AUG 8 - 2005

K051808

510(k) SUMMARY
Tokuyama Dental Corporation
ESTELITE FLOW QUICK

Name of Device

Trade or Proprietary Name:	ESTELITE FLOW QUICK
Common Name:	tooth shade resin material
Classification Name:	material, tooth shade, resin
Product Code:	EBF

Preparation Date

May 5, 2005

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

ESTELITE FLOW QUICK is a low viscous, light cured hybrid composite dental tooth shade resin material. It is intended for use in various dental procedures, including direct anterior and posterior restorations (particularly for small/shallow/tunnel shaped cavities), as the first layer of direct restorations, blocking out cavity undercuts before fabricating indirect restorations, and repair of porcelain/composite materials.

Technological Characteristics and Substantial Equivalence

The chemical structure of ESTELITE FLOW QUICK is nearly identical to that of Tokuyama's own PALFIQUE ESTELITE LV (K#002863). The only change is a slight modification to the formula by adding three new chemicals, each of which comprising more than 0.1% of the total ingredients, which results in a reduction in the curing time of the device.

The ESTELITE FLOW QUICK is substantially equivalent to Tokuyama's own PALFIQUE ESTELITE LV (K#002863) for purposes of FDA market authorization. Although the ESTELITE FLOW QUICK has a slightly different chemical formulation resulting in improved performance, these differences do not raise new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 8 - 2005

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: K051808
Trade/Device Name: Estelite Flow Quick
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: June 30, 2005
Received: July 08, 2005

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" (21 CFR 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,

Chiu S. Lin, PhD
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): K051808

Device Name: ESTELITE FLOW QUICK

Indications For Use:

For use as a tooth shade resin material in dental procedures

Prescription Use x AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

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

510(k) Number: K051808