K013236

OCT 1 7 2001

510(k) Summary

Trade Name: **LuxaBite**

Sponsor: DMG USA, Inc.
414 South State Street
Dover, DE 19901
Registration # not yet assigned
Owner/Operator No. 9005969

Device Generic Name: Dental bite registration material

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

Predicate Device:
The proposed DMG USA LuxaBite material is substantially equivalent to other currently marketed dental impression / bite registration materials and the DMG LuxaTemp temporary crown and bridge material K942830.

Product Description:
The LuxaBite dental bite registration material is composed of glass fillers in a matrix of multifunctional methacrylates. This quick setting material is provided in automixing cartridges, and can be dispensed directly onto the teeth. The material has a total working time of 45 seconds. LuxaBite sets up to a firm consistency with a slight amount of elasticity, and may be removed from the teeth within 2-½ minutes.

Indications for Use:
LuxaBite is indicated for use as a bite registration material for use in the production of crowns, bridges and dentures, and in orthodontic treatments. It may also be used as a provisional crown & bridge material.

Safety and Performance:
Substantial equivalence for this device was based solely on design and technical specifications; no performance or safety data was included in this premarket notification. The materials, performance specifications and essential design characteristics of the LuxaBite material are equivalent to those of the predicate devices. The proposed LuxaBite material complies with FDA's 1998 guidance document: *Dental Impression Materials – Premarket Notification.*

Conclusion:
Based on the indications for use, technological characteristics, and comparison to the predicate device, the LuxaBite material 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

OCT 1 7 2001

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

Re: K013236
Trade/Device Name: LuxAbite
Regulation Number: 872.3660
Regulation Name: Dental Bite Registration Material
Regulatory Class: II
Product Code: ELW
Dated: September 17, 2001
Received: September 28, 2001

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 Part 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

K013236

510(k) Number (if known): K013236

Device Name: LuxaBite

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(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)

Susan Runyon

(Division **Sign-Off)**
Division **of Dental, Infection Control,**
and **General Hospital Devices**
510(k) **Number** K013236