K014188

MAR 1 5 2002

510(k) SUMMARY

NAME & ADDRESS:

DENTSPLY International
570 West College Avenue
P.O. Box 872
York, PA 17405-0872
(717) 845-7511
~~Fax (717) 849-4762~~

P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: December 20,2001

TRADE OR PROPRIETARY NAME: NEW PROPHY POWDER

CLASSIFICATION NAME: Airbrush (ACCESSORY) 872.6080

PREDICATE DEVICES: Accessory to Cavitron Jet with SPS System K970342

DEVICE DESCRIPTION: NEW PROPHY POWDER is for use in DENTSPLY dental air polishing units. When the air polishing unit is in the JET mode, it produces a spray mixture of air, water, and powder to clean, polish and restore the natural esthetics of tooth enamel. NEW PROPHY POWDER is a new formulation and is for use with all DENTSPLY® Cavitron™ Prophy-Jet® Systems and DENTSPLY® Cavitron-Jet™ Systems. NEW PROPHY POWDER will be offered in two size bottles (a 2-oz. bottle/closure for sampling and an 8-oz. bottle/closure as standard). The bottles will have a wide mouth for easy dispensing and be packaged as six bottles per shipper.

INTENDED USE: For use with all DENTSPLY® Cavitron™ Prophy-Jet® Systems and DENTSPLY® Cavitron-Jet™ Systems for cleaning, polishing and restoring the natural esthetics of tooth enamel.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in NEW PROPHY POWDER have been used in legally marketed devices or were found safe for dental use.

NEW PROPHY POWDER has been evaluated and passed biocompatibility testing for cytotoxicity, acute oral toxicity, irritation, and sensitization.

We believe that the prior use of the components of NEW PROPHY POWDER in the legally marketed predicate device, the performance data provided, and the biocompatibility data provided support the safety and effectiveness of NEW PROPHY POWDER for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2002

Mr. P. Jeffery Lehn
Director, Corporate Compliance & Regulatory Affairs
Dentsply International
570 West College Avenue
York, Pennsylvania 17404

Re: K014188
Trade/Device Name: New Prophy Powder
Regulation Number: 872.4850
Regulation Name: Accessory to Dental Prophylaxis Units
Regulatory Class: II
Product Code: ELC
Dated: December 20, 2001
Received: December 21, 2001

Dear Mr. Lehn:

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 Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K014188

Device Name: **NEW PROPHY POWDER**

Indications for Use:

For use with all DENTSPLY® Cavitron™ Prophy-Jet® Systems and DENTSPLY® Cavitron-Jet™ Systems for cleaning, polishing and restoring the natural esthetics of tooth enamel.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number K014188

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)