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

Dmg Usa, Inc.
% Pam Papineau
Consultant, President
Delphi Medical Device Consulting, Inc.
5 Whitcomb Ave
Ayer, Massachusetts 01432

September 30, 2016

Re: K160443
Trade/Device Name: Tempocem Clear
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: August 30, 2016
Received: September 2, 2016

Dear Pam Papineau:

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, PhD
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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
TempoCem Clear

Indications for Use *(Describe)*
TempoCem Clear is indicated for:
• Temporary or semipermanent luting of temporary and permanent crowns, bridges, inlays and onlays.
• Temporary luting of temporary veneers
• Temporary or semipermanent luting of implant-borne dental prosthesis.

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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Section 5 – 510(k) Summary

1. Submitter Information

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Date prepared: 27 September 2016

2. Device Name

Name of device: TempoCem Clear
Common name: Temporary dental cement
Regulation number:21 CFR 872.3275(b)
Classification name: Dental Cement
Regulatory device class: II
Product code: EMA

3. Predicate Device

Primary predicate: Telio CS Link Systemp.link (K042846).
Reference predicate: Telio CS Cem Implant (K120432).

4. Device Description

TempoCem Clear is a transparent, dual-curing, resin-based dental cement for the temporary or semipermanent cementing of provisional resin-based composite restorations (crowns, bridges, inlays, onlays, veneers) to a tooth and for temporary or semipermanent luting to an implant abutment. The cement consists of two pastes (base and catalyst) packaged in a double-barreled plastic syringe. The pastes are automatically mixed when dispensed through the single-use mixing tips supplied with the device.

5. Indications for Use

- Temporary or semipermanent luting of temporary and permanent crowns, bridges, inlays and onlays.
- Temporary luting of temporary veneers.
- Temporary or semipermanent luting of implant-borne dental prosthesis.

6. Comparison to the Predicate Device

A comparison of TempoCem Clear with the primary predicate device indicates the following similarities and differences.

Definition or Property [unit]	**Product**	
	TempoCem Clear (proposed device) (K160443)	**Telio CS Link (predicate device) (K042846)**
Common name	Temporary dental cement	Temporary dental cement
Classification name	Cement, Dental 21 CFR 872.3275 (b)	Cement, Dental 21 CFR 872.3275 (b)
Product code	EMA	EMA
Indications for Use	Temporary or semipermanent luting of temporary and permanent crowns, bridges, inlays and onlays. Temporary luting of temporary veneers. Temporary or semipermanent luting of implant-borne dental prosthesis.	Temporary cementation of provisional restorations. The product has been designed to remain in the mouth for a maximum of 6 weeks.
Composition	Glass filling material in a matrix of multifunctional methacrylates. Catalyst, stabilizer, additives. Free from methyl methacrylate and peroxides. Percentage of filler: 40 wt % = 22 vol.% (0.02 – 2.5 µm).	Telio CS Link is composed of bismethacrylates (56 wt.%) and fillers (43 wt.%). Initiators, stabilizers and pigments are additional ingredients.
Curing mechanism	Dual-curing	Dual-curing
Maximum solubility measured as water solubility, dual-cure [µg/mm^3]	19.0 ± 1.3	9.1 ± 0.6
Water sorption, dual-cure [µg/mm^3]	65.5 ± 2.0	77.3 ± 1.4
Dimensional change after 7 days, dual-cure [%]	1.0 ± 0.1	1.7 ± 0.1
Gel time, self-cure [s]	65	165
Setting time, self-cure, measured as final setting time, excluding 30 s mixing time [s]	318	216
Bonding strength for intended use, dual-cure	Good to satisfactory	Good to satisfactory
Film thickness, dual-cure [µm]	6 ± 1	39 ± 3
Amount of heat generated during	43.1 ± 1.3	43.0 ± 0.5

