JAN 1 6 2004

510(k) Summary

Trade Name: **LuxaForm Plus**

Sponsor:

DMG USA, Inc.
414 South State Street
Dover, DE 19901
Registration # not yet assigned
Owner/Operator #9005969

Device Generic Name:

Temporary Crown and Bridge Resin Material

Classification:

According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Predicate Devices:

The proposed LuxaForm Plus is substantially equivalent to the currently marketed DMG USA LuxaForm material, which was cleared for marketing by FDA in K000951. In addition, the chemical composition of the LuxaForm Plus material includes materials found in both the Advantage Dental Products Temporary Crown Matrix Buttons as cleared in K900389 and the Heraeus Kulzer Paladur dental resin material, which was cleared in K915898.

Product Description:

The LuxaForm Plus is a detailed quick pre-impression matrix used in the fabrication of provisional crowns and bridges and can also be used as a bite registration material.

Indications for Use:

LuxaForm Plus is indicated for several uses:

- As a matrix in the fabrication of provisional dental crowns and bridges
- Mini "custom tray" for impressions
- Articulation of diagnostic molds
- Articulation of the working cast against the opposing arch
- For fabrication of a maxillary bite guard, a maxillary anterior or posterior bite plate or a maxillary anterior repositioning appliance
- Direct fabrication of Maxillary sports guard in the mouth without models

- Bite registration material either to be used directly or in combination with three way trays (e.g. Triple Trays from Premier)
- Reinforcement of three way trays
- For use in functional therapeutic cases as e.g. a Lucia Jig, anterior repositioning splint etc.
- Guiding matrix to help recreate anatomic form

Safety and Performance:

Substantial equivalence for this device was based on similarities in design, chemical composition and performance specifications as compared to predicate materials. The materials, performance specifications and essential design characteristics of the LuxaForm Plus are identical to those of the predicate devices.

Conclusion:

Based on the indications for use, technological characteristics, and comparison to predicate devices, the LuxaForm Plus has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 6 2004

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

Re: K033227
Trade/Device Name: Luxaform Plus
Regulation Number: 872-3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: December 31, 2003
Received: January 7, 2004

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.

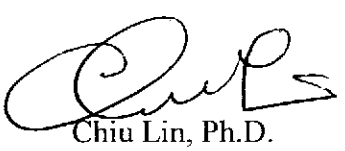
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: LuxaForm Plus

Indications for Use:

LuxaForm Plus is indicated for the following uses:

- As a matrix in the fabrication of provisional dental crowns and bridges
- Mini "custom tray" for impressions
- Articulation of diagnostic molds
- Articulation of the working cast against the opposing arch
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- Guiding matrix to help recreate anatomic form

(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: _____

Prescription Use ✓ OR Over-the -Counter Use ____
(Per 21 CFR 801.109)

Susan Runner

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

510(k) Number: K033227