September 7, 2023

Kulzer, LLC
David Vincent
Director, QA/RA
4315 S. Lafayette Blvd
South Bend, Indiana 46614

Re: K230644
Trade/Device Name: Signum opaque F
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: August 4, 2023
Received: August 4, 2023

Dear David Vincent:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, M.ChE.
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
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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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230644

Device Name

Signum opaque F

Indications for Use *(Describe)*

Light curing one-component opaquer to mask framework structures. Signum opaque F is the opaquer component for veneering materials and denture base materials (heat/cold curing denture acrylics) offered by Kulzer.

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) #: K230644

510(k) Summary

Prepared on: 2023-02-24

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) 299-5421
Applicant Contact	Mr. David Vincent
Applicant Contact Email	David.Vincent@kulzer-dental.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Signum opaque F
Common Name	Tooth shade resin material
Classification Name	Material, Tooth Shade, Resin
Regulation Number	872.3690
Product Code	EBF

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K152373	VITA VM LC FLOW	EBF

Device Description Summary

21 CFR 807.92(a)(4)

Signum opaque F is a light-curing, one component opaquer used for extraoral color-masking of framework structures for crowns, bridges, and/or partial dentures. The veneering composites are processed by dental technicians for dental restoration by veneering framework-supported restorations, such as metal or zirconia frameworks.

Signum opaque F is a paste stored in a syringe featuring a plunger and a closing cap. The product is dispensed and mixed and is then applied with a disposable brush until the scaffolding frame is completely covered. After polymerization, the crown or bridge is inserted into the oral cavity, adapted and connected to the remaining residual teeth or functionally adapted.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Light curing one-component opaquer to mask framework structures. Signum opaque F is the opaquer component for veneering materials and denture base materials (heat/cold curing denture acrylics) offered by Kulzer.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Our submission device, Signum opaque F and the predicate device, VITA VM LC Flow (K152373) have the same indications for use. They both are used in conjunction with bonding systems and provide a layer of resin type material to act as an opaquer. The opaquer is to mask framework structures. They both have the indication for extraoral use with veneering materials and denture base materials. VITA VM LC Flow (K152373) also has indications for individualization of acrylic teeth, long term temporaries, and reproduction of gingival areas. While the verbiage of the indications for use differs and the scope of the indications for use differs between the products, they are both indicated for extraoral use and have the indication to act as an opaque layer to mask the underlying metal frameworks.

Our indication for use for Signum opaque F is listed as one of the indications listed for the predicate device, VITA VM LC Flow (K152373). They are both used as an opaquer for color-masking of framework structures.

Technological Comparison

21 CFR 807.92(a)(6)

Signum opaque F and the predicate device, VITA VM LC Flow (K152373) are dispensed in a paste form. Signum opaque F's primary packaging is a 3ml syringe with plunger and closing cap. A dispensing tip is used for dispensing of the product. Signum opaque F is placed on the mixing block and stirred thoroughly. The opaque is applied with a suitable, disposable brush in several, uniform, semi-overlapping layers until the scaffolding frame is completely covered. Each layer must be polymerized individually. Vita VM LC Flow is also packaged in a syringe with a plunger to extrude product. After product is extruded, Vita VM LC recommends using a metal spatula to adjust thixotropically (their consistency can be changed – from firmer to softer – by slightly pressing onto them with an instrument). VITA VM LC Flow is then applied in layers and polymerized.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Mechanical testing was performed in regard to testing shear bond strength. This testing was performed on various metal frameworks (i.e. non-precious metal, precious metal, zirconium dioxide, PEEK (high performance polymers)).

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

All nonclinical testing was performed with conformity to applicable standards.

This clinical evaluation is based on internal data and scientific literature currently available about veneering composites and comparable medical devices. Veneering composites of Kulzer are marketed since 1994 for the same intended purpose without any hint for negative benefit-risk ratio. The final individualized medical devices, prepared in a conventional process, is well-established in the dental field. Therefore, clinical investigation with veneering composites c&b is not necessary and the route for this clinical evaluation is literature based.

In regard to the conforming standards of both Signum opaque F and the predicate device VITA VM LC Flow, the same standards are referenced. Therefore, it can be determined that the testing methods and results of both devices are in alignment and substantial equivalence can be concluded.