K073209

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

JAN 29 2008

Date Summary Prepared: November 2007

Device Name:

- Trade Name – Maxcem 2
- Common Name – Dental Cement
- Classification Name – Cement, Dental, per 21 CFR § 872.3275(b)

Devices for Which Substantial Equivalence is Claimed:

- Maxcem, *Kerr Corporation*
- Nexus 3, *Kerr Corporation*
- Optibond Solo Plus 3, *Kerr Corporation*

Device Description:

Maxcem 2 is a self-etch, self-adhesive resin cement offered in a paste/paste formulation indicated for indirect cementation of ceramic, resin and metal restorations including veneers. This product contains 69% filler by weight and is radiopaque. The dual-cure material is packaged in dual barrel syringes with single-use automix tips and optional curved dispensing tips to allow the user to deliver the desired volume of cement directly into the restoration or tooth prep.

Intended Use of the Device:

The intended use of Maxcem 2 is for cementation of all indirect restorations including ceramic, resin and metal-based inlays, onlays, crowns, bridges, posts, and veneers. Additional indications include core-buildup material, pit and fissure sealant, and cementation of crown restoration to implants. **Note**: Adhesive application on the prep is required for veneer cementation using Maxcem 2.

Substantial Equivalence:

Maxcem 2 is substantially equivalent to other legally marketed devices in the United States. *Maxcem 2* functions in a manner similar to *Maxcem, Optibond Solo Plus 3* and *Nexus 3*, all currently marketed by Kerr Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 2008

Ms. Colleen Boswell
Vice President, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K073209
Trade/Device Name: Maxcem 2
Regulation Number: 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: MZW, EMA
Dated: November 9, 2007
Received: November 14, 2007

Dear Ms. Boswell:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: *Maxcem 2*

Indications For Use:

Maxcem 2 is intended for cementation of all indirect restorations including ceramic, resin and metal-based inlays, onlays, crowns, bridges, posts, and veneers. Additional indications include core-buildup material, pit and fissure sealant, and cementation of crown restorations to implants.*

** Adhesive application on the prep is required for veneer cementation using Maxcem 2.*

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)

Susan Runner

K073209