K003658

JAN - 4 2001

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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Colleen Boswell - Contact Person

Date Summary Prepared: November 2000

Device Name:

- Trade Name – Temp-Bond NE 2
- Common Name – Temporary Dental Cement
- Classification Name – Dental Cement Other Than Zinc-Oxide Eugenol, per 21 CFR § 872.3275 (b)

Devices for Which Substantial Equivalence is Claimed:

- Kerr Corporation, *Temp-Bond NE*

Device Description:

The device is a non-eugenol temporary cement that is used for the cementation of temporary restorations. Temp-Bond NE 2 is a two-part, base/catalyst – paste/paste system. The product will not inhibit the set of permanent resin cements or soften acrylic temporary restorations. Temp-Bond NE 2 is indicated for patients who are allergic to eugenol.

Intended Use of the Device:

The intended use of Temp-Bond NE 2 is for the cementation of temporary restorations.

Substantial Equivalence:

Temp-Bond NE 2 is substantially equivalent to other legally marketed devices in the United States. The modified formulation of Temp-Bond NE functions in a manner identical to and is intended for the same use as the original Temp-Bond NE formula currently manufactured by Kerr Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 2001

Ms. Colleen Boswell
Director of Corporate Compliance
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K003658
Trade Name: Temp-Bond NE 2
Regulatory Class: II
Product Code: EMA
Dated: November 22, 2000
Received: November 28, 2000

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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" (21CFR 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/dsma/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: K003658

Device Name: Temp-Bond NE 2

Indications for Use:

Temp-Bond NE is a non-eugenol temporary cement used for the cementation of temporary restorations.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003658