

K973185

American Dental Products Inc.

NOV 14 1997



22 W 246 Sunnyside Rd.
Madinah, Illinois 60157-9705, USA
phone / fax: (630) 351-6284

510 (K) SUMMARY OF THE SAFETY AND EFFECTIVENESS : K. 973185

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 Fluoride, Quats and other ingredients which have been proven to be safe to be used in the dental industry for many years. 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 cys using normal safe practices in a highly professional manner.

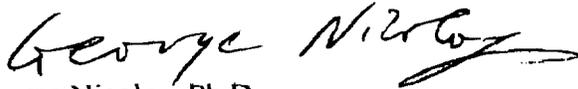
AMERICAN DENTAL PRODUCTS

More informations regarding the safety of the product are covered in the Material Safety Data Sheet for American Dental Products HB-35 Desensitizer with Fluoride, which copy please find enclosed.

Please be advised that our product American Dental Products HB-35 Desensitizer with Fluoride is not available on the market as of today, November 12, 1997, yet but we plan to market the product soon.

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

Sincerely Yours,



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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. George Nicolae
President
American Dental Products, Incorporated
22 W 246 Sunnyside Road
Medinah, Illinois 60157-9705

- NOV 14 1997

Re: K973185
Trade Name: American Dental Products HB-35 Desensitizer
With Fluoride
Regulatory Class: II
Product Code: KLE
Dated: August 20, 1997
Received: August 25, 1997

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.

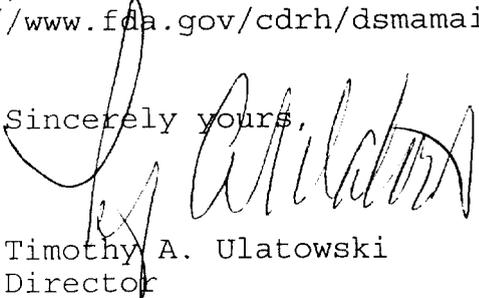
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4618. 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

Page _____ of _____

510(k) Number (if known): K 973185

Device Name: HB-35 DESENSITIZER WITH FLUORIDE

Indications For Use:

USE HB-35 DESENSITIZER WITH FLUORIDE FOR SENSITIVE TEETH.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Handwritten Signature]

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

510(k) Number K973185

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____