K100347

APR 30 2010

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

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
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Wendy Garman - Contact Person

Date Summary Prepared: April 2010

Device Name:

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

Devices for Which Substantial Equivalence is Claimed:

- Kerr Corporation, *OptiBond All-In-One*

Device Description:

OptiBond SE is a two-component self-etch universal adhesive system including a self-etch PRIMER and a universal ADHESIVE. The self-etch primer provides effective etching to uncut enamel and dentin, without the need for a separate phosphoric acid etch, thus simplifying the bonding procedure. The adhesive component is 15% filled with 0.4 micron barium glass to help reinforce bond strength. The material's chemistry allows for compatibility with all self-cure or dual-cure resin cements and core build-up materials. Dentists can therefore utilize *OptiBond SE* for their direct and indirect procedures without the need for a secondary bonding system.

Intended Use of the Device:

- *OptiBond SE* is a two-component self-etch universal adhesive system designed to be used for all direct and indirect applications including, but not limited to, the following:

Direct Applications

- Light-cured composite and compomer restorations
- Composite/ceramic/metal repairs
- Cavity sealing for amalgam restorations
- Sealing of hypersensitive and/or exposed root surfaces
- Core build-ups (self-cured, light-cured or dual-cured)

Indirect applications

- Veneers
- Porcelain, composite, and metal-based (including zirconia-based and alumina-based) inlays, onlays, crowns, bridges
- Endodontic posts
- Cavity sealing as a pretreatment for indirect restorations

Substantial Equivalence:

OptiBond SE is substantially equivalent to one other legally marketed device in the United States. *OptiBond SE* functions in a manner similar to and is intended for the same use as *OptiBond All-In-One* that is currently marketed by Kerr Corporation. A biocompatibility study was completed, which demonstrates that the material is safe for its intended use.

This 510(k) submission also includes data from bench testing used to evaluate the performance characteristics of *OptiBond SE* compared to the predicate device, *OptiBond All-In-One*. The characteristics evaluated include direct and indirect bonding strength to various materials readily found in the dental industry including, but not limited to dentin, enamel, composite, porcelain, gold and PFM.

Based upon the biocompatibility test and bench testing, the clinical performance of *Optibond SE* is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Kerr Corporation
Ms. Wendy Garman
Director, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

APR 30 2010

Re: K100347
Trade/Device Name: OptiBond SE
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: February 8, 2010
Received: February 12, 2010

Dear Ms. Garman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner

For Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100347

Indications for Use

510(k) Number (if known):

Device Name: *OptiBond SE*

Indications For Use:

OptiBond SE is a two-component self-etch universal adhesive system designed to be used for all direct and indirect applications including, but not limited to, the following:

Direct Applications

- Light-cured composite and compomer restorations
- Composite/ceramic/metal repairs
- Cavity sealing for amalgam restorations
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- Endodontic posts
- Cavity sealing as a pretreatment for indirect restorations

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ken Mulley for MSO

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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