JUL 31 1998

K982148

**SYBRON**
**DENTAL SPECIALTIES, INC.**

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

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
(714) 516-7488 - Facsimile
Colleen Boswell - Contact Person

Date Summary Prepared: June 1998

Device Name:

- Trade Name - Prodigy 2
- Common Name - Dental Composite Restorative Material
- Classification Name - Tooth Shade Resin Material, per 21 CFR § 872.3690

Devices for Which Substantial Equivalence is Claimed:

- Heraeus Kulzer, Inc., *Solitaire®*
- Jeneric/Pentron Inc., *Alert*
- Dentsply/Caulk, a division of Dentsply International Inc., *SureFil™*

Device Description:

The device is a visible light cured dental composite restorative material. Due to the material's unique handling characteristics, Prodigy 2 is suggested for use in Class I and Class II cavity situations. However, Prodigy 2 may also be used in all classes of cavities, wherever an additional resistance to pack is deemed necessary.

Intended Use of the Device:

The intended use of Prodigy 2 is for use in Class I and Class II cavities. It may also be used in all classes of cavities wherever an additional resistance to pack is deemed necessary.

Substantial Equivalence:

Prodigy 2 is substantially equivalent to several other legally marketed devices in the United States. The dental composite restoratives marketed by Heraeus Kulzer, Inc., Jeneric/Pentron Inc. and Dentsply/Caulk, a division of Dentsply International Inc., function in a manner similar to and are intended for the same use as the product manufactured by Kerr Dental Materials Center.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 1998

Ms. Colleen Boswell
Manager, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 W. Collins Avenue
Orange, California 92867

Re: K982148
Trade Name: Prodigy 2
Regulatory Class: II
Product Code: EBF
Dated: June 17, 1998
Received: June 18, 1998

Dear Ms. Boswell:

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,

S. Nutman for

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

Enclosure

K982148

Section I - Indications for Use

510(k) Number: K982148

Device Name: Prodigy 2

Indications for Use:

Prodigy 2 is a dental composite restorative material intended to be used in Class I and Class II cavities. It may also be used in all classes of cavities wherever an additional resistance to pack is deemed necessary.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K982148