

K07 2746

510(k) SUMMARY
Tokuyama Dental Corporation
E-1 ESTHETIC COMPOSITE SYSTEM

DEC 04 2007

Name of Device

Trade or Proprietary Name: E-1 ESTHETIC COMPOSITE SYSTEM
Common Name: tooth shade resin material
Classification Name: material, tooth shade, resin
Product Code: EBF

Preparation Date

September 12, 2007

510(k) Sponsor

Tokuyama Dental Corporation
38-9 Taitou 1-chome, Taitou-ku
Tokyo
110-0016
Japan

510(k) Sponsor Contact

Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W., Suite 1100
Washington, DC 20005
Phone: (202) 783-5070
Facsimile: (202) 783-2331

Intended Use

The E-1 ESTHETIC COMPOSITE SYSTEM tooth shade resin material is a light-cured, radiopaque, submicron-filled composite resin system for use in dental procedures such as anterior and posterior restorations including occlusal surfaces, direct bonded composite veneers, diastema closures, and the repair of porcelain/composites.

Technological Characteristics and Substantial Equivalence

The E-1 ESTHETIC COMPOSITE SYSTEM device is substantially equivalent to multiple predicate devices (K#980051 and K#051808) with respect to flexural strength, water sorption, solubility, and depth of cure for various curing times. Although the E-1 ESTHETIC COMPOSITE SYSTEM device may have slightly different performance characteristics than the predicate devices, these differences do not raise new questions of safety or effectiveness. All ingredients used in the E-1 ESTHETIC COMPOSITE SYSTEM are biocompatible, as demonstrated by their common use in similar dental devices such as the predicate devices identified above.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 04 2007

Tokuyama Dental Corporation
C/O Mr. Keith A. Barritt, Esq.
Fish & Richardson P.C.
1425 K Street, N.W., Suite 1100
Washington, District of Columbia 20005

Re: K072746

Trade/Device Name: E-1 Esthetic Composite System
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: September 26, 2007
Received: October 2, 2007

Dear Mr. Barritt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

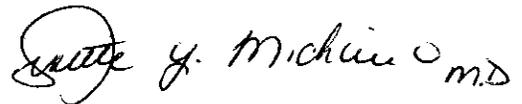
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Chiu Lin, M.D." with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): unknown **K072746**

Device Name: E-1 ESTHETIC COMPOSITE SYSTEM

Indications for Use:

The E-1 ESTHETIC COMPOSITE SYSTEM is for use as a tooth shade resin material in dental procedures.

Prescription Use
(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Rimmer

(Signature)
Special Representative, General Inquiries
Division of Dental Devices

K072746