



Food and Drug Administration  
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September 10, 2015

Sybron Dental Specialties  
Ms. Courtney Clark  
Regulatory Affairs Manager  
1717 W. Collins Avenue  
Orange, CA 92867

Re: K151526  
Trade/Device Name: Zone, Zone A1, Zonefree  
Regulation Number: 21 CFR 872.3275  
Regulation Name: Dental Cement  
Regulatory Class: II  
Product Code: EMA  
Dated: August 12, 2015  
Received: August 13, 2015

Dear Ms. Clark:

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

 Tina Kiang  
-S

for Erin I. Keith, M.S.  
Director  
Division of Anesthesiology,  
General Hospital, Respiratory, Infection  
Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151526

Device Name

Zone/Zone A1 and ZoneFree

Indications for Use (Describe)

Zone/Zone A1 and ZoneFree are Zinc Oxide Non-Eugenol temporary cements used for the cementation of temporary restorations .

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**SECTION 5. 510(k) SUMMARY**  
**for**  
**Zone/Zone A1 and ZoneFree Temporary Dental Cement**

1. Submitter Information:

Sybron Dental Specialties  
 1717 W. Collins Ave.  
 Orange CA, 92687

Contact Person: Courtney Clark  
 Telephone Number: 714-516-7426  
 Fax Number: 714-516-7472

Date Prepared: June 5, 2015

2. Device Name:

- Proprietary Name: Zone, Zone A1 and ZoneFree
- Classification Name: Cement, Dental
- CFR Number: 872.3275
- Device Class: 2
- Product Code: EMA

3. Predicate Device:

Zone, Zone A1 and ZoneFree are substantially equivalent to the legally marketed device Temp-Bond NE 2 Temporary Zinc Oxide Non-Eugenol Cement (K003658) cleared on January 4, 2001, product code EMA.

4. Description of Device:

Zone, Zone A1 and ZoneFree are Zinc Oxide Non-Eugenol temporary cements. They are self-cure materials that set by a reaction between Zinc Oxide present in the catalyst paste and Dimer Acid present in the base paste. The proposed temporary cements are to be placed in the mouth for up to 30 days. Zone comes in three options – the standard Zone cement, Zone A1 shade cement, and ZoneFree a translucent variant. The design of ZoneFree is based on Zone, but uses only small particle size Zinc Oxide to achieve both translucency and color-blending properties. Zone and Zone A1 are designed to set one minute slower than ZoneFree. The delivery systems include an automix syringe, 15 ml syringe, and a unit dose. Zone and Zone A1 are also available in a tube delivery.

Accessories Used with Zone	Manufacturer of Accessory
Automix tips	Sulzer Mixpac AG Ruetistrasse 7 Haag Sankt gallen, Switzerland 9469

5. Indications for Use:  
 Zone/Zone A1 and ZoneFree are Zinc Oxide Non-Eugenol temporary cements used for the cementation of temporary restorations.

6. Description of Substantial Equivalence:  
Technological Characteristics

The designs of Zone, Zone A1 and ZoneFree are similar to the predicate Temp-Bond NE 2 (K003658), as they are all Zinc Oxide Non-Eugenol temporary cements based on reaction between Zinc Oxide and Dimer Acid. They are all considered Type I, class 2B cements compliant to ISO 3107 Dentistry -- Zinc oxide/eugenol cements and zinc oxide/non-eugenol cements. Although the chemical compositions of the subject and predicate devices are not identical, they have been determined to be substantially equivalent in terms of mechanical performance and biocompatibility.

Non-Clinical Performance Data

Non-clinical performance data included testing for Work time, Set time, Film thickness, Arsenic Content and Compressive Strength, as well as Biocompatibility and Stability testing. The following standards were utilized for the non-clinical performance testing:

- Guidance for Industry and FDA Staff: Dental Cements -Premarket Notification [510(k)] Submissions, August 18, 1998
- ISO 10993-1: 2009 Biological evaluation of medical devices
- ISO 10993-5:2009 Biological Evaluation of Medical Devices- Part 5: Tests for in Vitro Cytotoxicity
- ISO 3107:2011 Dentistry -- Zinc oxide/eugenol cements and zinc oxide/non-eugenol cements

**Table 5.1: Predicate and Proposed Device Comparison Table**

<b>Element</b>	<b>Predicate Temp-Bond NE 2</b>	<b>Proposed Zone/Zone A1/ZoneFree</b>
510(k)	K003658	To be assigned
Trade Name	Temp-Bond NE 2	Zone/Zone A1/ZoneFree Temporary Cement
Target Users	Licensed dental professionals	Licensed dental professionals
Device Description	Temp-Bond NE is a non-eugenol temporary cement used for the cementation of temporary restorations.	Zone/Zone A1 and ZoneFree are Zinc Oxide Non-Eugenol temporary cements used for the cementation of temporary restorations.
Common Name	Dental Zinc Oxide Non-eugenol Cements	Dental Zinc Oxide Non-eugenol Cements
Classification Name	Cement, Dental	Cement, Dental
Class	2	2
Product Code	EMA	EMA
Storage	Ambient Temperature	Ambient Temperature
Curing Mechanism	Reaction of Zinc Oxide and Dimer	Reaction of Zinc Oxide and

<b>Element</b>	<b>Predicate Temp-Bond NE 2</b>	<b>Proposed Zone/Zone A1/ZoneFree</b>
	Acid	Dimer Acid
Material Compatibility	Biocompatibility meets requirements	Biocompatibility meets requirements
Shelf Life	24 months based on real time data	24 months based on real time data
Work time	Minimum of 90 seconds	Minimum of 90 seconds
Set time per ISO 3107	Pass	Pass
Film thickness per ISO 3107	Pass	Pass
Arsenic content per ISO 3107	Pass	Pass
Compressive strength per ISO 3107	Pass	Pass
Configurations/Dimensions	Automix syringe, tubes, unit dose	Automix syringe, 15 ml syringe, tubes, unit dose

Clinical Performance Data

Clinical performance testing has not been performed for Zone/Zone A1 or ZoneFree.

Conclusion as to Substantial Equivalence

The technological characteristics of Zone/Zone A1 and ZoneFree are very similar to the predicate, TempBond NE 2 (K003658), and the intended use is the same. Based on the results of internal stability, performance based on ISO 3701, and biocompatibility testing, Zone/Zone A1 and ZoneFree are substantially equivalent to the predicate, TempBond NE 2 (K003658).