November 20, 2020

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

Re: K202413
Trade/Device Name: LC ResinCal PC
Regulation Number: 21 CFR 872.3250
Regulation Name: Calcium Hydroxide Cavity Liner
Regulatory Class: Class II
Product Code: EJK
Dated: August 11, 2020
Received: August 24, 2020

Dear Christian Bottcher:

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,

for Srinivas “Nandu” Nandkumar, Ph. D.
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)*

K202413

Device Name

LC ResinCal PC

Indications for Use *(Describe)*

1. Pulp capping agent

2. Liner

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.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. Submitter

Name of company:	S&C Polymer Silicon- und Composite Spezialitäten GmbH
Address:	Robert-Bosch-Str. 2, 25335 Elmshorn, Germany
Phone:	0049 4121 483 0
Fax:	0049 4121 483 184
Contact person:	Dr. Christian Böttcher
Date prepared:	20. November 2020

2. Device name

Trade name:	LC ResinCal PC
Common name:	Liner and pulp capping material
Device classification name: (Regulation description)	Calcium hydroxide cavity liner
Regulatory number:	872.3250
Product code:	EJK
510(k) number:	K202413

3. Device description

Resin modified light cure pulp capping material / liner (indications from labeling).

4. Intended use of the devices

LC ResinCal PC is a light cure resin reinforced pulp capping material with MTA-fillers, designed to perform as a barrier and to protect the pulp. Its physical properties and uses are similar to the predicate device.

5. Indication for use of the devices

- Pulp capping agent
- Liner

Detailed information on the indication of the subject device LC ResinCal PC can be found in the device description of this 510(k) submission.

6. Device for which substantial equivalence is claimed

Primary predicate device:	TheraCal LC (Bisco)
510(k) number:	K063237 (introduced into the US-Market 2006)

7. Device comparison with the predicate device

The primary predicate device TheraCal LC (Bisco) has been found to be substantially equivalent under the 510(k) premarket notification as class II dental device under CFR 872.3250 Code EJK.

	Subject device LC ResinCal PC	Primary predicate device TheraCal LC (Bisco)
Description	Resin modified light cure pulp capping material / liner	Resin-Modified Calcium Silicate Pulp Protectant/Liner
Intended use	Light cure resin reinforced pulp capping material with MTA-fillers, designed to perform as a barrier and to protect the pulp.	Light-cured resin-modified calcium silicate pulp protectant/liner designed to perform as a barrier and to protect the dental pulpal complex.
Mechanism of action	Light curing	Light curing
Indications	- Pulp capping agent - Liner	- Pulp capping agent - Liner
Ingredients (general description)	- Portland cement - Photo intiators - Resins (e.g. BIS-GMA*)	- Portland cement - Photo intiators - Resins (e.g. BIS-GMA*)
Form of delivery	black syringe	black syringe

* BIS-GMA (Bisphenol A-glycidyl methacrylate)

8. Similarities and differences
8.1. Similarities

LC ResinCal PC and the primary predicate device TheraCal LC (Bisco) have a similar description and intended use as a light cure resin reinforced pulp capping material with MTA-fillers, designed to perform as a barrier and to protect the pulp. The mechanism of action and the indications (as pulp capping agent and liner) are also the same. The general chemical composition, the working properties (intensity, wavelength and curing time) and the physical properties (working time, depth of cure, barcol hardness and calcium release) are very similar, as described in the device description and in the substantial equivalence discussion of this 510(k) submission.

8.2 Differences

The detailed chemical composition of the subject device LC ResinCal PC, as described in the device description of this 510(k) submission differs from the chemical composition of the primary predicate device TheraCal LC (Bisco).

Discussion of the differences

The additional ingredients of the subject device LC ResinCal PC are typical ingredients for dental materials. A research on the FDA medical device premarket notification (510(k)) database shows, that all ingredients have been used in the other products which are already 510(k) registered and are therefore allowed to be marketed in the United States.

9. Conclusion

The comparison worked out above and the further elaboration of information within this 510(k) submission demonstrate that the subject device LC ResinCal PC is substantially equivalent to the primary predicate device TheraCal LC (Bisco) in terms of description, intended use, indications for use, chemical composition.