September 17, 2024

Kulzer, LLC
Lucas Harmon
Regulatory & Quality Engineer
4315 S Lafayette Blvd
South Bend, Indiana 46614

Re: K240660
Trade/Device Name: Signum composite flow; Signum universal bond; Signum metal bond ; Signum composite; Signum matrix; Signum liquid; Signum cre-active
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: February 9, 2024
Received: March 8, 2024

Dear Lucas Harmon:

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,

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)*

K240660

Device Name

Signum composite flow;
Signum universal bond;
Signum metal bond ;
Signum composite;
Signum matrix;
Signum liquid;
Signum cre-active

Indications for Use *(Describe)*

Signum metal bond:
- Bonding agent between framework surfaces made of metal alloys (precious metal, non-precious metal or titanium) and (meth-) acrylate-based veneering materials in conjunction with micromechanical retention.
- Bonding agent between partial framework surfaces made of metal alloys (precious metal, non-precious metal or titanium) and (meth-) acrylate-based veneering materials or denture base materials (hot or auto-polymerizates).
- Bonding agent for extraoral repair of metal supported composite veneers.

Signum universal bond:
Metal
- Bonding agent between framework surfaces made of metal alloys (precious metal, non-precious metal or titanium) and (meth-) acrylate-based veneering materials in conjunction with macro-mechanical retentions.
- Bonding agent between partial framework surfaces made of metal alloys (precious metal, non-precious metal or titanium) and (meth-) acrylate-based veneering materials or denture base materials (hot or auto-polymerizates).
- Bonding agent for the extraoral repair of metal-supported composite veneers.

Zirconium dioxide
- Bonding agent between frameworks, implant abutments and single crowns made of ZrO_2 and light-curing veneering materials.
- Bonding agent for the extraoral repair of composite veneers on ZrO_2 frameworks.

High performance polymers (PEEK)
- Bonding agent between frameworks, implant abutments and individual crowns made of high performance polymers and light-curing veneering materials.
- Bonding agent between partial framework surfaces made of high-performance polymers and light-curing veneering materials or denture base materials (hot or auto-polymerizate).
- Bonding agent for the extraoral repair of composite veneers on PEEK frameworks.

Signum liquid:
For light-curing veneering materials from Kulzer:
- Restoring the dispersion layer of light curing veneering materials.

Signum composite / Signum composite flow / Signum matrix:
Suitable for veneering the following dental framework materials:
Metal alloys (precious metal, non-precious or titanium), zirconia, high-performance polymers (PEEK)

Suitable for partial alteration of the colour and shape of the following dental materials:
• PMMA
• Photopolymers

Suitable for the following prosthetic restorations:
• full and partial veneers for permanent framework-supported crowns and bridges
• veneering removable combination prosthetics (telescopic and tapered crowns and at-tachment prosthetics)
• veneering of superstructures/tertiary structures on implants
• metal-free front tooth and posterior tooth temporary restorations
• alteration of the colour and shape of Kulzer acrylic denture teeth
• alteration of the colour and shape of acrylic-based frameworks (PMMA).
• alteration of the colour and shape of Kulzer photopolymers that are approved for char-acterisation with Signum components (according to the photopolymer instructions for use)

Signum cre-active:
Individual characterization (e.g., of enamel cracks, white spots, imitation fillings, enamel wedges, intermediate colour layers, abrasion surfaces, fissures) of
• light-curing Kulzer veneering materials,
• Kulzer denture acrylic teeth and PMMA,
• (meth-)acrylate-based 3D printing photopolymers in accordance with the photopolymer instructions for use

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.

