March 6, 2023

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

Re: K222445
Trade/Device Name: LC ChromeFlow
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBC
Dated: February 1, 2023
Received: February 6, 2023

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,

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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222445

Device Name

LC ChromeFlow

Indications for Use *(Describe)*

- Small restorations
- Extended fissure sealings
- Restorations of class III, IV and V
- Lining of cavities

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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S&C Polymer GmbH | Robert-Bosch-Str. 2 | D-25335 Elmshorn

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Center for Devices and Radiological Health
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file: 003_510(k) Summary_LC ChromeFlow.doc

Elmshorn, March 01st 2023

510(k) Summary - LC ChromeFlow - K222445

Dear Ladies & Gentleman,

attached you will find the 510(k) summary for the product LC ChromeFlow.

Sincerely yours,

S & C Polymer
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Dr. Christian Boettcher
Reg. Compliance Officer
Official Correspondent to FDA

510(k) Summary

1. Submitter

Name of company:	S&C Polymer Silicon- und Composite Spezialitaeten GmbH
Address:	Robert-Bosch-Str. 2, 25335 Elmshorn, Germany
Phone:	0049 4121 483 0
Fax:	0049 4121 483 184
Contact person:	Dr. Christian Boettcher
Date prepared:	March 01st 2023

2. Device name

Trade name:	LC ChromeFlow
Common name:	Tooth Shade Resin Material
Device classification name:	Material, Tooth Shade, Resin
Regulatory number:	872.3690
Product code:	EBF

3. Predicate device

Predicate device I:	LC GlossFill XR (S&C)
510(k) Number:	K182778 (introduced into the US-Market 2019)
Predicate device II:	Tetric EvoFlow (Ivoclar Vivadent)
510(K) Number:	K993783 (introduced into the US-Market 1999)
Referenced device:	LC Microhybrid (S&C Polymer)
510(k) Number:	K984484 (introduced into the US-Market 1999)

4. Device description

LC ChromeFlow is a light cure flowable radiopaque composite. LC ChromeFlow can be used for a lot of natural tooth shades due to its continuous color matching properties.

5. Intended use / Indications for use of the device

LC ChromeFlow is a flowable light cure resin based dental restorative material which is indicated to be used for small restorations; extended fissure sealings; restorations of class III, IV and V and lining of cavities. The indications for use of the subject device LC ChromeFlow is covered by the indications for use of the predicate devices LC Glossfill XR (S&C) and/or Tetric EvoFlow (Ivoclar Vivadent).

The patient population is intended for all ages that need a restoration as prescribed by a dentist.

6. Device comparison with the predicate device

The predicate devices has been found to be substantially equivalent under the 510(k) premarket notification as class II dental device under CFR 872.3690 product code EBF.

	Subject device LC ChromeFlow	**Predicate device LC Glossfill XR (S&C)**	**Predicate device Tetric EvoFlow (Ivoclar Vivadent)**
Intended use	Flowable light cure resin based dental restorative material	Light cure resin based dental restorative material	Light-curing flowable resin based dental restorative material
Mechanism of action	light cure	light cure	light cure
Form of delivery	-syringe -application tips	-syringe -application tips	-syringe -preloaded tips (named Cavifil)
Prescription use	yes	yes	yes
Appearance	paste	paste	paste
Indications for use	equal	equal	equal
Ingredients (general description)	-methacylate-based resins -photo initiators -fillers -pigments	-methacylate-based resins -photo initiators -fillers -pigments	-methacylate-based resins -photo initiators -fillers -pigments
Physical properties	according to ISO 4049	according to ISO 4049	according to ISO 4049

7. Conclusion

The comparison worked out above and the further elaboration of information within this 510(k) submission demonstrate that the subject device LC ChromeFlow is substantially equivalent to the predicate devices LC GlossFill XR (S&C) and Tetric EvoFlow (Ivoclar Vivadent) in terms of description, intended use, indications for use, chemical composition and physical properties. The information given above do not raise different questions of safety and effectiveness. The devices are as safe and effective as the predicate devices.