June 27, 2024

Saremco Dental AG
% Nevine Erian
Regulatory Consultant
BQC Consulting, LLC
24341 Barbados Dr.
Dana Point, California 92629-92629

Re: K240823
Trade/Device Name: els extra low shrinkage® composite & els extra low shrinkage® flow
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: March 21, 2024
Received: March 26, 2024

Dear Nevine Erian:

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.

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,

FDA

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., 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

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)*

K240823

Device Name

els extra low shrinkage® composite & els extra low shrinkage® flow

Indications for Use *(Describe)*

els extra low shrinkage® composite & els extra low shrinkage® flow are restorative materials intended for the reconstruction or correction of natural dentition.

els extra low shrinkage® composite is indicated for:
- Restoration of class I, II, III, IV and V cavities on anterior and posterior teeth
- Indirect anterior and posterior restorations including inlays, onlays and veneers
- Aesthetic corrections of interdental spaces, enamel hypoplasia, discolorations
- Splinting

els extra low shrinkage® flow is indicated for:
- Restorations with minimally invasive preparation technique
- Restorations of small cavities and extended fissure sealing
- Alternate restorations for undercut cavities
- Restorations of class III - V including wedged shaped defects and cervical caries
- Repair of fillings, veneers and methacrylate-based temporary restorations
- First layer of fillings for Class I and II
- Interlocking of loosened teeth
- Adhesive attachment of indirect composite and ceramic restorations

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.

K240823 – 510(k) Summary

Submitter	**Saremco Dental AG** Gewerbestrasse 4 CH-9445 Rebstein, Switzerland Establishment Reg. No. 3008582054
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Date Prepared June 24, 2024

Trade/Device Names	els extra low shrinkage® composite els extra low shrinkage® flow
Common Name	Tooth Shade Resin Material
Classification Name & Regulation Number	Tooth Shade Resin Material – 21 CFR 872.3690
Product Code	EBF

Predicate Devices

DENU Composite Resin (HDI, Inc.) – K213339 – **Primary Predicate**

Brilliant EverGlow Flow (Coltene/Whaledent AG) – K190597 – ***Reference Device***

Brilliant Componeer (Coltene/Whaledent AG) – K191385 – ***Reference Device***

Venus Diamond flow (Heraeus Kulzer GmbH) – K091635 – ***Reference Device***

Device Description

els extra low shrinkage® composite is classified as a **Type 1, Class 2, Group 1 & 2** Polymer-based restorative material according to ISO 4049:2009 – Dentistry – Polymer-based restorative materials.

els extra low shrinkage® flow is classified as **Type 2, Class 2, Group 1** Polymer-based restorative material according to ISO 4049:2009 – Dentistry – Polymer-based restorative materials.

Statement of Intended Use

els extra low shrinkage® composite & els extra low shrinkage® flow are light-cured methacrylate-based resins that are intended to be used to fill and restore small to large defects or carious lesions in teeth. The patient population includes individuals with permanent dentition needing restoration.

Statement of Indication for Use

els extra low shrinkage® composite & els extra low shrinkage® flow are restorative materials intended for the reconstruction or correction of natural dentition.

els extra low shrinkage® composite is indicated for:

- Restoration of class I, II, III, IV and V cavities on anterior and posterior teeth
- Indirect anterior and posterior restorations including inlays, onlays and veneers
- Aesthetic corrections of interdental spaces, enamel hypoplasia, discolorations
- Splinting

els extra low shrinkage® flow is indicated for:

- Restorations with minimally invasive preparation technique
- Restorations of small cavities and extended fissure sealing
- Alternate restorations for undercut cavities
- Restorations of class III - V including wedged shaped defects and cervical caries
- Repair of fillings, veneers and methacrylate-based temporary restorations
- First layer of fillings for Class I and II
- Interlocking of loosened teeth
- Adhesive attachment of indirect composite and ceramic restorations

Material Composition

els extra low shrinkage® composite & els extra low shrinkage® flow are composed of methacrylate-based resins, dental glass-filler, photo initiators and pigments.

