K980051

EXHIBIT D

FEB 24 1998

510(k) Summary

Submitted by: Daniel J. Manelli
Farkas & Manelli, P.L.L.C.
1233 20th Street, NW (Suite 700)
Washington, DC 20036

On behalf of Tokuyama America, Inc.
510(k) Submission: Tokuso Mac Bond II
December 30, 1997

The product is a tooth shade resin material for use in dental restorations. It may be used with Tokuyama's Mac Bond II or other brands of similar bonding agents. It is not intended for OTC use. It contains materials that are common in dental use and pose no health hazard when used according to directions.

The Use of the product is contra-indicated for patients who are hypersensitive to methacrylate monomers. It should not be allowed to come into contact with skin or eyes. Should contact with the skin occur, the affected area should be washed thoroughly with soap and water. Should the product come into contact with the eyes, it should be immediately rinsed out thoroughly with water and a physician should be contacted at once.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Daniel J. Manelli
Attorney
Tokuyama America, Incorporated
C/O Farkas & Manelli, P.L.L.C.
1233 20th Street N.W. #700
Washington, DC 20036

FEB 24 1998

Re: K980051
Trade Name: Palfique Estelite Paste
Regulatory Class: II
Product Code: EBF
Dated: December 30, 1997
Received: January 6, 1998

Dear Mr. Manelli:

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 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,

Patricia Cucevich/for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT C

510(k) Number (if known): K980051

Device Name: Palfique Estelite Paste

Indications For Use:

For use as a tooth shade resin material in dental procedures

(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 K980051

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)