December 5, 2025

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

Re: K252151
Trade/Device Name: els unibond
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: November 29, 2025
Received: December 1, 2025

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.

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252151

Please provide the device trade name(s).

els unibond

Please provide your Indications for Use below.

- Direct restorations with light-curing composite-based materials.
- Indirect restorations: at the use of light-curing composite cements to fix inlays, onlays, crowns and bridges.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary - K252151

Submitter	**Saremco Dental AG** Gewerbestrasse 4 CH-9445 Rebstein, Switzerland Establishment Reg. No. 3008582054
Contact	Dr. Christoph Evers Head of R&D **Phone** +41 71 775 80 90 **Fax** +41 71 775 80 99 **E-Mail** christoph.evers@saremco.ch
Official Correspondent	Nevine Erian Regulatory Consultant **BQC Consulting, LLC** 24341 Barbados Dr. Dana Point, CA 92629 **Phone** (949) 370-7155 **E-mail** nevine@bqcconsulting.com
Date Prepared	December 3, 2025

Trade/Device Names	els unibond
Common Name	Dental Adhesive
Classification Name & Regulation Number	Resin Tooth Bonding Agent – 21 CFR 872.3200
Product Code	KLE

Predicate Devices

K-Bond Universal (Spident Co., Ltd.) – K241445 – **Primary Predicate**

Scotchbond Universal (3M ESPE AG) – K110302 – **Secondary Predicate**

Adhese Universal DC (Ivoclar Vivadent, AG) – K210804 – ***Reference Device***

Device Description

els unibond is an extra low shrinkage, light-curing, single component, self-etching adhesive, used to create a permanent marginal-gap-free adhesion between the tooth structure and the light-curing filling/fixing material, e.g. els extra low shrinkage® composite and els extra low shrinkage® flow.

Intended Use

els unibond promotes adhesion of direct or indirect prosthesis for reconstruction or correction of functionally compromised natural dentition (e.g., deficient teeth).

Statement of Indication for Use

- Direct restorations with light-curing composite-based materials.
- Indirect restorations: at the use of light-curing composite cements to fix inlays, onlays, crowns and bridges.

Material Composition

els unibond is composed of monomers, film formers, fillers, solvents, initiators, silanization agents and stabilizers.

Technological Characteristics

els unibond is a light cured extra low shrinkage adhesive.

Non-Clinical Performance Testing

els unibond was tested for shear bond strength.

Bench test results allowed us to conclude that els unibond meets its intended uses.

Biocompatibility

Els unibond was tested for cytotoxicity, irritation and intracutaneous reactivity, and delayed type hypersensitivity. A comprehensive biocompatibility risk assessment was conducted by a licensed toxicologist and concluded that els unibond meets 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 adhesives in the clinical environment has been well established. No human clinical testing was performed to support the substantial equivalence of els unibond.

Substantial Equivalence

The technical characteristics of els unibond are substantially equivalent to the predicate devices.

Material

els unibond is a resin-based adhesive as the predicate devices.

Physical Properties

els unibond has similar physical properties as the predicate devices.

Comparison of els unibond to Predicate Devices

Attribute	**els unibond**	**K-Bond Universal**	**Scotchbond Universal**	**Adhese Universal DC**
Indications				
Direct restorations with light-curing composite-based materials.	Yes	Yes	Yes	Yes
Indirect restorations: at the use of light-curing composite cements to fix inlays, onlays, crowns and bridges.	Yes	Yes	Yes	Yes
Physical Properties				
Packaging	Bottle	Bottle	Bottle	Bottle
Uncured Physical State	Yellow Liquid	Yellow Liquid	Yellow Liquid	Yellow Liquid
Cured Physical State	Colorless Solid	Colorless Solid	Colorless Solid	Colorless Solid
Shear Bond Strength Self-etch enamel [MPa]	15.1	15.9	26.4	25

Attribute	els unibond	K-Bond Universal	Scotchbond Universal	Adhese Universal DC
Shear Bond Strength Self-etch dentin [MPa]	25.6	24.2	35.8	38
Shear Bond Strength Total etch enamel [MPa]	27.8	20.6	32.4	33
Shear Bond Strength Total etch dentin [MPa]	34.2	29.4	31.8	38
Material Comparison				
Chemical Composition	Monomers, fillers, solvents, initiators, silanization agents and stabilizers	Monomers, fillers, solvents, initiators, silanization agents and stabilizers	Monomers, fillers, solvents, initiators, silanization agents and stabilizers	Solvents, (adhesive) monomers, film formers, fillers, initiators, and stabilizers
Technical Attributes				
Product Code(s)	KLE	KLE	KLE	KLE, LBH
One-component dental adhesive	Yes	Yes	Yes	Yes
Fabrication Method	Light Cured	Light Cured	Light Cured	Dual Cured
Sterile	No	No	No	No
Rx or OTC	Rx	Rx	Rx	Rx

Differences between els unibond and Predicate Devices

The differences in the physical properties and chemical compositions between els unibond and the predicate devices do not impact safety and effectiveness, as the finished clinical product is a biocompatible dental adhesive, regardless of the material variation.

Conclusion

Information provided in this application demonstrates that els unibond is substantially equivalent to the predicate devices. els unibond shares the same indications, similar material composition, similar physical properties and technological characteristics as the predicate devices.