JUN 7 2002

[CLEARFIL SA PRIMER, Kuraray Medical Inc.]

K021427

510(k) SUMMARY

1. Submitter

1) Name	KURARAY MEDICAL INC.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-8622, Japan
3) Contact person	Koji Nishida Dental Material Department
4) Date	March , 2001
5) Contact person in U.S.A.	Masaya Sasaki Kuraray America, Inc. 101 East 52nd Street, 26th Floor, New York, NY 10022 Telephone : (212)-986-2230 (Ext.115) Facsimile : (212)-867-3543

2. Name of Device

1) Proprietary Name	CLEARFIL SA PRIMER
2) Classification Name	Resin tooth bonding agent (21CFR 872.3200)
3) Common/Usual Name	Adhesion primer

3. Predicate device:

The predicate devices are as follows.

1. CLEARFIL LINER BOND SYSTEM by Kuraray Co., Ltd. (K943166)
2. CLEARFIL PHOTO BOND by Kuraray Medical Inc. (K012432)

4. Description for the premarket notification

CLEARFIL SA PRIMER is the adhesion primer to enhance the bond strength to dentine of CLEARFIL PHOT BOND when used in conjunction with it. Therefore this device is classified into Adhesion primer, CFR 21 Section 872.3200, because it is a device containing dimethacrylate monomer intended to be painted on the interior of a prepared cavity of a tooth to improve retention of a restoration, such as a composite filling.

5. Statement of the intended use

The intended use is as follow when this device is used in conjunction with a phosphoric acid etching agent and a bonding agent contained in CLEARFIL PHOTO BOND (K012432)

1) A dentin and enamel bonding system for composite resin restoration

6. Statement of the technological characteristics and safety

6-1. Technological characteristics

This device is a same solution of N-Methacryloyl-5-Aminosalicilic acid and is essentially the same as the adhesion primer, SA PRIMER, of CLEARFIL LINER BOND SYSTEM (K943166). When used in conjunction with CLEARFIL PHOTO BOND (K012432), this device is applied on the etched tooth structures with the phosphoric acid etching agent before application of the bonding agent. In case of CLEARFRIL LINER BOND SYSTEM, the adhesion primer is applied on the etched/conditioned tooth structures with the citric acid-calcium chloride conditioner, CA

Agent, before application of the bonding agent which is a component of CLEARFIL PHOTO BOND. Therefore the technological characteristics of this device is substantially same to CLEARFIL LINER BOND SYSTEM (K943166).

6-2. Safety

This device is a same solution of N-Methacryloyl-5-Aminosalicilic acid and is essentially the same as the adhesion primer, SA PRIMER, of CLEARFIL LINER BOND SYSTEM (K943166). Therefore the safety of this device are completely the same as SA PRIMER of CLEARFIL LINER BOND SYSTEM.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 7 2002

Kuraray Medical, Incorporated
C/O Masaya Sasaki
Kuraray America, Incorporated
101 East 52nd Street, 26th Floor
New York, New York 10022

Re: K021427
Trade/Device Name: CLEARFIL SA PRIMER
Regulation Number: 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: April 25, 2002
Received: May 03, 2002

Dear Masaya Sasaki:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/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

Indications for Use

CLEAFIL SA PRIMER is indicated for the following applications:

1) A dentin and enamel bonding system for composite resin restoration

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Part 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021427