLOCK are used for the following indications
- Crowns, inlays, onlays and veneers
- Implant-supported crowns

The i-BLOCK is used for the following indication:
- Implant-supported crowns

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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DATE OF APPLICATION: 24.04.2024

K241131

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1 Device Name

Trade Name:	*edelweiss CAD/CAM T-BLOCK;* *edelweiss CAD/CAM C-BLOCK;* *edelweiss CAD/CAM i-BLOCK* *Ceramir CAD/CAM T-BLOCK;* *Ceramir CAD/CAM C-BLOCK;* *Ceramir CAD/CAM i-BLOCK;*
Common Name:	*CAD/CAM Block*
Device Classification Name:	*Material, Tooth Shade, Resin*

2 Classification / Product Code

The edelweiss CAD/CAM BLOCKs and Ceramir CAD/CAM BLOCKs can be classified according to following device name and product code:

Device	Regulation Description	Regulation Medical Specialty	Review Panel	Product Code	Regulation Number	Device Classification
edelweiss CAD/CAM BLOCK Ceramir CAD/CAM BLOCK	Tooth shade resin material	Dental	Dental	EBF	872.3690	II

3 Predicate Device / Reference Device

Device	Predicate Device / Reference Device	510(k) Number	510(k) Holder
edelweiss CAD/CAM BLOCK	BRILLIANT Crios (Primary Predicate Device)	K181500	Coltene/Whaledent AG
Ceramir CAD/CAM BLOCK	Nanocomposite (Reference Device)	K080480	DMG USA, Inc.

4 Device Description

The edelweiss CAD/CAM BLOCK and the Ceramir CAD/CAM Block are hybrid glass blocks used for the fabrication of indirect single-tooth restorations using CAD/CAM technology. The edelweiss CAD/CAM BLOCK and the Ceramir CAD/CAM BLOCK are available in the three different variants T-BLOCK, C-BLOCK and i-BLOCK and five shades.

T-BLOCKs are highly translucent blocks that mimic the optical properties of natural enamel.
C-BLOCKs are high chromatic blocks corresponding to the color shades A0, A1, A2 and A3.
i-BLOCKs are highly translucent and highly chromatic blocks, which have a pre-produced Ti-base interface.

The uniqueness of the edelweiss CAD/CAM BLOCK and the Ceramir CAD/CAM BLOCK lies in the manufacturing process, in which a hybrid glass block is produced by the patented process of vitrification and laser sintering. As a result, the edelweiss CAD/CAM BLOCK and the Ceramir CAD/CAM BLOCK combines the properties of the current CAD/CAM systems in a single block. It has properties comparable to those of feldspar glass-ceramics.

5 Indications for Use

T-BLOCK and C-BLOCK are used for the following indications

- Crowns, inlays, onlays and veneers
- Implant-supported crowns

The i-BLOCK is used for the following indication:

- Implant-supported crowns

6 Technological Characteristics

The technological characteristics of edelweiss CAD/CAM BLOCK and Ceramir CAD/CAM BLOCK are the same as the technological characteristics of the predicate device.

6.1 Device Characteristics Table

Company	edelweiss dentistry products gmbh (New Device)	Coltene/Whaledent AG (Predicate Device)	DMG USA, Inc. (Reference Device)	Result
Device Name	edelweiss CAD/CAM BLOCK Ceramir CAD/CAM BLOCK	BRILLIANT Crios	Nanocomposite	-
Regulation Number	§872.3690	§872.3690	§872.3690	Substantially Equivalent
Class	II	II	II	Substantially Equivalent
Product Code	EBF	EBF	EBF	Substantially Equivalent
510(k) number	K241131	K181500	K080480	-
Review Panel	Dental	Dental	Dental	Substantially Equivalent
Indications for Use	T-BLOCK and C-BLOCK are used for the following indications - Crowns, inlays, onlays and veneers - Implant-supported crowns The i-BLOCK is used for the following indication: - Implant-supported crowns	BRILLIANT Crios is indicated for: - Crowns, inlays, onlays and veneers Implant-supported crowns	Nanocomposite is indicated for: - Restorations of all cavity classes - Fabrication of direct inlays, onlays and indirect veneers - Core build-up after tooth preparation with the root canal post - Machinable Composite for Restorations - Indirect Inlays/Onlays	Substantially Equivalent, the new device and predicate device have the same intended use and are used for permanent tooth restorations.
Physical State	Cured blocks	Cured blocks	Viscous paste	Substantially Equivalent
Structure	Polymer resin / ceramic hybrid composite	Polymer resin composite	Polymer resin / ceramic hybrid composite	Substantially Equivalent
Resin Matrix Monomers	Bis-GMA, UDMA, EBPADMA	Bis-GMA, Bis-EMA, TEGDMA, UDMA	Bis-GMA, UDMA, EBPADMA	Substantially Equivalent, the new device and predicate device both contain Bis-GMA and UDMA in their resin matrix.
Filler	Silica, barium glass	Silica, barium glass	Silica, barium glass	Substantially Equivalent
Sizes	12, 14	12, 14	n/a	Substantially Equivalent
Flexural Strength	200 (MPa)	198 (MPa)	100 (MPa)	Substantially Equivalent.

Company	edelweiss dentistry products gmbh (New Device)	Coltene/Whaledent AG (Predicate Device)	DMG USA, Inc. (Reference Device)	Result
Flexural Modulus	20 (GPa)	10.3 (GPa)	-	Substantially Equivalent
Compressive Strength	550 (MPa)	426 (MPa)	300 (MPa)	Substantially Equivalent
Packaging	Mandrel mounted; five to a box	Mandrel mounted; five to a box	Syringe (3g)	Substantially Equivalent
Usage	Single Patient, multiple use	Single Patient, multiple use	Single Patient, multiple use	Substantially Equivalent
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Substantially Equivalent
Biocompatibility	Conforms with ISO 10993-1	Conforms with ISO 10993-1	Conforms with ISO 10993-1	Substantially Equivalent
Performance	Conforms with ISO 4049 ISO 10477	Conforms with ISO 4049	Conforms with ISO 4049	Substantially Equivalent

7 Non-Clinical Performance Testing

As part of demonstrating substantial equivalence of edelweiss CAD/CAM BLOCKs and Ceramir CAD/CAM BLOCKs to the predicate device, edelweiss dentistry products gmbh submitted final finished devices for extensive testing in accordance with recognized consensus standards and voluntary standards, as well as to the company's own internal test protocols.
Testing evaluated flexural strength, flexural modulus, compressive strength and biocompatibility of the subject device, as well as other related physical properties. The subject device passed all required testing.

8 Substantial Equivalence Summary / Conclusion

Based on available 510(k) information provided herein our edelweiss CAD/CAM BLOCKs and Ceramir CAD/CAM BLOCKs have the same intended use, indications for use and are fabricated into permanent tooth restorations using the same CAD/CAM manufacturing methods as the predicate device BRILLIANT Crios. In addition to that our edelweiss CAD/CAM BLOCKs and Ceramir CAD/CAM BLOCKs have the same clinical, biological and technological characteristics as the predicate device BRILLIANT Crios. Any minor differences in the materials used to make the subject device when compared to the predicate device have been successfully evaluated by edelweiss dentistry products gmbh through extensive performance and biocompatibility testing on their device. such that the information submitted to the FDA demonstrates that the subject device is as safe and effective as the predicate device and does not raise any new questions of safety and effectiveness. edelweiss CAD/CAM BLOCKs and Ceramir CAD/CAM BLOCKs, as designed and manufactured by edelweiss dentistry products gmbh, have been determined to be substantially equivalent to BRILLIANT Crios blocks.