OCT 22 2001

K013237

510(k) Summary

Trade Name: **StatusBlue**

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

Device Generic Name: Dental impression 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 StatusBlue material is substantially equivalent to other currently marketed dental impression materials including the 3M/ESPE Dimension Penta impression material (K974231).

Product Description:
The StatusBlue dental impression material is a dimensionally stable polyvinyl siloxane material designed as an alternative to alginate impression materials. It will be supplied in prefilled, ready-to-use MixStar cartridges. StatusBlue is intended for use in commercially available impression trays.

Indications for Use:
StatusBlue is indicated for use as a dental impression 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 StatusBlue material are equivalent to those of the predicate devices. The proposed StatusBlue material complies with ISO 4823 (Dental Elastomeric Impression Materials).

Conclusion:
Based on the indications for use, technological characteristics, and comparison to the predicate device, the StatusBlue 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 22 2001

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

Re: K013237
Trade/Device Name: StatusBlue
Regulation Number: 872.3660
Regulation Name: Dental Impression 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

K013237

510(k) Number (if known): K013237

Device Name: StatusBlue

Indications for Use:

StatusBlue is indicated for use as a dental impression material in the following applications:

- Situation impressions of any kind;
- Impressions for the preparation of provisionals;
- Impressions for orthodontic models;
- Impressions of the opposing jaw;
- Impressions for the manufacture of model cast 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)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013237