3/8/99

SYBRON DENTAL SPECIALTIES

K990498

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: February 1999

Device Name:

- Trade Name - OptiBond Solo Plus
- Common Name - Bonding Agent
- Classification Name - Resin Tooth Bonding Agent, per 21 CFR § 872.3200

Devices for Which Substantial Equivalence is Claimed:

- Dentsply International, *Prime & Bond 2.1*

Device Description:

The device is a multi-purpose bonding agent designed to be used in direct situations including composite to enamel and/or dentin, composite repair, porcelain repair, composite to metal, amalgam bonding and bonding composite core build-up materials. Additionally, because the device contains a dual cure catalyst, OptiBond Solo Plus can be used for indirect situations as well including veneers, onlays, inlays, crowns, Maryland bridges and post cementation.

Intended Use of the Device:

The intended use of OptiBond Solo Plus is for bonding in direct situations, i.e., composite to enamel and/or dentin, composite repair, porcelain repair, composite to metal, amalgam bonding, bonding composite core build-up materials, and indirect situations, i.e., veneers, onlays, inlays, crowns, Maryland bridges, post cementation.

Substantial Equivalence:

OptiBond Solo Plus is substantially equivalent to other legally marketed devices in the United States. The bonding agent marketed by Dentsply International 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

MAR - 8 1999

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

Re: K990498
Trade Name: Optibond Solo Plus
Regulatory Class: II
Product Code: KLE
Dated: February 16, 1999
Received: February 17, 1999

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

K990498

Section I - Indications for Use

510(k) Number: K990498

Device Name: OptiBond Solo Plus

Indications for Use:

OptiBond Solo Plus is a multi-purpose bonding agent designed to be used in direct situations, i.e., composite to enamel and/or dentin, composite repair, porcelain repair, composite to metal, amalgam bonding, bonding composite core build-up materials, and indirect situations, i.e., veneers, onlays, inlays, crowns, Maryland bridges, post cementation.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K990498