DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Debra Gillaspy
Official Correspondent
Medental International
1246 Clear Creek Road
Evergreen, Colorado 80439

DEC 16 1997

Re: K973919
Trade Name: Cavity Varnish (Intermediary Varnish and Dentinal Tubuli Seal)
Regulatory Class: II
Product Code: LBH
Dated: October 7, 1997
Received: October 15, 1997

Dear Ms. Gillaspy:

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) 594-4692. 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

MEDENTAL INTERNATIONAL
1246 Clear Creek Road
Evergreen, CO 80439
Establishment # 1723973

510(k) Number: Not Yet Assigned K973919

Device Name: Cavity Varnish (Intermediary Varnish and Dentinal Tubuli Seal)

Indications for Use:

Cavity varnish is used for sealing cavities before restorations. It provides a barrier against the passage of irritants from cements or other restorative materials and reduces the penetration of oral fluids at the restoration-tooth interface into the underlying dentin. It also minimizes postoperative sensitivity when applied to dentinal surfaces under newly placed restorations.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973919

Prescription Use Yes or Over the Counter Use No