MAR 1 4 2000

American Dental Products Inc.

603 B Country Club Drive
Bensenville, IL 60106-1329, USA

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510 (K) SUMMARY: K 994368

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.If the product accidentally gets into the eye, flush immediately with plenty of water and consult a physician. The product must be handled by a dentist professional according with the instructions and Material Safety Data Sheet, wearing gloves, avoiding contact with skin, and eyes using normal safe practices in a highly professional manner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 14 2000

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

Re: K994368
Trade Name: American Dental Products Caries - Detector Plus
Regulatory Class: II
Product Code: LFC
Dated: December 22, 1999
Received: December 27, 1999

Dear Mr. 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 (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) 594-4690. 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

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DENTAL MANUFACTURERS OF AMERICA

K994368

AMERICAN DENTAL PRODUCTS
CARIES-DETECTOR PLUS
INDICATIONS FOR USE

CARIES INDICATOR PLUS (CARIES STAIN) is indicated for detection of caries through the staining of the outer layer of carious dentin.

Warranty: American Dental Products Inc. recognizes its responsability to replace such quantity of their products as are proven to be defective. American Dental Products Inc. does not accept liability for any loss or damage direct or consequential arising out of the use of or the liability to use the products described herein. Before using, the user shall determine the suitability of the product for its intended use and user assumes all risk and liability whatsoever in connection therewith.

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Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994368