510(k) Summary

Trade Name:	**Luxatemp Ultra/Star**
Date Prepared:	August 16, 2010
Sponsor:	DMG USA, Inc. 23 Frank Mossberg Drive Attleboro, MA 02703 Owner/Operator No. 9005969
Device Generic Name:	Temporary crown and bridge material
Classification:	According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.
Regulation:	21 CFR 872.3770; Product Code EBG

SEP 28 2010

Indications for Use:
Luxatemp Ultra/Star is a self-curing or dual-curing composite for the fabrication of temporary crowns and bridges, inlays, onlays and veneers.

Luxatemp Ultra/Star is intended for the fabrication of:

- temporary crowns
- bridges
- inlays
- onlays
- long-term temporaries
- temporary veneers

Luxatemp Ultra/Star is also indicated for incorporation of most mechanically anchored attachment components into the acrylic base of a denture, an overdenture or partial denture.

Device Description:
Luxatemp Ultra/Star is a self-curing or dual-curing composite for the fabrication of temporary crowns and bridges, inlays, onlays and veneers. Luxatemp Ultra/Star will be supplied in 2 formulations; one is self-curing and the other is dual-cure. The 2 formulations vary slightly in composition to achieve the desired curing properties. The Luxatemp Ultra/Star dual-cure and self-cure formulations will be supplied in both Smartmix syringes and Automix cartridges. "Luxatemp Ultra" and "Luxatemp Star" are different trade names for the same material

Predicate Device:
Luxatemp Ultra/Star is substantially equivalent to the currently marketed DMG USA Luxatemp and Luxatemp Solar products cleared in K013674. Luxatemp / Luxatemp Solar and Luxatemp Ultra/Star differ only slightly in material composition, resulting in improved material properties (e.g., compressive and flexural strength) and curing time. A light-cure inducing component has also been added to allow for dual-cure.

Safety and Performance:
Luxatemp Ultra/Star is a temporary crown and bridge material that complies with the requirements described in ISO 7405:2008 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry. Performance testing has been performed to demonstrate that Luxatemp Ultra/Star is equivalent to or better than the predicate devices in terms of several material properties including compressive strength, flexural strength, tensile strength, hardness, water sorption, working time and curing time. Where applicable, the test methods and requirements described in ISO 4049:2000 Dentistry – Polymer-based filling, restorative and luting materials.

Conclusion:
Based on the indications for use, technological characteristics, and comparison to the predicate device, the Luxatemp Ultra/Star has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

DMG USA, Incorporated
C/O Ms. Pamela Papineau
Delphi Medical Device Consulting
5 Whitcomb Avenue
Ayer, Massachusetts 01432

SEP 28 2010

Re: K101710
Trade/Device Name: Luxatemp Ultra/Star
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: August 16, 2010
Received: August 25, 2010

Dear Ms. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101710

510(k) Number (if known): K101710

Device Name: **Luxatemp Ultra/Star**

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Product Indications for Use:

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Prescription Use X OR Over-the -Counter Use ____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101710