DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

3M ESPE Dental Products
c/o Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

February 6, 2017

Re: K170330
Trade/Device Name: 3M™ Protemp™ Cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: January 31, 2017
Received: February 2, 2017

Dear Mark Job:

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,

Susan Runner DDS, MA

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
3M™ Protemp™ Cement Temporary Dental Cement

Indications for Use *(Describe)*
- Temporary cementation of provisional restorations
- Temporary cementation of final 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

3. 510(k) Summary

3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144-1000

510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Submitter…… 3M ESPE Dental Products
2510 Conway Avenue
St. Paul, MN 55144-1000 USA

Contact person……..…. Idalia M. Stark, MS
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Submission Date: January 31, 2017
Trade Name: 3M™ Protemp™ Cement Temporary Dental Cement
Classification Name: Dental Cement
Regulation Number: 21 CFR 872.3275
Product Code: EMA
Classification Panel: Dental
Device Classification: Class II

Predicate Device:
Temp-Bond™ NE (K003658)
Reference Device:
RelyX™ Luting Plus Automix Resin Modified Glass Ionomer Cement (K111185)

Description of Device:

3M™ Protemp™ Cement Temporary Dental Cement is a radiopaque, temporary cement used for temporary or provisional fixation of dental restorations. It is a self-curing cement, with an option for tack light curing of any excess cement for ease of clean up. As a non-eugenol cement, Protemp™ Cement Temporary Dental Cement is suitable for use on patients with sensitivity to eugenol.

Protemp™ Cement Temporary Dental Cement consists of a base and catalyst paste packaged in a proprietary automix delivery dispenser with a self-sealing cap. The automix delivery dispenser offers convenience over traditional hand mixed cements. Compared to leading automix systems, the proprietary delivery dispenser is designed to generate less waste and also has a lower extrusion force for ease of use.

It is available in two shades, Opaque and Translucent.

Intended Use/Indications for Use Comparison:

	Protemp™ Cement Temporary Dental Cement	**Temp-Bond™ NE K003658**
Intended Use	Temporary Dental Cement	Temporary Dental Cement
Indications for Use	• Temporary cementation of provisional restorations. • Temporary cementation of final restorations.	• Temporary cement used for the cementation of temporary restorations.[1] • Temp-Bond is a temporary cement for trial cementing restorations or cementing temporary crowns and bridges.[2]

[1] Indications from FDA 510(k) clearance letter enclosure.
[2] Indications from Kerr website: https://www.kerrdental.com/kerr-restoratives/temp-bond-temporary-dental-cement

Technological Properties Comparison:

PROPERTIES	Protemp™ Cement Temporary Dental Cement	Temp-Bond™ NE K003658
Formulation	Non-eugenol Methacrylate and water based resin	Non-eugenol Zinc oxide
Intended Use	Temporary dental cement	Temporary dental cement
Recommended Cure mode	Self-curing with option for tack light curing of excess cement	Self-curing
Inorganic Fillers	Yes	Yes
Releases Fluoride	Yes*	No
Radiopaque	Yes	Yes
Manufacturer Recommended Working Time (minutes:seconds)	1:30	≥ 1:30
Manufacturer Recommended Setting Time (minutes:seconds)	5:00 after seating in the mouth	≤ 7:00 after mixing
Available shades	Opaque/Translucent	Universal
Dispensing System	Automix/Multi-dose	• Automix/Multi-dose • Unidose® • Tube-Tube/Multi-dose
Storage conditions	2°-27° C/ 35°-80° F	Ambient temperature

*- Fluoride release profile supplied in 510(k) per FDA Guidance *Dental Cements – Premarket Notification (August 18, 1998)*

Performance Testing:

Bench testing consistent with the clinical application and intended use was used to evaluate the performance of Protemp™ Cement Temporary Dental Cement compared to the predicate device Temp-Bond™ NE (K003658). Properties evaluated include: working and setting times, bonding strength, optimum film thickness, compressive strength, extrusion force, radiopacity, dimensional change and fluoride release profile.

Based on the testing results, 3M ESPE Dental Products concludes that Protemp™ Cement Temporary Dental Cement is substantially equivalent to the predicate device Temp-Bond™ NE.

Animal and Clinical Testing

No animal or clinical testing was submitted in this 510(k).

Biocompatibility Testing

3M's biocompatibility assessment, developed for this new product using standard risk assessment techniques of ISO14971:2007 and consideration of FDA & internationally recognized guidelines including:

- ISO 10993-1;2009
- ISO 10993-3:2014
- ISO 10993-5:2009
- ISO 10993-6:2007
- ISO 10993-10:2010
- ISO 10993-11:2006
- ISO 10993-12:2012
- ISO 7405:2008/Amd 1 2013

The assessment concluded that the product is biocompatible for its intended use.

Conclusion

Protemp™ Cement Temporary Dental Cement is substantially equivalent to the predicate device Temp-Bond™ NE in terms of intended use, indications for use, dispensing system, technological characteristics, and physical and mechanical properties. The information presented in this 510(k) submission demonstrate that

Protemp™ Cement Temporary Dental Cement is as safe, as effective and is demonstrated to be substantially equivalent to the predicate device.

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