

KA73961

DEC 17 1997

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
Fax: 612-736-0990
Trade Name: 3M™ Dent System II Plus
Common Names: Resin cement, luting composite, luting cement
Classification Name: Dental cement, other than zinc oxide-eugenol
(21 CFR §872.3275)
Predicate Devices: 3M™ Scotchbond™ Resin Cement
Bisco Resinomer™
Bisco Duolink™

3M™ Dent System II Plus is a two part, radiopaque dual-curing luting composite. This device, as well as the predicate devices, are based on methacrylate resin chemistry. The 3M™ Dent System II Plus Paste A alone can be cured by exposure to a dental visible light curing unit. When Pastes A and B are mixed, the material will chemically cure without exposure to light or can be cured by exposure to visible light.

3M™ Dent System II Plus is used in conjunction with a dental adhesive system to bond *direct and indirect* restorations. The predicate devices, when taken as a whole have the same intended uses.

3M™ Dent System II Plus and predicate devices have similar technological characteristics as indicated by their methacrylate resin chemistry. This is further validated by the comparative results of the bench tests conducted. These tests include shear bond strength, compressive and diametral tensile strengths, and film thickness.

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lael J. Pickett
Regulatory Affairs Specialist
3M Dental Company
3M Dental Products Laboratory
3M Center, Building 260-2B-12
St. Paul, Minnesota 55144

DEC 17 1997

Re: K973961
Trade Name: 3M™ Dent System II Plus
Regulatory Class: II
Product Code: EMA
Dated: October 14, 1997
Received: October 16, 1997

Dear Ms. Pickett:

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 (Pre-market 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 requirement, 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

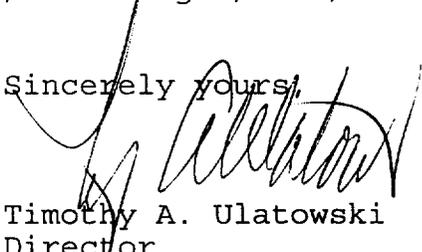
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not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4618. 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

510(k) Number (if known): K973961

Device Name: 3M™Dent System II Plus

Indications For Use: This device is indicated for direct and indirect dental bonding applications.

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

[Signature]
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Dental, Infection Control,
and General Hospital Devices

Prescription Use Yes K973961
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No