Technological Characteristics

els extra low shrinkage® composite & els extra low shrinkage® flow are light cured radiopaque microhybrid composites with extremely low shrinkage stress.

Non-Clinical Performance Testing

els extra low shrinkage® composite & els extra low shrinkage® flow were tested and met the applicable requirements of the following ISO standard ISO 4049:2009 – Dentistry – Polymer-based restorative materials

Bench test results allowed us to conclude that els extra low shrinkage® composite & els extra low shrinkage® flow meet their intended uses.

Biocompatibility

els extra low shrinkage® composite & els extra low shrinkage® flow meet the biocompatibility requirements of the following standards:

- ISO 10993-1:2018 – Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 7405:2018 Dentistry – Evaluation of Biocompatibility of Medical Devices Used in Dentistry

Clinical Performance Data

The performance of methacrylate-based polymer resins in the clinical environment has been well established. No human clinical testing was performed to support the substantial equivalence of els extra low shrinkage® composite & els extra low shrinkage® flow.

Substantial Equivalence

The technical characteristics of els extra low shrinkage® composite & els extra low shrinkage® flow are substantially equivalent to the predicate devices.

Material

els extra low shrinkage® composite & els extra low shrinkage® flow are resin-based materials as the predicate devices.

Physical Properties

els extra low shrinkage® composite & els extra low shrinkage® flow have similar physical properties as the predicate devices.

Comparison of saremco els extra low shrinkage® composite (els composite for short) to Predicate Devices

Attribute	els composite	DENU Composite Resin	Brilliant Componeer	Rationale for Difference
Indi-cations	**els extra low shrinkage® composite** is a restorative material intended for the reconstruction or correction of natural dentition. - Restoration of class I, II, III, IV and V cavities on anterior and posterior teeth - Indirect anterior and posterior restorations including inlays, onlays and veneers - Aesthetic corrections of interdental spaces, enamel hypoplasia, discolorations - Splinting	DENU Composite Resin is indicated for use in: - Direct anterior and posterior restorations - Core buildup - Splinting - Indirect anterior and posterior restorations including inlays, onlays and veneers	Clinical indications - Restoration of caries defects - Reconstruction of lost tooth substance due to attrition, abrasion, erosion - Restoration of tooth fractures - Correction of anatomical malformation Cosmetic indications - Optimisation of old composite restorations - Extending incisors - Correction of malpositioned teeth - Cosmetic corrections for tooth discolouration or incorrect shading - Closure of diastema	The verbiage describing the indications for Use of els composite and the predicate, DENU Composite resin, is slightly different. The wording used by the primary predicate (namely: “Direct anterior and posterior restorations”) describes a much broader field in comparison to “Restoration of class I, II, III, IV and V cavities on anterior and posterior teeth“. The indications "Indirect anterior and posterior restorations including inlays, onlays and veneers" and "Splinting" are equal on both sides. The formulations describing the indications for the use of els composite and the predicate "Brilliant Componeer" are different. The wording of the predicate (namely: " - Restoration of caries defects - Reconstruction of lost tooth substance due to attrition, abrasion, erosion - Restoration of tooth fractures - Correction of anatomical malformation") also describes a much broader range compared to the indications of the els composite "Restoration of class I, II, III, IV and V cavities on anterior and posterior teeth", "Indirect anterior and posterior restorations including inlays, onlays and veneers" and "Splinting". The other indications of the predicate device "Brilliant Componeer" in comparison to the proposed els composite hybrid list the esthetic corrections: (Cosmetic indications - Optimization of old composite restorations - Extending incisors - Correction of mal-positioned teeth - Cosmetic corrections for tooth discoloration or incorrect shading - Closure of diastema"), whereby a much broader range of esthetic corrections is also mentioned here in comparison to els composite.

