K033022

NOV 2 1 2003

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company:	3M ESPE AG
Street:	ESPE Platz
ZIP-Code, City:	D-82229 Seefeld
Federal State:	Bavaria
Country:	Germany
Establishment Registration Number:	9611385
Official Correspondent:	Dr. Andreas Petermann, Manager U.S. Regulatory Affairs
Phone:	011-49-8152-700 1395
Fax:	011-49-8152-700 1869
E-mail:	andreas.petermann@mmm.com
Date:	September 23, 2003

Name of Device

Proprietary Name:	Protemp™ 3 Garant™
Classification Name	Temporary Crown and Bridge Resin
Common Name:	Composite based Temporary Crown and Bridge Material

Predicate Device:

Protemp™ H by 3M ESPE, K 002364

3M™ Quik Temp Temporization Material, K 001114

Description for the Premarket Notification

Protemp 3 Garant is a temporary crown and bridge resin intended to make a temporary prosthesis, such as a crown or bridge, for use until a permanent restoration is fabricated. Temporary crown and bridge resin is designated at 21 C.F.R § 872.3770 as a Class II device.

Like Protemp H, Protemp 3 Garant is available in the proven Garant™ mixing and dispensing system.

To provide evidence for safety biocompatibility testing was carried out. The results show that Protemp 3 Garant is a safe device.

To prove the effectiveness of Protemp 3 Garant, the performance characteristics of Protemp 3 Garant were compared to those of the respective predicate devices.

In summary, the temporary crown and bridge resin Protemp 3 Garant described in this 510(k) premarket notification submission is, in our opinion, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2003

Dr. Andreas Petermann
Manager, U.S. Regulatory Affairs
3M ESPE AG
ESPE Platz
Seefeld, D-82229
GERMANY

Re: K033022
Trade/Device Name: Protemp™ 3 Garant™
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: September 23, 2003
Received: September 25, 2003

Dear Dr. Petermann:

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.

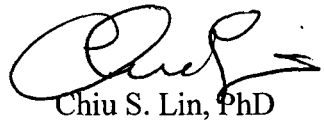
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), 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) you may obtain. 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,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033022

Device Name: Protemp™ 3 Garant™

Indications For Use:

Fabrication of temporary crowns, bridges, inlays, onlays and veneers.

Crown lining material for 3M ESPE Prefabricated Temporary Crowns.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033022