K012307

AUG 2 3 2001

510(k) Summary

Trade Name: **LuxaCore / LuxaCore Dual**

Sponsor: DMG USA, Inc.
414 South State Street
Dover, DE 19901

Registration # not yet assigned

Device Generic Name: Dental core build-up and restorative material

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

Predicate Devices: Centrix Encore (Alpha-Dent); K932826
Core Paste (Den-Mat); K872510
Bisfil 2B (BISCO); K964000
LuxaCore (Zenith); K982201

Product Description:

LuxaCore:
LuxaCore is a chemical-curing, radiopaque two-component core build-up material supplied in automix delivery systems or as a handmix material.

LuxaCore Dual:
LuxaCore Dual is a dual cure (chemical and/or light cure), radiopaque two-component core build-up material supplied in automix delivery systems or as a handmix material

Indications for Use:
The principal use for LuxaCore and LuxaCore Dual is as a core material either with adhesives or with pins or posts.

LuxaCore and LuxaCore Dual can also be used for:

- Luting of abutments to dentures (LuxaCore)
- Splinting of teeth in combination with wires, Kevlar or Ribbond-type materials
- Repair material for provisionals
- Bite registration material.
- Build up material for plastic bite rails (occlusal individualisation).
- Cement for pins and posts
- Semipermanent restorative material (e.g., in childrens' teeth)

Safety and Performance:
This submission is an Abbreviated 510(k) as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), DMG USA, Inc. has provided information to demonstrate

conformity with FDA's guidance document entitled ***Dental Composites - Premarket Notification***, November 1998 and ISO 4049 – Dentistry – Polymer-based filling, restorative and luting materials.

Conclusion:
Based on their indications for use, technological characteristics, and comparison to predicate devices, the LuxaCore / LuxaCore Dual materials have been shown to be safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2001

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

Re: K012307
Trade/Device Name: Luxacore/Luxacore Dual
Regulation Number: 872.3690
Regulatory Class: II
Product Code: EBF
Dated: July 6, 2001
Received: July 23, 2001

Dear Ms. Papineau:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012307

510(k) Number (if known): _____

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- Cement for pins and posts
- Semipermanent restorative material (e.g., in childrens' teeth)

LuxaCore can be used for luting of abutments to dentures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012307