AUG 0 1 2002

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

K021450

Submitter

Company: .....3M ESPE AG
Street: .....ESPE Platz
ZIP-Code, City: .....D-82229 Seefeld
Federal State: .....Bavaria
Country: .....Germany
Establishment Registration Number: ...9611385
Official Correspondent: .....Dr. Andreas Petermann,
Manager U.S. Regulatory Affairs
Phone: 011-49-8152-700 1395
Fax: 011-49-8152-700 1869
E-mail: .....Andreas.Petermann@mmm.com
US Agent: .....Don H. McKenzie
Regulatory Manager
Phone: 651-736-9286
Fax: 651-736-0990
E-mail: .....dhmckenzie@mmm.com

Date: .....May 3, 2002

Name of Device

Proprietary Name: .....Clinpro™ Prophy Powder
Classification Name: .....Ultrasonic Scaler
Common Name: .....Cleaning Powder

Predicate Device

New Prophy Powder by Dentsply .....K 014188

Description for the Premarket Notification

Clinpro Prophy Powder is classified as a class II medical device because it is a device intended for use during dental cleaning and periodontal therapy to remove deposits and stains from teeth (Ultrasonic Scaler, 21 C.F.R. § 872.4850).

Clinpro Prophy Powder is intended for use in dental polishing units. The air polishing unit produces a stream of water, air and Clinpro Prophy Powder to clean and polish tooth surfaces.

3M ESPE's new cleaning powder Clinpro Prophy Powder described in this premarket notification submission is, in our opinion, substantially equivalent to the predicate device New Prophy Powder by Dentsply

In our opinion, the substantial equivalence to the predicate device and the performance and biocompatibility data provide evidence that safety and effectiveness requirements of Clinpro Prophy Powder are completely met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 1 2002

Mr. Andreas Petermann
Manager U.S. Regulatory Affairs
3M ESPE AG Dental Products
ESPE Platz
Seefeld,Bavaria
GERMANY D-82229

Re: K021450
Trade/Device Name: Clinpro Prophy Powder
Regulation Number: 872.6080
Regulation Name: Airbrush
Regulatory Class: II
Product Code: KOJ
Dated: May 3, 2002
Received: May 6, 2002

Dear Mr. Petermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

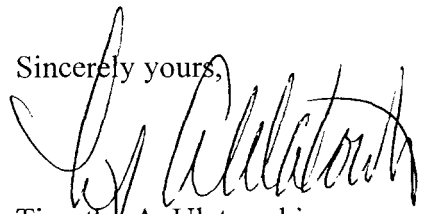
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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 Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

(As Required by 21 C.F.R. § 801.109)

510(k) Number: K021450

Device Name: Clinpro Prophy Powder

Indications for use: Cleaning, polishing and restoring the natural esthetics of tooth enamel

Prescription use: ☑ Over-the counter use ☐

Susan Runco

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021450