K991961

AUG -9 1999

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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Trade Name:	3M™ LVR System
Common Names:	Tooth shade resin material, light cure restorative Resin cement, luting composite, luting cement Dental sealant, pit and fissure sealant.
Classification Name:	21 CFR § 872.3690 Tooth Shade Resin Material 21 CFR § 872.3275 Dental cement, Class II. 21 CFR § 872.3765 Pit and fissure sealant, Class II
Predicate Devices:	DYRACT® FLOW, DENTSPLY Caulk AELITEFLO™, Bisco Dental Products Revolution Flowable Paste Product, Kerr Corp. TETRIC® FLOW Flowable Ceromer, Ivoclar Vivadent

3M™ LVR System is a single part, light curing restorative composite. This device, as well as the predicate devices, are based on methacrylate resin chemistry incorporating an inorganic filler.

The 3M™ LVR System can be used as a: base/liner under direct restorations, pit and fissure sealant, veneer cement, undercut blockout, restorative for minimal - shallow Class V preparations, restorative for minimally invasive cavity preparations (including air abrasion and tunnel preparations), repair of small defects in composite and ceramic indirect restorations (including veneers, inlays, onlays, crowns and bridges), repair of small marginal defects in direct restorations and for repair of acrylic temporary marginal defects. This product can be used for both anterior and posterior restorations and functions as a permanent veneer cement.

3M™ LVR System 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 Watts shrinkage, wear resistance, compressive strength, diametral tensile strength, film thickness, Thermal Expansion Coefficient, flow and water sorption.

The 3M™ LVR System also meets ISO 4049-1988 "Dentistry – Resin-based filling materials".

Based on the conclusions drawn from the safety analysis conducted for this device and the results of the bench testing, 3M™ LVR System II Plus 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 -9 1999

Mr. Lael J. Pickett
Regulatory Affairs Specialist
3M Dental Products Laboratory
3M Center, Building 260-2B-09
St. Paul, Minnesota 55144-1000

Re: K991961
Trade Name: 3M™ LVR SYSTEM
Regulatory Class: II
Product Code: EBF
Dated: June 2, 1999
Received: June 10, 1999

Dear Mr. 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 (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

K991961

510(k) Number (if known): K991961

Device Name: 3M™ LVR System

Indications For Use: This device is indicated for:

- Base/liner under direct restorations
- Pit and fissure sealant
- Veneer Cementation
- Undercut blockout
- Restoration of minimal, shallow, Class V preparations
- Restoration of minimally invasive cavity preparations, including air abrasion and tunnel preparations
- Repair of small defects in composite and ceramic indirect restorations including veneers, inlays, onlays, crowns and bridges
- Repair of small marginal defects in direct restorations
- Repair of acrylic temporary marginal defects

(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, Infection Control,
and General Hospital Devices
510(k) Number K991961