DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 1999

Ms. Caroline M. Zaleski
Trans-Atlantic Dental
46 Arctic Parkway
Trenton, New Jersey 08638

Re: K983461
Trade Name: Uni-Flex Resin
Regulatory Class: II
Product Code: EBI
Dated: January 11, 1999
Received: January 14, 1999

Dear Ms. Zaleski:

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

Trans-Atlantic Dental
46 Arctic Parkway
Trenton, NJ 08638
Tel/Fax (609) 695-0168

Indications for Use Statement

Device Name: Uni-Flex Resin

Uni-flex Resin is a flexible material that is used to produce the denture base in prosthetic partials.

This material is packed and sealed in aluminum cartridges which are especially made to fit the Injection Mold System machine. To begin the production of a partial a cartridge is heated to 490'F. This allows the material becomes molten. The process of melting lasts ten minutes. After the material becomes molten the operator turns the handle of the Injection Mold System. This forces the material to inject into a previously prepared dental mold encased in an Injection Mold Flask. After the injection the cool down period lasts three minutes, the operator must remove the flask from the machine during this time. Then a twenty minute bench cool down period follows, only after the twenty minutes mold is removed from the flask. After this elapsed time the denture is now ready for finishing and high shine polish.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983461

NOT A PRESCRIPTION DEVICE