AUG 10 1998

K981647

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:	Lael J. Pickett Regulatory Affairs Specialist
Address:	3M Dental Products Laboratory 3M Center, Building 260-2B-12 St. Paul, MN 55144-1000
Telephone:	612-733-3594
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Trade Name:	3M™ Dent II System
Common Names:	Tooth shade resin material
Classification Name:	Tooth shade resin material (21 CFR §872.3690)
Predicate Devices:	3M™ Z100™ Restorative Prisma TPH™ Spectrum XRV™ Herculite® Alert™ SureFil™

3M™ Dent II System is a visible-light activated, radiopaque restorative material. This device, as well as the predicate devices, are based on monomer chemistry.

3M™ Dent II System is used in conjunction with a dental adhesive system for both anterior and posterior restorations. The predicate devices, when taken as a whole, have the same intended uses.

3M™ Dent II System II and 3M™ Z100™ Restorative, Prisma TPH™ Spectrum and XRV™ Herculite® devices have similar technological characteristics as indicated by their TEGDMA and BISGMA monomer chemistry. This is further validated by the comparative results of the bench tests conducted. These tests include shrinkage, diametral tensile strength, compressive strength, wear and hardness.

3M™ Dent II System and Alert™, SureFil™ have similar depth of cure based on laboratory bench tests conducted.

Based on the conclusions drawn from the safety analysis conducted for this device and the results of the bench testing, 3M™ Dent II System is safe, effective and performs as well or better than the predicate devices mentioned above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 1998

Ms. Rebecca L. Hannack
Regulatory Affairs
3M Dental Products Laboratory
3M Center, Building 260-2B-12
St. Paul, Minnesota 55144-1000

Re: K981647
Trade Name: 3M™ Dent II System
Regulatory Class: II
Product Code: EBF
Dated: May 7, 1998
Received: May 11, 1998

Dear Ms. Hannack:

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 (if known):_____

Device Name: 3M Dent II System

Indications For Use:

Indications:

* Direct anterior restorations including:
  - Class III, IV, V, and VI
  - Veneers
  - Incisal edge repair

* Direct posterior restorations including:
  - Class I or II
  - Sandwich technique with glass ionomer resin material
  - Cusp Buildups

* Core Buildups

* Splinting

* Indirect anterior and posterior restoration including:
  - Inlays
  - Onlays
  - Veneers

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyer

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981647

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)