K974105

JAN - 9 1998

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7425 - Phone
(714) 516-7488 - Facsimile
Wendy A. Urtel - Contact Person

Date Summary Prepared: October 1997

Device Name:

- Trade Name - Kerr Compomer
- Common Name - Light-Curable Dental Restorative Material
- Classification Name - Tooth Shade Resin Material, 21 CFR § 872.3690

Devices for Which Substantial Equivalence is Claimed:

- *Dyract*, Dentsply
- *Compoglass*, Vivadent

Device Description:

The device is a single-component light-curable dental restorative material that contains a fluoride releasing agent used for the restoration of all class cavities. Kerr Compomer is available in Vita® shading in a Unidose delivery system.

Intended Use of the Device:

The intended use of Kerr Compomer is to be a light-curable dental restorative material containing a fluoride releasing agent that is used in dentistry as a filling material for all class cavities.

Substantial Equivalence:

The dental restorative material is substantially equivalent to several other legally marketed devices in the United States. The dental restorative materials marketed by Dentsply and Vivadent function in a manner similar to and is intended for the same use as the product manufactured by Kerr\Dental Materials Center.

®Vita is a registered trademark of Vita Zahnfabrik.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Wendy A. Urtel
Regulatory Affairs Specialist
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92667

JAN - 9 1998

Re: K974105
Trade Name: Kerr Compomer
Regulatory Class: II
Product Code: EBF
Dated: October 29, 1997
Received: October 31, 1997

Dear Ms. Urtel:

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4618. 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

510(k) Number (if known): K974105

Device Name: Kerr Compomer

Indications For Use:

Kerr Compomer is a light-curable dental restorative material containing a fluoride releasing agent intended to be used in dentistry as a filling material for all class cavities.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974105

Prescription Use Yes (Per 21 CFR 801.109) OR Over-The-Counter Use No

(Optional Format 1-2-96)