Attribute	els composite	DENU Composite Resin	Brilliant Componeer	Rationale for Difference
Physical Properties				
Physical State	Uncured resin paste	Uncured resin paste	Polymerized prefabricated hybrid composite enamel shell	After light curing, els composite and Denu Composite Resin perform the same as Brilliant Componeer
Material Color	Various shades	Various shades	Various shades	Shade differences do not affect device performance
Packaging	Prefilled syringes & tips	Prefilled syringes	Preformed shells in box	Packaging differences do not impact cured device performance
Compressive Strength	Avg. = 289.8 MPa	187.4 MPa	285 MPa	Though different compressive strength values, in subject and predicate devices, higher strength of els composite does not affect substantial equivalence.
Surface Hardness	Avg. = 76 Vicker's Hardness	43.86 KHN	Unknown	Surface hardness values are not comparable due to lack of available data. Vicker's Hardness is a typical standard for composites.
Performance Testing	ISO 4049	ISO 4049	ISO 4049	-
Flexural Strength	Avg. = 116.3 MPa	135.74 MPa	125.4 MPa	Though different values, subject and predicate devices meet same ISO 4049 performance requirements

Attribute	els composite	DENU Composite Resin	Brilliant Componeer	Rationale for Difference
Water Sorption	Avg. =14.7 µg/mm3	18.48 µg/mm3	18.2 µg/mm3	Though different values, subject and predicate devices meet same ISO 4049 performance requirements
Solubility	Avg. = 0.8 µg/mm3	0.82 µg/mm3	0.3 µg/mm3	Though different values, subject and predicate devices meet same ISO 4049 performance requirements
Depth of Cure	≥ 1.5 mm	≥ 1.5 mm	≥ 1.5 mm	-
Radiopacity	Avg. = 2.8 mm Al	3.2 mm Al	3.2 mm Al	Though different values, subject and predicate devices meet same ISO 4049 performance requirements
Material Comparison				
Chemical Characterization	Methacrylate-based resins, dental glass-filler, photo initiators and pigments.	Methacrylate-based resins, dental glass-filler, photo initiators and pigments.	Methacrylate-based resins, dental glass-filler, photo initiators and pigments.	-
Technical Attributes				
Product Code(s)	EBF	EBF, EBC & EJK	EBF	Subject device has less indications than predicates
Fabrication Method	Light Cured	Light Cured	Light Cured	After light curing, els composite and Denu Composite Resin perform the same as Brilliant Componeer
Curing Wavelength	400 - 500 nm	400 - 500 nm	Unknown	-
Polymerization Method	UV Curing Light	UV Curing Light	UV Curing Light	-
Sterile	No	No	No	-
Rx or OTC	Rx	Rx	Rx	-

Comparison of saremco els extra low shrinkage® flow (els flow for short) to Predicate Devices

Attribute	Els flow	BRILLIANT EverGlow Flow	Venus Diamond flow	Rationale for Differnce
Indi-cation	els extra low shrinkage® flow is a restorative material intended for the reconstruction or correction of natural dentition. els extra low shrinkage® flow is indicated for: Restorations with minimally invasive preparation technique Restorations of small cavities and extended fissure sealing Alternate restorations for undercut cavities Restorations of class III - V including wedged shaped defects and cervical caries Repair of fillings, veneers and methacrylate-based temporary restorations First layer of fillings for Class I and II Interlocking of loosened teeth Adhesive attachment of indirect composite and ceramic restorations	BRILLIANT EverGlow Flow Universal and Translucent shades are suitable for: - Direct class V fillings (cervical caries, root erosion, wedge-shaped defects) - Fillings in the anterior tooth region (Class III and IV) - Small fillings of all cavity classes (not occlusion-bearing) - Blocking out of undercuts - Adhesive luting of indirect composite and ceramic restorations in as far as accuracy of fit and light permeability are given - Repairs of direct and indirect composite restorations - Preventive resin restorations - Cavity lining BRILLIANT EverGlow Flow opaque shade is also suitable for: - Aesthetic corrections (e.g. deviations in chroma) - Masking of dark areas	- Enlarged fissure sealing - Cavity lining - as the first layer for Class I and II cavities - Class V fillings - Minimally invasive Class I and II fillings in areas not subjected to masticatory forces - Minimally invasive Class III fillings - Small repairs of direct and indirect restorations combined with a suitable bonding agent - Interlocking of loosened teeth	The formulations describing the indications for the use of els-Flow and the predicate "Brilliant Everglow flow" are very similar. Only the indication "blocking of loosened teeth" is not mentioned. Although not explicitly mentioned, all indications describe "fillings with minimally invasive preparation technique", which also covers this indication of els flow. The formulations describing the indications for the use of els Flow and the "Venus Diamond flow" predicate are also very similar. However, the indications "Replacement fillings in cavities with undercuts" and "Adhesive cementation of indirect composite or ceramic restorations" are missing here, but these are covered by the "Brilliant Everglow flow" predicate.

