MAY 13 1999

K990482

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:	Rebecca L. Hannack Advanced Regulatory Affairs Associate
Address:	3M Dental Products Division 3M Center, Bldg. 260-2B-12 St. Paul, MN 55144
Telephone: Fax:	(651)737-1105 (651)736-0990

Trade Name:	3M™ Clinpro™ Prophy Paste
Common Name:	Prophylaxis Paste
Classification Name:	Oral cavity abrasive polishing agent (21 CFR 872.6030)
Predicate Devices:	Hawe Cleanic® Prophylaxis Paste Nupro® Prophylaxis Paste with Fluoride

3M™ Clinpro™ Prophy Paste is to be used for cleaning and polishing procedures as part of a professionally administered prophylaxis treatment.

3M™ Clinpro™ Prophy Paste is composed of an abrasive, a flavorant, a colorant, and also contains fluoride.

3M™ Clinpro™ Prophy Paste has similar technological characteristics as the predicate devices in that they all contain an abrasive, flavorant, colorant, and fluoride. This is further validated by the comparative results of the bench tests conducted including stain removal, surface roughness, and relative dentin and enamel abrasion.

Based on the conclusions drawn from the safety analysis conducted for this device and the results of the bench testing, 3M™ Clinpro™ Prophy Paste is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 1999

Ms. Rebecca L. Hannack
Advanced Regulatory Affairs Associate
Minnesota Mining and Manufacturing Company
Dental Products Division
3M Center, Building 260-2B-12
St. Paul, Minnesota 55144

Re: K990482
Trade Name: 3M™ Clinpro™ Prophy Paste, Model 12611
Regulatory Class: I
Product Code: EJR
Dated: February 10, 1999
Received: February 16, 1999

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 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

510(k) Number: _____

Device Name: 3M™ Clinpro™ Prophy Paste

Indications for Use:

To be used for cleaning and polishing procedures as part of a professionally administered prophylaxis treatment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K990452

Prescription Use ✓ OR Over-the-Counter Use _____