NOV 18 1998

K983370

SYBRON DENTAL SPECIALTIES

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
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Colleen Boswell - Contact Person

Date Summary Prepared: September 1998

Device Name:

- Trade Name - Prodigy - 3
- Common Name - Light-Curable Dental Restorative Material
- Classification Name - Tooth Shade Resin Material, per 21 CFR § 872.3690

Devices for Which Substantial Equivalence is Claimed:

- Kerr Corporation, *Revolution*

Device Description:

The device is a light cured, hybrid resin dental restorative which incorporates BIS-GMA chemistry along with a proprietary glass filler (approximately 55%) to yield a flowable non-slumping restorative material. Prodigy - 3's combination of flowability and direct application system simplifies material placement and minimizes finishing to result in a consistently superior restoration.

Intended Use of the Device:

The intended use of Prodigy - 3 is for the restoration of Class III, Class IV, and Class V cavities, repair of enamel defects, repair of porcelain restorations, minor occlusal build-ups in non-stress bearing areas, sealing pits and fissures, cementing ceramic/composite veneers, incisal abrasions, and core build-ups.

Substantial Equivalence:

Prodigy - 3 is substantially equivalent to other legally marketed devices in the United States. The composite restorative material marketed by Kerr Corporation functions in a manner similar to and is 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

NOV 18 1998

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

Re: K983370
Trade Name: Prodigy - 3
Regulatory Class: II
Product Code: EBF
Dated: September 23, 1998
Received: September 24, 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,

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

Enclosure

Section I - Indications for Use

510(k) Number: K983370

Device Name: Prodigy - 3

Indications for Use:

Prodigy- 3 is a flowable, light cure hybrid resin restorative designed to be used as a filling material for Class III, Class IV, and Class V restorations. Additional functions include: repair of enamel defects, repair of porcelain restorations, minor occlusal build-ups in non-stress bearing areas, pit and fissure sealant, cement for ceramic/composite veneers, incisal abrasions, and core build-ups.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983370

Prescription Use ✓
(Per 21 CFR 801.109)