

JUN 10 1999

# American Dental Products Inc.



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510 (K) SUMMARY: K 991099

The Safe Medical Devices Act of 1990 requires all persons submitting a pre-market notification submission to include either (1) a summary of the safety and effectiveness information in the pre-market notification submission upon which an equivalence determination could be based (510(k) summary), or (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information.

In order to comply with the above requirements, we would like to state that our product's efficacy is comparable with other brands which are on the market.

Third party testing shows that the efficacy of our products is comparable or better than other brands which are on the market.

Regarding the safety of the product, please be advised that the product contains ingredients which have been proven to be safe to be used in the dental industry for many years. However a mishandling of Phosphoric Acid Gel, if become in contact with eyes, will cause blindness. Wash immediately eyes with plenty of water and get immediate medical attention. The product must be handled by a dentist professional according with the instructions and Material Safety Data Sheet, wearing gloves, avoiding contact with skin, tissue gum and eyes using normal safe practices in a highly professional manner.

AMERICAN DENTAL PRODUCTS

More informations regarding the safety of the product are covered in the Material Safety Data Sheet for American Dental Products Etch-Detector, which copy please find enclosed.

Please be advised that our product American Dental Products Etch-Detect is not available on the market as of today, March 25, 1999, yet but we plan to market the product soon.

The descriptive information presented here satisfy the requirements of the SMMA of 1990.

Sincerely Yours,



George Nicolae, Ph.D.  
President and  
Official Correspondent  
AMERICAN DENTAL PRODUCTS INC.

Etchdet7



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 10 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

George Nicolae, Ph.D.  
President and Official Correspondent  
American Dental Products, Incorporated  
603 B Country Club Drive  
Bensenville, Illinois 60106-1329

Re: K991099  
Trade Name: American Dental Products Etch-Detector  
Regulatory Class: II  
Product Code: EBC  
Dated: May 24, 1999  
Received: May 28, 1999

Dear Dr. Nicolae:

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 (Pre-market 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.

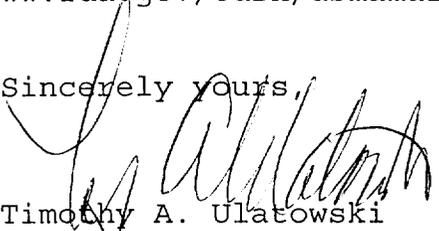
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Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws 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 (if known): K 991099

Device Name: AMERICAN DENTAL PRODUCTS ETCH-DETECT

Indications For Use:

USE ETCH-DETECT TO DETECT RESIDUAL  
DECAY (DENATURED PROTEIN) WHILE ETCHING  
DENTINE IN THE "TOTAL ETCH" TECHNIQUE

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use    
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

*Susan Rinn*

(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K991099