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510(k) #: K240660

510(k) Summary

Prepared on: 2024-09-16

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Kulzer, LLC
Applicant Address	4315 S Lafayette Blvd South Bend IN 46614 United States
Applicant Contact Telephone	(574) 299-5444
Applicant Contact	Mr. Lucas Harmon
Applicant Contact Email	Lucas.Harmon@kulzer-dental.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Signum composite flow; Signum universal bond; Signum metal bond ; Signum composite; Signum matrix; Signum liquid; Signum cre-active
Common Name	Tooth shade resin material
Classification Name	Material, Tooth Shade, Resin
Regulation Number	872.3690
Product Code(s)	EBF

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K961434	VITA ZETA CROWN AND BRIDGE ACRYLIC VENEERING SYS	EBF
K152373	VITA VM LC Flow	EBF
K211854	VITA Akzent LC	EBD

Device Description Summary

21 CFR 807.92(a)(4)

Signum Bondings (Signum metal bond, Signum universal bond) are intended for dental works in the laboratory as an adhesion promoter between a given framework made of zirconium dioxide, dental alloys, high performance composites, PMMA, and a second material (e.g. composites or acrylics). These primers are only applied in the laboratory. After completion of the restorative work, Signum bondings are encapsulated between framework and the restoration/veneering material and a direct contact to the patient is very unlikely.
Signum metal bond is a liquid stored in a 5 mL bottle with dropper and red cap.
Signum universal bond is a liquid stored in a 5 mL bottle with dropper and blue cap.

Signum liquid is indicated for light-curing veneering materials from Kulzer to simplify modeling procedures and restore the dispersion layer of light-curing veneering materials.
Signum liquid is foreseen for dental works in the laboratory, where an adhesion promoter between a given composite layer and a second acrylate based material, including necessary modeling procedures is necessary. After completion of the restorative work, Signum

liquid is encapsulated between both layers and a direct contact to the patient is very unlikely.
Signum liquid is a liquid stored a 5 mL bottle with a spout and red cap.

Signum composite, Signum composite flow, and Signum matrix are veneering composites for crowns and bridges. The veneering composites are processed by dental technicians for dental restoration by veneering framework supported restorations (for example metal or zirconia frameworks).
After light activated polymerization the restoration is inserted into the oral cavity of a specific patient as a custom made device, adapted and connected to the remaining residual teeth or functionally adapted.
The veneering composites are pastes stored in a syringe featuring a plunger and a closing cap.

Signum cre-active are a light-curing color fluids for crown and bridge techniques and prosthetics.
Signum cre-active is used in the dental laboratory to create customized characterizations of dental prosthetic works, that are then inserted into the oral cavity of a specific patient as individualized medical devices, adapted, and connected to the remaining residual teeth or functionally adapted to the edentulous alveolar ridge. Since, cured Signum cre-active layers must be covered with veneering material, there is no direct patient contact.
Signum cre-active are liquids stored in a syringe featuring a plunger and a closing cap.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Signum metal bond:
- Bonding agent between framework surfaces made of metal alloys (precious metal, non-precious metal or titanium) and (meth-) acrylate-based veneering materials in conjunction with micromechanical retention.
- Bonding agent between partial framework surfaces made of metal alloys (precious metal, non-precious metal or titanium) and (meth-) acrylate-based veneering materials or denture base materials (hot or auto-polymerizates).
- Bonding agent for extraoral repair of metal supported composite veneers.

Signum universal bond:
Metal
- Bonding agent between framework surfaces made of metal alloys (precious metal, non-precious metal or titanium) and (meth-) acrylate-based veneering materials in conjunction with macro-mechanical retentions.
- Bonding agent between partial framework surfaces made of metal alloys (precious metal, non-precious metal or titanium) and (meth-) acrylate-based veneering materials or denture base materials (hot or auto-polymerizates).
- Bonding agent for the extraoral repair of metal-supported composite veneers.

Zirconium dioxide
- Bonding agent between frameworks, implant abutments and single crowns made of ZrO_2 and light-curing veneering materials.
- Bonding agent for the extraoral repair of composite veneers on ZrO_2 frameworks.

