July 3, 2019

S&C Polymer Silicon- und Composite Spezialitaeten GmbH
Christian Boettcher
Offical Correspondent to FDA, Reg. Compliance Officer
Robert-Bosch-Str. 2
Elmshorn, 25335 GERMANY

Re: K182780
Trade/Device Name: XP Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: April 4, 2019
Received: April 8, 2019

Dear Christian Boettcher:

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,

Srinivas Nandkumar, Ph.D.
Acting Assistant Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182780

Device Name

XP Composite

Indications for Use *(Describe)*

- Restoration of deciduous teeth
- Posterior restorations (class I and II)
- Anterior restorations (class III and IV)
- Class V restorations
- Veneering of discoloured anterior teeth
- Splinting of mobile teeth
- Extended fissure sealing in molars and premolars
- Repair of composite and ceramic veneers

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) Summary

K182780

Submitter

Name of Company:	S&C Polymer Silicon- und Composite Spezialitaeten GmbH
Address:	Robert-Bosch-Strasse 2, D-25335 Elmshorn (Germany)
Phone:	0049 4121 483 0
Fax:	0049 4121 483 184
Contact Person:	Dr. Christian Boettcher
Date of Preparation:	01. April 2019

Device Name:

Trade Name:	XP Composite
Common Name:	Dental restorative material
Classification Name:	Material, Tooth Shade, Resin, per 21CFR § 872.3690
Classification:	II
Product Code:	EBF

Devices for which Substantial Equivalence is Claimed:

Tetric EvoCeram (Ivoclar Vivadent), K042819

Device Description:

“XP Composite” is a light cure composite.

Intended Use of the Devices:

“XP Composite” as well as “Tetric EvoCeram” (Ivoclar Vivadent) are light cure resin based dental restorative materials.

Indication for Use of the Devices:

The indications for use of “XP Composite” as well as “Tetric EvoCeram” (Ivoclar Vivadent) are identical and are as follows:

	Subject Device XP Composite	Predicate Device Tetric EvoCeram
Restoration of deciduous teeth	yes	yes
Posterior restorations (class I and II)	yes	yes
Anterior restorations (class III, IV)	yes	yes
Class V restorations	yes	yes
Veneering of discoloured anterior teeth	yes	yes
Splinting of mobile teeth	yes	yes
Extended fissure sealing in molars and premolars	yes	yes
Repair of composite and ceramic veneers	yes	yes

Performance Data:

Non-clinical performance data for this device included the following: compressive strength, working time, consistency and radiopacity.
Testing also included water sorption, water solubility, flexural strength and depth of cure were all tested according to ISO 4049.

Technological Characteristics:

	Subject device XP Composite	Predicate device Tetric EvoCeram
Appearance	paste	paste
Form of delivery	black syringe application tips	black syringe application tips
Method of polymerization	light cure	light cure
Application	extrusion via pressure (onto the back of the syringe resp. onto the back of the tip) followed by application	extrusion via pressure (onto the back of the syringe resp. onto the back of the tip) followed by application
Ingredients (general description)	methacrylate-based resins photo initiators fillers pigments	methacrylate-based resins photo initiators fillers pigments
Mechanism of Action	application light curing	application light curing

Conclusion:

In regard to the intended use, the indication for use, the target population, the anatomical sites, the design, the performance, the standards to be met, the materials, and the biocompatibility the product of this submission is substantially equivalent to the predicate device.