



April 27, 2026

Voco GmbH
% Dave Yungvirt
CEO
Third Party Review Group, LLC
7 Giralda Farms, Suite 120a
Madison, New Jersey 07940

Re: K261357
Trade/Device Name: Grandio disc multicolor
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF
Dated: April 24, 2026
Received: April 24, 2026

Dear Dave Yungvirt:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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,

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

510(k) Number (if known)
K261357

Device Name
Grandio disc multicolor

Indications for Use (Describe)

Intended purpose:

Customised crowns, inlays, onlays, veneers and implant-retained crowns, 3-unit bridges as well as veneers of frameworks of indirect restorations in the anterior and posterior regions.

Indication:

Lack of tooth substance, partial edentulism and complete edentulism.

Fields of application:

Without framework

- Inlays, onlays, veneers
- Crowns, implant-retained crowns
- 3-unit bridges (not Inlay bridges, Cantilever bridges and Maryland bridges)

With supporting framework

- Veneers of supporting frameworks irrespective of the selected manufacturing process.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(k) Summary

510(k) Number: K261357

Submitter: VOCO GmbH, Anton-Flettner-Str. 1-3, 27472
Cuxhaven, Germany

Contact: Dr. T. Gerkensmeier, Regulatory Affairs, Tel: +49 (0) 4721 719 200,
t.gerkensmeier@voco.de

Prepared By: K. Fröhlich, Regulatory Affairs, k.froehlich@voco.de

Date Prepared: 24 April, 2026

Device Identification

Trade Name:	Grandio disc multicolor
Common Name:	Restorative resin material
Classification Name:	Tooth shade resin material
Regulation Number:	872.3690
Product Code:	EBF
Class:	Class II
Classification Panel:	Dental

Legally Marketed Predicate Device:



AMBARINO® High-Class, (K222723); Manufacturer: Creamed GmbH & Co. Produktions- und Handels KG

Device Description: Grandio disc multicolor is a nano-hybrid composite CAD/CAM disc with 86% by weight of inorganic fillers for the manufacture of customised, permanent single-tooth restorations, 3-unit bridges and/or framework-supported prosthetic restorations.

Statement of Intended Use: Customised crowns, inlays, onlays, veneers and implant-retained crowns, 3-unit bridges as well as veneers of frameworks of indirect restorations in the anterior and posterior regions.

Substantial Equivalence: Information provided in this application shows that the product is substantially equivalent to the predicate device. Comparisons of the physical properties of the Grandio disc multicolor to the predicate devices are included in this application.

The table below compares Grandio disc multicolor to the predicate device with respect to its physical state, structure, materials, mechanical properties, indications for use, biocompatibility and performance testing, and provides detailed information regarding the basis for the determination of substantial equivalence.

Elements of Comparison	Subject Device	Predicate Device	Similarities / Differences
Device Name	Grandio disc multicolor	AMBARINO® High-Class	-
Manufacturer	VOCO GmbH	Creamed	-
510(k) #	pending	K222723	-
Product Code	EBF	EBF	Same
Regulation	§872.3690	§872.3690	Same
Class	II	II	Same
Review Panel	Dental	Dental	Same
Device Image			-
Indications for Use	<p><u>Fields of application:</u> <u>Without framework</u> – Inlays, onlays, veneers – Crowns, implant-retained crowns</p> <p>– 3-unit bridges (not Inlaybridges, Cantileverbridges and Marylandbridges)</p> <p><u>With supporting framework</u> – Veneers of supporting frameworks irrespective of the selected manufacturing process.</p>	<p>For fabrication of inlays/ onlays, laminate veneers, anterior and posterior full crown restorations, and implant crowns and bridges by dental professionals and manufacturers using a dental CAD/CAM system.</p>	Similar

Physical State	Cured discs in a variety of shapes and shades	Cured blocks and discs in a variety of shapes and shades	Same
Structure	Polymer resin / ceramic hybrid composite	Polymer resin / ceramic hybrid composite	Same
Methacrylate-based Resin Matrix	14.44% EtoBG, UDMA, BisGMA, TEGDMA	29% UDMA, BDDMA	Similar. The subject and predicate devices contain UDMA in their resin matrix.
Filler Content	86% inorganic silica-based glass and silica	70% inorganic silica-based glass and barium glass	Similar
Sizes	12, 15, 18	14, 40, 98, 100	The size ranges are comparable.
Flexural Strength	315.9 MPa	192.61 MPa	Similar
Modulus of Elasticity	12.95 GPa	6.10 GPa	Similar
Compressive Strength	524.06 MPa	562.91 MPa	Similar
Water absorption (EN ISO 10477)	14.67 [$\mu\text{g}/\text{mm}^3$]	12.64 [$\mu\text{g}/\text{mm}^3$]	Similar
Water solubility (EN ISO 10477)	-0.18 [$\mu\text{g}/\text{mm}^3$]	-2.11 [$\mu\text{g}/\text{mm}^3$]	Same
Packaging	One disc per box.	One disc per box, or for mandrel mounted blocks, six small or two large to a box	Same for disc.
Usage	Single Patient, multiple use	Single Patient, multiple use	Same
Sterility	Non-Sterile	Non-Sterile	Same
Biocompatibility	Conforms with ISO 10993-1	Conforms with ISO 10993-1	Same

Performance	Conforms with ISO 4049	Conforms with ISO 4049	Same
--------------------	------------------------	------------------------	------

Non-Clinical Performance Data: As part of demonstrating substantial equivalence of Grandio disc multicolor to the predicate device, VOCO GmbH submitted final finished devices for extensive testing in accordance with the applicable parts of the following voluntary standards, as well as to the company's own internal test protocols:

- ISO 4049, Dentistry – Polymer-based Restorative Materials
- ISO 7405, Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
- ISO 10993-1, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process

Testing evaluated flexural strength, flexural modulus, compressive strength, water absorption, water solubility and biocompatibility of the subject device, as well as other related physical properties. The subject device exceeded all minimum test standards, and all documented test results were substantially equivalent to the predicate device.

Design Characteristics: The geometry of the Grandio disc multicolor is a disc form as defined by the CAD/CAM manufacturer. The material will be inserted into the CAM machine and milled into its final form, then polished and ready for placement thereafter. This design is substantially equivalent to the predicate device.

Biocompatibility: Biocompatibility tests were conducted on Grandio disc multicolor with regard to cytotoxicity, irritation, sensitization, and genotoxicity. All tests were inconclusive.

Conclusion: Grandio disc multicolor has the same or similar intended use, indications for use, physical attributes, and are fabricated into permanent tooth restorations using the same CAD/CAM manufacturing methods as AMBARINO® High-Class. Different sizes are available for the submitted device. All performance data of the two devices are similar, and both exceed the minimum requirements. Any minor differences in the materials used to make the subject device when compared to the predicate device have been successfully evaluated by the manufacturer 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.

Grandio disc multicolor, as designed and manufactured by VOCO GmbH, have been determined to be substantially equivalent to AMBARINO® High-Class.