High performance polymers (PEEK)
- Bonding agent between frameworks, implant abutments and individual crowns made of high performance polymers and light-curing veneering materials.
- Bonding agent between partial framework surfaces made of high-performance polymers and light-curing veneering materials or denture base materials (hot or auto-polymerizate).
- Bonding agent for the extraoral repair of composite veneers on PEEK frameworks.

Signum liquid:
For light-curing veneering materials from Kulzer:
- Restoring the dispersion layer of light curing veneering materials.

Signum composite / Signum composite flow / Signum matrix:
Suitable for veneering the following dental framework materials:
Metal alloys (precious metal, non-precious or titanium), zirconia, high-performance polymers (PEEK)

Suitable for partial alteration of the colour and shape of the following dental materials:
• PMMA
• Photopolymers

Suitable for the following prosthetic restorations:
• full and partial veneers for permanent framework-supported crowns and bridges
• veneering removable combination prosthetics (telescopic and tapered crowns and at-tachment prosthetics)

• veneering of superstructures/tertiary structures on implants
• metal-free front tooth and posterior tooth temporary restorations
• alteration of the colour and shape of Kulzer acrylic denture teeth
• alteration of the colour and shape of acrylic-based frameworks (PMMA).
• alteration of the colour and shape of Kulzer photopolymers that are approved for char-acterisation with Signum components (according to the photopolymer instructions for use)

Signum cre-active:
Individual characterization (e.g., of enamel cracks, white spots, imitation fillings, enamel wedges, intermediate colour layers, abrasion surfaces, fissures) of
• light-curing Kulzer veneering materials,
• Kulzer denture acrylic teeth and PMMA,
• (meth-)acrylate-based 3D printing photopolymers in accordance with the photopolymer instructions for use

Indications for Use Comparison

21 CFR 807.92(a)(5)

Signum Metal Bond/Signum Universal Bond:
In comparison to VITA VM LC Primer (K961434), Signum Metal Bond/Signum Universal Bond have the same indications for use in which the device may act as a bonding agent between metal surfaces (non-precious metal, titanium), (meth-)acrylate-based materials, ZrO2 surfaces, and high-performance polymers (PEEK). While the verbiage and the scope of indications for use slightly differs between the products, they are equally indicated to act as an adhesive bonding agent for various framework surfaces.

Signum Liquid:
In comparison to VITA VM LC Modelling Liquid (K961434), Signum Liquid has the same indications for use in which the device may act in the layering process of dental materials. While the verbiage and the scope of indications for use slightly differs between the products, they are equally indicated to act in the layering process.

Signum Composite:
In comparison to VITA VM LC (K961434), Signum Composite has the same indications for use in which the device may be used for full and partial frameworks, including crowns, bridges, telescopic crowns, and implant suprastructures. While the verbiage and the scope of indications for use slightly differs between the products, they are equally indicated for the veneering of frameworks.

Signum Composite Flow/Signum Matrix:
In comparison to VITA VM LC Flow (K961434 & K152373), Signum Composite Flow/Signum Matrix has the same indications for use in which the device may be used for full and partial frameworks, including crowns, bridges, telescopic crowns, and implant suprastructures. While the verbiage and the scope of indications for use slightly differs between the products, they are equally indicated for the veneering of frameworks.

Signum Cre-active:
In comparison to VITA Akzent LC (K961434 & K211854), Signum Cre-active has the same indications for use in which the device may be used for the characterization/restoration of veneering materials, and acrylic teeth, 3D-print polymers. While the verbiage and scope of indications for use slightly differs between the products, they are equally indicated for the characterization/restoration of the listed materials.

