

K081554

MAR 18 2009

510(k) SUMMARY  
Tokuyama Dental Corporation  
TOKUYAMA TISSUECARE  
Denture Relining, Repairing, Or Rebasing Resin Material Kit

**Name of Device**

Trade or Proprietary Name: TOKUYAMA TISSUECARE denture relining, repairing,  
or rebasing resin material kit

Common Name: denture relining, repairing, or rebasing resin material

Classification Name: resin, denture, relining, repairing, rebasing

Product Code: EBI

**Preparation Date**

May 8, 2008

**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 TOKUYAMA TISSUECARE denture relining, repairing, or rebasing resin material kit is a tissue conditioner and temporary liner for removable dentures. It is a prescription device intended for short-term use for conditioning of soft tissue distorted or damaged by the wearing of ill-fitting dentures, and for use as a temporary lining to make existing dentures more comfortable immediately after tooth extraction or oral surgery.

### Technological Characteristics and Substantial Equivalence

The main components of the TOKUYAMA TISSUECARE kit are:

- (1) powder (containing polyalkyl methacrylate and amorphous silica filler);
- (2) liquid (containing polyalkyl acrylate plasticizer and ethanol); and
- (3) adhesive (containing polyalkyl methacrylate and ethyl acetate).

The liner is formed by combining the powder and the liquid. The adhesive is used to bond the acrylic surface (it cannot be used to bond nylon, metal, or silicone surfaces). The TOKUYAMA TISSUECARE device utilizes a plasticizer that allows for continuous malleability and almost no surface roughness of the lining material when used in the short term.

The TOKUYAMA TISSUECARE denture relining, repairing, or rebasing resin material kit is substantially equivalent to several predicate devices, including Austenal's "Myerson's Permasoft Soft Reline Material" (K#933468).

Although the TOKUYAMA TISSUECARE denture relining, repairing, or rebasing resin material kit may have slightly different performance characteristics than the predicate devices, these differences do not raise new questions of safety or effectiveness. The efficacy of the device has been shown to be substantially equivalent pursuant to ISO10139-1:1991, and all ingredients used in the TOKUYAMA TISSUECARE denture relining, repairing, or rebasing resin material kit are biocompatible.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Tokuyama Dental Corporation  
C/o Mr. Keith Barritt  
Fish and Richardson P.C.  
1425 K Street, NW  
Suite 1100  
Washington, DC 20005

MAR 18 2009

Re: K081554  
Trade/Device Name: TOKUYAMA TISSUECARE  
Regulation Number: 21 CFR 872.3760  
Regulation Name: Denture Relining, Repairing, or Rebasing Resin  
Regulatory Class: II  
Product Code: EBI  
Dated: March 13, 2009  
Received: March 16, 2009

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Ginette Y. Michaud, M.D.  
Acting Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

K081554

Indications for Use

510(k) Number (if known): unknown

Device Name: TOKUYAMA TISSUECARE

Indications for Use:

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Prescription Use  X   
(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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Ken Mahy for MSR*

(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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