December 12, 2024

Bredent GmbH & Co. KG
Christine Pakebusch
Regulatory Affairs Manager
Weissenhorner Str. 2
Senden, 89250
GERMANY

Re: K240735
Trade/Device Name: visio.lign color, visio.lign shield
Regulation Number: 21 CFR 872.3310
Regulation Name: Coating Material For Resin Fillings
Regulatory Class: Class II
Product Code: EBD, EBI, ELM
Dated: November 15, 2024
Received: November 15, 2024

Dear Christine Pakebusch:

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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Respiratory, ENT, and Dental Devices
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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)*

K240735

Device Name

visio.lign color,
visio.lign shield

Indications for Use *(Describe)*

visio.lign color: Characterization with colour effects on the surface of composite restorations, denture base materials and artificial denture teeth.
visio.lign shield: Surface coating and wear resistance of composite restorations, denture base materials and artificial denture teeth.

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.

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510(k) #: K240735

510(k) Summary

Prepared on: 2024-11-15

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	bredent GmbH & Co. KG
Applicant Address	Weissenhorner Str. 2 Senden 89250 Germany
Applicant Contact Telephone	+49 7309 872-53
Applicant Contact	Christine Pakebusch
Applicant Contact Email	christine.pakebusch@bredent.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	visio.lign color ; visio.lign shield
Common Name	Coating material for resin fillings
Classification Name	Coating, Filling Material, Resin
Regulation Number	872.3310
Product Code(s)	EBD

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K133836	Optiglaze Color	EBD

Device Description Summary

21 CFR 807.92(a)(4)

Description
visio.lign shield & color is a light-curing, transparent or coloured, acrylate-based glossy coating.
visio.lign color achieves colour effects on the surface of composite restorations, denture base materials and artificial denture teeth.
visio.lign color is available in 17 shades.
visio.lign shield provides a surface coating on composite restorations, denture base materials and artificial denture teeth. visio.lign shield is available in the thin-bodied version visio.lign shield LV and in the higher-viscosity version visio.lign shield HV.
Indication of Use
visio.lign color: Characterization with colour effects on the surface of composite restorations, denture base materials and artificial denture teeth.
visio.lign shield: Surface coating and wear resistance of composite restorations, denture base materials and artificial denture teeth.
User profile:
The product must only be used by doctors, dentists, dental technicians and suitably trained dental staff.
Use environment:
Dental laboratories, dental surgeries, and clinics.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

visio.lign color: Characterization with colour effects on the surface of composite restorations, denture base materials and artificial denture teeth.
visio.lign shield: Surface coating and wear resistance of composite restorations, denture base materials and artificial denture teeth.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Indication for Use
The predicate and the subject device are both intended for the use on restorations.
The predicate and the subject device achieve both characterization via colour effects on restorations.
Both products obtain surface smoothness via their surface coating.
The predicate device can be used for composite restorations, acrylic denture bases and artificial acrylic teeth. This can be compared with the indicated materials for the subject device.

Technological Comparison 21 CFR 807.92(a)(6)

Composition and technological characteristics:
The subject and the predicate device share the same curing mechanism with similar composition.
Biocompatibility:
The biocompatibility assessment for both devices was made in accordance to ISO 10993 1:2009.
Summary:
Based on available 510(k) information provided herein, the products of visio.lign color & shield are considered substantial equivalent to the predicate device in terms of indications for use, material, technology, design and performance specifications.
There are no differences between the devices which would raise new concerns regarding safety or effectiveness.

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

Performance Bench testing:
Substantial equivalence was demonstrated by the following performance tests: Bond strength, Colour stability, Surface roughness and Viscosity.

Not Applicable

The performance of the subject device was tested with the same kind of Bench testings as the predicate device. The design specifications of the subject device were met in the bench testings carried out. This demonstrates that the product fulfills its intended purpose and device description and shows substantial equivalence to the predicate device.