April 14, 2015

S & C Polymer Silicon- und Composite Spezialitäten GmbH  
Dr. Christian Boettcher  
Official Correspondent / Director Regulatory Affairs  
Robert-Bosch-Strasse 2  
Elmshorn, Schleswig-Holstein 25335  
GERMANY

Re: K141047  
Trade/Device Name: LC Calcium Hydroxide Liner  
Regulation Number: 21 CFR 872.3250  
Regulation Name: Calcium Hydroxide Cavity Liner  
Regulatory Class: II  
Product Code: EJK  
Dated: March 5, 2015  
Received: March 9, 2015

Dear Dr. 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.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K141047

Device Name
LC Calcium Hydroxide Liner

Indications for Use (Describe)
Application to dentin as a protective barrier between restorative materials and deep vital dentin (indirect pulp capping)
Lining of cavities for following filling procedures

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY
Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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."
The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:
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510(k) Summary

**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: April 6th 2015

**Device Name:**

<table>
<thead>
<tr>
<th>Trade name</th>
<th>LC Calcium Hydroxide Liner</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Name</td>
<td>Calcium Hydroxide Liner</td>
</tr>
<tr>
<td>Classification Name</td>
<td>Liner, Cavity, Calcium Hydroxide, per 21CFR § 872.3250</td>
</tr>
<tr>
<td>Classification</td>
<td>II</td>
</tr>
<tr>
<td>Product Code</td>
<td>EJK</td>
</tr>
</tbody>
</table>

**Devices for which Substantial Equivalence is Claimed:**
Calcimol LC, VOCO GmbH, K 924182

**Device description:**

LC Calcium Hydroxide Liner is a radiopaque one component visible light curing liner containing calcium hydroxide. It is intended for indirect pulp capping and for lining of cavities where filling procedures will follow and can be applied in thin layers followed by light curing of the material. The chemical components include fillers, resins, an alkalining agent, as well an initiator.

**Intended Use of the Devices:**

LC Calcium Hydroxide Liner is intended for:

- Application to dentin as a protective barrier between restorative materials and deep vital dentin (indirect pulp capping)
- Lining of cavities for following filling procedures
**Performance Data:**
Non-clinical performance data for this device included the following:
Working time, the barcol hardness and the pH-value.
Testing also included water sorption, water solubility, and flexural strength, and depth of cure were all tested according to ISO 4049.

**Technological Characteristics:**

<table>
<thead>
<tr>
<th></th>
<th>Subject device</th>
<th>Predicate device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>white paste</td>
<td>white paste</td>
</tr>
<tr>
<td>Form of delivery</td>
<td>black syringe</td>
<td>black syringe</td>
</tr>
<tr>
<td>Method of polymerization</td>
<td>light cure</td>
<td>light cure</td>
</tr>
<tr>
<td>Application</td>
<td>extrusion via pressure</td>
<td>extrusion via pressure</td>
</tr>
<tr>
<td></td>
<td>onto the back of the syringe</td>
<td>onto the back of the syringe</td>
</tr>
<tr>
<td></td>
<td>followed by application</td>
<td>followed by application</td>
</tr>
<tr>
<td></td>
<td>through needles</td>
<td>through needles</td>
</tr>
<tr>
<td>Ingredients (general description)</td>
<td>fillers</td>
<td>fillers</td>
</tr>
<tr>
<td></td>
<td>resins</td>
<td>resins</td>
</tr>
<tr>
<td></td>
<td>alkalining agent</td>
<td>alkalining agent</td>
</tr>
<tr>
<td></td>
<td>initiators</td>
<td>initiators</td>
</tr>
<tr>
<td>Mechanism of Action</td>
<td>application</td>
<td>application</td>
</tr>
<tr>
<td></td>
<td>light curing</td>
<td>light curing</td>
</tr>
</tbody>
</table>

The subject device shares both similarities and differences to the noted predicate. The subject device has the same chemical composition as the predicate device; however, the subject device has been reformulated using different quantities of the chemical components. Performance testing was done to validate the change in the chemical composition and the subject device was found to perform as well as the predicate.

In regards 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.