Technological Comparison

21 CFR 807.92(a)(6)

Signum Metal Bond/Signum Universal Bond:
Signum Metal Bond/Signum Universal Bond and the predicate device, VITA VM LC Primer (K961434), are composed of two parts (I and II). Signum Metal Bond I/Signum Universal Bond I and VITA VM LC PRIMER I are added to a mixing dish applied with a disposable brush to serve as a primer. Signum Metal Bond II/Signum Universal Bond II and VITA VM LC PRIMER II are then applied with a disposable brush and followed with an opaque material for color coverage. The design, principle of operation, etc. are very similar between Signum Metal Bond/Signum Universal Bond and the predicate device VITA VM LC Primer with minor difference in technological characteristics.

Signum Liquid:
Signum Liquid and the predicate device, VITA VM LC Modelling Liquid (K961434), are both utilized in the layering process and are applied to the veneering material surface sparingly. The design, principle of operation, etc. are very similar between Signum Liquid and the predicate device VITA VM LC Modelling Liquid with minor difference in technological characteristics.

Signum Composite:
Signum Composite and the predicate device, VITA VM LC (K961434), are both utilized after the preparation of the framework. Both products are also utilized with the necessary other system products during the veneering of frameworks. The design, principle of

operation, etc. are very similar between Signum Composite and the predicate device VITA VM LC with minor difference in technological characteristics.

Signum Composite Flow/Signum Matrix:
Signum Composite Flow/Signum Matrix and the predicate device, VITA VM LC Flow (K961434 & K152373), are packaged in a syringe with a plunger to extrude product. They are all applied in layers and polymerized.
The design, principle of operation, etc. are very similar between Signum Composite/Signum Matrix and the predicate device VITA VM LC Flow with minor difference in technological characteristics.

Signum Cre-active:
Signum Cre-active and the predicate device, VITA Akzent LC (K961434 & K211854), are both fluids utilized after the proper preparation of the surface. Both products are applied in layers and then polymerized. The design, principle of operation, etc. are very similar between Signum Cre-active and the predicate device VITA Akzent LC with minor difference in technological characteristics.

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

For Signum composite, Signum composite flow and Signum matrix mechanical testing was performed in regard to depth of cure, flexural strength and bond strength.

For Singum liquid, Signum metal bond and Signum universal bond mechanical testing was performed in regard to shear bond strength with precious metal non-precious metal, zirconium and PEEK (high performance polymers).

For Signum cre-active mechanical testing was performed in regard to viscosity and curing depth.

Thermal testing was preformed in the shelf-life report, utilizing testing methods at differing temperatures.

The clinical evaluation for Signum composite, Signum composite flow and Signum matrix is based on internal data and scientific literature currently available about veneering composites and comparable medical devices. Signum composite is marketed since 1999, Signum composite flow since 2011 and Signum matrix since 1999. The benefit-risk-ratio for the use of Signum veneering composites c&b in the intended purpose is positive.
The application of veneering composites c&b is state-of-the-art both technologically and concerning the medical application.
Specific questions of this clinical evaluation were answered, therefor a clinical investigation with veneering composites c&b is not necessary and the route for this clinical evaluation is literature based.

The clinical evaluation for Signum metal bond, Signum universal bond and Signum liquid (summed up by the term "Signum bondings") is based on currently available scientific literature. Clinical studies with Signum metal bond as well as with similar medical devices were identified and PMS data were considered as well. Signum metal bond is marketed since 2007, Signum universal bond since 2022 and Signum liquid since 1983 (for Dentacolor / Artglass liquid).
Specific questions of this clinical evaluation were answered with adquate and suitable data from the literature. Therefor a clinical investigation with Signum bondings is not necessary and the route for this clinical evaluation is literature based.
The benefit-risk-ratio of Signum bondings is positive.

The clinical evaluation for Signum cre-active is based on currently available scientific literature.
Signum cre-active is marketed since 1991 (formerly Dentacolour cre-active).
Specific questions of this clinical evaluation were answered with adequate and suitable data from literature search and internal documentation. Color-Fluids can be considered as well established technology. The adequate safety and performance of the evaluated devices was proven within this clinical evaluation with data from product surveillance and from scientific literature.
The benefit risk ratio for Signum cre-active is positive.