Definition or Property [unit]	Product	
	TempoCem Clear (proposed device) (K160443)	**Telio CS Link (predicate device) (K042846)**
setting (dual-cure), measured as peak polymerization temperature [°C]		
Compressive strength, dual-cure [MPa]	78 ± 8	43 ± 6
Flexural strength, dual-cure [MPa]	5.4 ± 0.3	6.4 ± 0.2
Shear bond strength, dual-cure [MPa]	8.7 ± 1.9	7.8 ± 2.0
Fluoride release, measured as cumulative value over 28 days, dual-cure [ppm]	8.0 ± 2.2	No data (does not contain NaF)

TempoCem Clear is similar to the predicate device Telio CS Link in that they are both automixing, transparent, dual-curing temporary resin dental cements to be used for cementing restorations such as crowns, bridges, inlays and onlays. The devices have substantially equivalent physical and mechanical properties.

TempoCem Clear is different from the predicate device in that it contains sodium fluoride. The subject and predicate devices have slightly different Indications for Use language. The Indications for Use for Telio CS Link do not mention, but do not exclude, the use for specific restorations (temporary and permanent crowns, bridges, inlays, onlays, and veneers). The Intended Use for Telio CS Link as presented in the K042846 Summary was: "For the temporary cementation of temporary inlays, onlays, partial crowns, crowns or bridges." The differences in the Indications for Use affect neither the Intended Use nor substantial equivalence.

The reference predicate device, Telio CS Cem Implant, has the same FDA Product Code (EMA= Dental cement) as TempoCem Clear. Telio CS Cem Implant is a self-curing resin cement with lightcuring option for the esthetic, temporary, reversible / semi-permanent cementation of restorations on implant abutments. The Indications for Use for Telio CS Cem Implant ("Reversible/semi-permanent cementation of long-term temporary and permanent restorations on implant abutments") are similar to the specific Indication for Use for TempoCem Clear ("Temporary or semipermanent luting of implant-borne dental prosthesis."). The composition of Telio CS Cem Implant (bismethacrylates (approx. 52 %wt.) and fillers (approx. 46 %wt.). Initiators, stabilizers, auxiliaries and pigments are additional components.) is substantially equivalent to TempoCem Clear. Thus TempoCem Clear is similar to the reference predicate Telio CS Cem Implant in composition, curing and indications.

7. Non-Clinical Performance Data

Physical and mechanical properties of TempoCem Clear were investigated and compared to the predicate device in accordance with FDA's 1998 Guidance for Industry and FDA Staff: Dental Cements - Premarket Notification (chemistry of the

setting reaction, working and setting times, solubility, dimensional change, bonding strength, film thickness, heat generated during setting and biocompatibility). Comparative data relevant for temporary, dual-curing cements demonstrate substantial equivalence of TempoCem Clear to the predicate device, Telio CS Link.

The biocompatibility testing was performed according to the FDA 1998 Guidance and the following consensus standard:

- ISO Standard 7405 Second edition (2008): Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

Equivalence in biocompatibility to the predicate device was demonstrated in cytotoxicity studies.

In addition, TempoCem Clear can be compared to other currently marketed dental products also manufactured by DMG: Luxatemp Ultra (K101710), Luxatemp / Luxatemp-Solar (K013674) and Luxatemp Automix (K924830). These dual-cure or auto-cure devices are not temporary cements, but have many similarities in curing mechanism and composition with TempoCem Clear. For example, the same auto-cure system and many of the same resin and pigment components are used in TempoCem Clear. The Luxatemp products have been marketed world-wide for over 25 years, and there is considerable clinical experience with these products and their components. This experience provides further evidence for the biocompatibility of the materials in TempoCem Clear.

8. Clinical Performance Data

Not applicable. Clinical performance testing has not been performed for the proposed device.

9. Conclusions

Based on the device Indications for Use, composition and physical / mechanical properties, TempoCem Clear has been shown to be substantially equivalent to the predicate device.