3M Dental Products Laboratory

3M Center, Building 260-2B-09
St. Paul, MN 55144-1000
612 733 3149

JUN 11 1998

K981325

3M

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Name:	Amy E. Fowler
Address:	3M Dental Products Laboratory 3M Center, Building 260-2B-12 St. Paul, MN 55144-1000
Phone:	(612) 736-1590
Fax:	(612) 736-0990
E-mail:	aefowler@mmm.com
Date:	April 10, 1998
Trade Name:	3M™ M.G. Material
Common Names:	Bite registration material, occlusal registration material
Classification Name:	Impression material (21 CFR 872.3660) Class II
Predicate devices:	3M™ Imprint™ II Vinyl Impression Material System 3M™ Fast Set Bite Registration Material Heraeus Kulzer Memoreg™ C.D. Bite Registration Material Parkell Blu-Mousse® AutoMix Cartridges

3M™ M.G. Material is designed to make fast, accurate, and rigid interocclusal records. The material has a consistency which resists slumping and offers minimal resistance to closure to ensure proper occlusion. 3M™ M.G. Material may also be used as a matrix material when fabricating custom temporary crowns and bridges. It is a two-part vinyl polysiloxane paste with an addition-cure reaction. The base and catalyst pastes are extruded from dual-barrel cartridges through a mixing tip onto the occlusal surfaces of the teeth. The material quickly cures into a rigid impression.

3M™ M.G. Material is designed for making impressions that record the occlusal relationship of the upper and lower dental arches. It is also intended to be used as a matrix when fabricating temporary crowns and bridges. The predicate devices do not specifically say they are intended for use as matrices. However, the labeling for temporary crown and bridge materials has indirectly indicated the predicate devices for this use for many years. This use does not present any new issues of safety or efficacy.

3M™ M.G. Material and the predicate devices have similar technological characteristics as indicated by their vinyl polysiloxane addition-cure chemistry. This is further validated by the comparative results of the bench tests conducted, including strain in compression, detail reproduction, mixed consistency, and linear dimensional change.

Based on the safety analysis and the bench tests, 3M™ M.G. Material is safe, effective, and performs as well or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 1998

Ms. Amy E. Fowler
Regulatory Affairs
3M Dental Products Laboratory
3M Center, Building 260-2B-09
St. Paul, Minnesota 55144-1000

Re: K981325
Trade Name: 3M M.G. Material
Regulatory Class: II
Product Code: ELW
Dated: April 10, 1998
Received: April 13, 1998

Dear Ms. Fowler:

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 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

510(k) Number: _____

Device Name: 3M™ M.G. Material

Indications For Use:
3M™ M.G. Material is designed to make interocclusal records and to be used as a matrix material when fabricating custom temporary crowns and bridges.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of,
and General Hospital Devices
510(k) Number K98 R25

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