



K062409

Date: August 16, 2006

510(k) Summary

NOV - 8 2006

1. 510(k) owner (submitter)

- 1) Name KURARAY MEDICAL INC.
- 2) Address 1621 Sakazu, Kurashiki, Okayama 710-0801, Japan
- 3) Contact person Michio Takigawa  
Quality Assurance Department
- 4) Contact person in U.S. Koji Nishida  
KURARAY AMERICA, INC.  
600 Lexington Avenue, 26th Floor  
New York, NY 10022  
Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676  
Fax: (212)-867-3543

2. Name of Device

- 1) Trade / Proprietary name K-ETCHANT GEL
- 2) Classification name Resin tooth bonding agent  
(21 CFR section 872.3200. Product code: KLE)
- 3) Common name Etching agent

3. Predicate device

The aim of this submission is to market K-ETCHANT GEL, which has been one of the components in CLEARFIL PHOTO BOND, independently as a single device "K-ETCHANT GEL".

- 1) CLEARFIL PHOTO BOND
  - 510(k) Number: K943165  
K012432 (modification)
  - Product Code: KLE
  - 21 CFR Section: 872.3200
  - Applicant: KURARAY MEDICAL INC.
- 2) PULPDENT ETCH-RITE ROYALE
  - 510(k) Number: K031915
  - Product Code: KLE
  - 21 CFR Section: 872.3200
  - Applicant: PULPDENT CORPORATION

4. Description of device

K-ETCHANT GEL is an etching agent consists of 40 % phosphoric acid aqueous solution and colloidal silica. It is classified into resin tooth bonding agent, 21 CFR Section 872.3200, because it is a device intended to be painted on the interior of a prepared cavity of a tooth to improve retention of a restoration.

5. Intended use

K-ETCHANT GEL is intended to be used for the following indication;  
- Etching the enamel and dentine for adhesive restorations

6. Substantial equivalence

K-ETCHANT GEL has been one of the components in, and will be marketed independently as a single device "K-ETCHANT GEL" from CLEARFIL PHOTO BOND.

The applicant device, is essentially the same as K-ETCHANT GEL in CLEARFIL PHOTO BOND that its safety and effectiveness are substantially equivalent to this predicate device. It shares the same intended use with other legally marketed devices of this kind marketed single item such as PULPDENT ETCH-RITE ROYALE.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Kuraray Medical, Incorporated  
C/O Mr. Koji Nishida  
General Manager  
Kuraray America, Incorporated  
600 Lexington Avenue, 26<sup>th</sup> Floor  
New York, New York 10022

NOV - 8 2006

Re: K062409  
Trade/Device Name: K-ETCHANT GEL  
Regulation Number: 872.3690  
Regulation Name: Tooth Shade Resin Material  
Regulatory Class: II  
Product Code: EBF  
Dated: August 16, 2006  
Received: August 24, 2006

Dear Mr. Nishida:

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,



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): K 062409

Device Name: K-ETCHANT GEL

Indications for Use:

- 1) Etching the enamel and dentine for adhesive restorations.

Prescription Use   X   AND/OR Over-The-Counter Use   N/A    
(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: K 062409