JUN - 9 2000 K001114

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.

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Date:	March 31, 2000
Trade Name:	3M™ Quik Temp Temporization Material
Common Names:	Temporary Crown and Bridge Resin
Classification Names:	Temporary crown and bridge resin 21 CFR §872.3770 Class II
Predicate devices:	3M™ ISO-Temp™ Temporary Material

3M™ Quik Temp Temporization Material is a multi-phase temporary crown and bridge resin. This device, as well as the predicate device, are based on methacrylate resin chemistry.

The 3M™ Quik Temp Temporization Material is a light curing temporary crown and bridge material and is not intended to be permanent.

3M™ Quik Temp Temporization Material and the predicate device have similar technological characteristics. This is further validated by the comparative results of the bench tests conducted. These tests include Barcol Hardness, Compressive Strength, Diametral Tensile Strength, Flexural Strength, and Watts Shrinkage, and Vertical Flow.

Based on the conclusions drawn from the safety analysis conducted on this device and the results of the bench testing, 3M™ Quik Temp Temporization Material is safe, effective and performs as well, or better, than the predicate device mentioned above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2000

Ms. Cheri A. Smokovich
Advance Regulatory Affairs Associate
3M Dental Products Laboratory
3m Center, Building 260-2B-12
St. Paul, Minnesota 55144-1000

Re: K001114
Trade Name: 3M™ Quik Temp Temporization Material
Regulatory Class: II
Product Code: EBG
Dated: March 30, 2000
Received: April 6, 2000

Dear Ms. Smokovich:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (21 CFR 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/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

Device Name: 3M™ Quik Temp Temporization Material

Indications for Use:

- Temporization of single unit crowns
- Temporization of multiple-unit bridges
- Temporization of inlays, onlays, and veneers
- Temporization of implants
- Crown lining for prefabricated crowns

(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, Infectio· ·trol,
and General Hospital Devic

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