K081702

11. Summary of Safety and Effectiveness

SEP - 5 2008

Submitter

Name of company: S&C Polymer Silicon- und Composite Spezialitaeten GmbH
Address: Robert-Bosch-Strasse 5, D-25335 Elmshorn (Germany)
Phone: 0049 4121 483 0
Fax: 0049 4121 483 184
Contact Person: Dr. Christian Boettcher

Date of preparation: June 2008

Device Name:

Trade name: Zinc Oxide Cem
Common Name: Zinc Oxide Cement (consisting of Carboxylate Cem and Phosphate Cem)
Classification Name: Cement Dental, per 21CFR § 872.3275

Devices for which Substantial Equivalence is Claimed:

Carboxylate Cem: Carbocem Zinc Polycarboxylate Cement, Scientific Pharmaceuticlas Inc., K993324
Phosphate Cem: ZinFos Zinc Phosphate Cement, Scientific Pharmaceuticlas Inc., K982913

Device description:

Zinc Oxide Cem consist of two different cements:
Carboxylate Cem consists of a polyacrylic/water containing liquid and a zinc oxide/magnesiumoxide containing powder.
Phosphate Cem consists of a phosphoric acid/water containing liquid and a zinc oxide/magnesiumoxide containing powder.

Intended Use of the Device:

Carboxylate Cem: Cementation of crowns and bridges on non-vital teeth where retention is of primary concern. Also for use as a temporary filling material.
Phosphate Cem: For permanent cementation of crowns and bridges on non-vital teeth where the use of conventional Zinc phosphate cements is judged appropriate.

Substantial Equivalence:

Zinc Oxide Cem is substantially equivalent to other legally marketed devices in the United States. The Cements marketed by S&C Polymer Silicon- und Compositen Spezialitaeten GmbH function in a manner similar to and is intended for the sam use as the products marketed by Scientific Pharmaceuticals Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Dr. Christian Boettcher
Regulatory Compliance Officer
S & C Polymer Silicon-Und Composite Spezialitaeten GmbH
Robert-Bosch-Strasse 5
Elmshorn, Schleswig-Holstein 25335
GERMANY

Re: K081702
Trade/Device Name: Carboxylate Cem, Phosphate Cem
Regulation Number: 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: June 12, 2008
Received: June 17, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081702

9. Statement of Indication for Use

510(k) Number (if known): -

Device Name: Zinc Oxide Cem

Indications for Use:

Carboxylate Cem:

For temporary or permanent cementation of crowns and bridges on non-vital teeth where retention is of primary concern. Also for use as a temporary filling material.

Phosphate Cem:
For permanent cementation of crowns and bridges on non-vital teeth where the use of conventional Zinc phosphate cements is judged appropriate.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081702

Prescription Use: or Over-The-Counter Use