Attribute	els flow	BRILLIANT EverGlow Flow	Venus Diamond flow	Rationale for Difference
Physical Properties				
Physical State	Uncured resin paste	Uncured resin paste	Uncured resin paste	-
Material Type	Polymer resin composite	Polymer resin composite	Polymer resin composite	-
Material Color	Various shades	Various shades	Various shades	Shade differences do not affect device performance
Packaging	Prefilled syringes	Prefilled syringes	Prefilled syringes	-
Compressive Strength	Avg. = 225.1 MPa	415 MPa	332 MPa	Though different compressive strength values, in subject and predicate devices, els flow is only used for small cavities, which do not require higher compressive strength
Surface Hardness	Avg. = 55 Vicker's Hardness	Unknown	Unknown	No available data to compare with
Performance Testing	ISO 4049	ISO 4049	ISO 4049	-
Flexural Strength	Avg. = 116.5 MPa	96 MPa	117 MPa	Though different values, subject and predicate devices meet same ISO 4049 performance requirements
Water Sorption	Avg. = 19.0 µg/mm^3	23 µg/mm^3	≤40 µg/mm^3	Though different values, subject and predicate devices meet same ISO 4049 performance requirements
Solubility	Avg. = 1.5 µg/mm^3	2.0 µg/mm^3	≤ 7.5 µg/mm^3	Though different values, subject and predicate devices meet same ISO 4049 performance requirements
Depth of Cure	≥ 1.5 mm	≥ 1.5 mm	≥ 1.5 mm	-
Radiopacity	Avg. = 1.3 mm Al	2.2 mm Al	3.1 mm Al	Though different values, subject and predicate devices meet same ISO 4049 performance requirements

Attribute	els flow	BRILLIANT EverGlow Flow	Venus Diamond flow	Rationale for Difference
Material Comparison				
Chemical Characterization	Methacrylate-based resins, dental glass-filler, photo initiators and pigments.	Methacrylate-based resins, dental glass-filler, photo initiators and pigments.	Methacrylate-based resins, dental glass-filler, photo initiators and pigments.	-
Technical Attributes				
Product Code(s)	EBF	EBF	EBF, EBC & LBH	Subject device has less indications than Venus Diamond flow
Fabrication Method	Light Cured	Light Cured	Light Cured	-
Curing Wavelength	400 - 500 nm	430 - 490 nm	450 - 480 nm	Subject device curing wavelength is comparable to predicates
Polymerization Method	UV Curing Light	UV Curing Light	UV Curing Light	-
Sterile	No	No	No	-
Rx or OTC	Rx	Rx	Rx	-

Differences between els extra low shrinkage® composite & els extra low shrinkage® flow and Predicate Devices

The differences in the physical properties and chemical compositions between els extra low shrinkage® composite & els extra low shrinkage® flow and the predicate devices do not impact the substantial equivalence, as the finished clinical product is a custom-fitted biocompatible restoration regardless of the material variation.

Conclusion

Information provided in this application demonstrates that els extra low shrinkage® composite & els extra low shrinkage® flow are substantially equivalent to the predicate devices. els extra low shrinkage® composite & els extra low shrinkage® flow share the

same indications for use, similar material composition, similar physical properties and technological characteristics as the predicate devices.