K992326

OCT 8 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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|---|---|
| Name: | Lael J. Pickett<br>Regulatory Affairs Specialist |
| Address: | 3M Dental Products Laboratory<br>3M Center, Building 260-2B-12<br>St. Paul, MN 55144-1000 |
| Telephone: | 612-733-3594 |
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|---|---|
| Trade Name: | 3M™ Clinpro™ Sealant |
| Common Names: | Dental sealant, pit and fissure sealant. |
| Classification Name: | 21 CFR § 872.3765 Pit and fissure sealant, Class II |
| Predicate Devices: | 3M™ Concise™ Light Cure White Sealant, 3M |

3M™ Clinpro™ Sealant is a single part, light curing, pit and fissure sealant. This device, as well as the predicate device, are based on methacrylate resin chemistry.

The 3M™ Clinpro™ Sealant can be used as a pit and fissure sealant. It is intended to be used on posterior teeth and is not permanent.

3M™ Clinpro™ Sealant and the predicate device 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, Ambient Light Sensitivity, Cure Time, Depth of Cure, and Uncured Film Thickness.

The 3M™ Clinpro™ Sealant also meets ISO 6874-1988 "Dental resin-based pit and fissure sealants".

Based on the conclusions drawn from the safety analysis conducted on this device and the results of the bench testing, 3M™ Clinpro™ Sealant 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

OCT 8 1999

Ms. Lael J. Pickett
Regulatory Affairs Specialist
3M Company
Dental Products Division
3M Center, Building 260-2B-12
St. Paul, Minnesota 55144-1000

Re: K992326
Trade Name: 3M™ Clinpro™ Sealant
Regulatory Class: II
Product Code: EBC
Dated: July 7, 1999
Received: July 12, 1999

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 (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™ Clinpro™ Sealant

Indications For Use: This device is indicated for:

- Pit and fissure sealant

(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) Pamela D. Scott for Susan Runner
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992326