K991462

10. 510(k) Summary or Statement

SUMMARY

Gentleman:

This submission is pursuent to paragraph 510(k) of the Federal Drug and Cosmetic Act of May, 1976 (as amended) (Title 21 USC). All informations contained herein are to be considered and treated as CONFIDENTIAL COMMERCIAL INFORMATION.

It is the intention of S & C Polymer GmbH to manufacture the LC MICROFILL cited above which can be used as a tooth filling material.

S & C Polymer spezializes in manufacturing, distributing and marketing numerous dental materials and related items worldwide.

It is S & C Polymer GmbH`s intention to manufacture the cited product herein at its facility located at Robert-Bosch-Straße 5, D-25335 Elmshorn (formerly Offenauer Weg 19, D-25335 Bokholt-Hanredder), Germany, employing Good Manufacturing Practices (GMP`s) pursuant and according to Title 21 CFR. S & C Polymer GmbH is certified to DIN EN ISO 9001 / DIN EN 46001 and Medical Device Directive 93/42/EEC, annex II.

LC MICROFILL may be offered and marketed in the United States by DISCUS Inc. and/or Pharmex, in which case S & C Polymer will maintain control and govern the production and primary packaging. The claims, labels, instructions and indications consistent with this submission and final FDA 510(k) clearance to market will be controlled by DISCUS Inc. or Pharmex.

The cited LC MICROFILL S & C Polymer GmbH manufactures for DISCUS Inc. and/or Pharmex is commonly used in current dental materials.

The purpose of this material for use by the dentist is to clinically fill human teeth (restauration in the case of mostly destroyed tooth structure). The material is in general placed against an applied adhesive system.

The chemical composition and use of the LC MICROFILL material is the same as the material of RE-NAMEL of COSMEDENT, INC., 5419 N. Sheridan Road, Chicago, IL 60640, USA. S & C Polymer GmbH`s intended use, performance, indications, proposed labels and instructions for use (see attached) are substantially similar to the above predicted device.

Respectfully submitted

Jürgen Engelbrecht, Ph. D.
Regulatory Compliance Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 1999

Jurgen Engelbrecht, Ph.D.
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S & C Polymer GmbH
Silicon- und Composite Spezialitaten GmbH
Robert-Bosch-Str.5
D - 25335
ELMSHORN

Re: K991442
Trade Name: LC MICROFILL
Regulatory Class: II
Product Code: EBF
Dated: March 1, 1999
Received: April 26, 1999

Dear Dr. Engelbrecht:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K991442

9. Statement of Indications for Use

510(k) Number (if known): K991442

Device Name: LC MICROFILL

Indications for Use:

LC MICROFILL is a light cure microfill composite for tooth fillings (see enclosed Instruction for Use, MSDS).

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number _____

Prescription Use: ✓ or Over-The-Counter Use: