KURARAY CO., LTD.

12-39, 1-Chome, Umeda, Kita-ku, Osaka 530-8611, JAPAN
Phone : +81-6-6348-2603
Facsimile: +81-6-6348-2552

510(k) SUMMARY

1. Submitter

1) Name	KURARAY CO., LTD.
2) Address	1-12-39, Umeda, Kita-ku, Osaka 530-8611, Japan
3) Telephone	81(Japan)-6-6348-2603
4) Facsimile	81(Japan)-6-6348-2552
5) Contact person	Yoshinori Nagase Dental Material Department Medical Products Division
6) Date	January 6, 1999

2. Representing (Subsidiary of KURARAY CO., LTD.)

1) Name	KURARAY AMERICA INC.
2) Address	30th Fl. Metlife Building, 200 Park Avenue, New York, NY 10166
3) Telephone	(212)-986-2230
4) Facsimile	(212)-867-3543
5) Contact person	Koji Fujita President

3. Name of Device

1) Proprietary Name	CLEARFIL SE BOND
2) Classification Name	Resin tooth bonding agent (21CFR 872.3200)
3) Common/Usual Name	Resin-based dental adhesive system

4. Predicate devices:

1.	CLEARFIL LINER BOND 2V by KURARAY CO.,LTD.	(K974486)
2.	CLEARFIL LINER BOND 2 by KURARAY CO.,LTD.	(K943170)
3.	CLEARFIL PHOTO BOND by KURARAY CO.,LTD.	(K943165)
4.	PRIME & BOND 2.1 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT WITH ACTIVATOR by DENTSPLY	(K964525)
5.	GLUMA ONE BOND by HERAEUS KULZER, INC.	(K974390)
6.	ONE STEP UNIVERSAL DENTAL ADHESIVE SYSTEM by BISCO, INC.	(K#unknown)
7.	ALL-BOND 2 by BISCO, INC.	(K910860)
8.	OPTIBOND by KERR MFG.CO	(K934690)

5. Description for the premarket notification

CLEARFIL SE BOND is classified into the resin tooth bonding agent, CFR 21 Section 872.3200, because it is a device composed of materials such as dimethacrylate monomers intended to painted on the interior of a prepared cavity of a tooth to improve retention of restorative materials.

This product is similar and substantially equivalent in design, composition and function to the

similar products which are identified in the paragraph 4 of this summary; all of which are safe, effective and beneficial.

6. Statement of the intended use

This device is used for the following indications. Each indication is same to that of similar products.

1) Direct filling restorations using light-curing composite or compomer
   a) CLEARFIL LINER BOND 2V by KURARAY CO., LTD. (K974486)
   b) CLEARFIL LINER BOND 2 by KURARAY CO., LTD. (K943170)
   c) PRIME & BOND 2.1 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT WITH ACTIVATOR by DENTSPLY (K964525)
   d) GLUMA ONE BOND by HERAEUS KULZER, INC. (K974390)

2) Cavity sealing as a pretreatment for indirect restorations
   a) CLEARFIL LINER BOND 2V by KURARAY CO., LTD. (K974486)
   b) ONE STEP UNIVERSAL DENTAL ADHESIVE SYSTEM by BISCO, INC. (K#unknown)
   c) ALL-BOND 2 by BISCO, INC. (K910860)
   d) OPTIBOND by KERR MFG.CO (K934690)

3) Treatment of hypersensitive and/or exposed root surfaces
   a) CLEARFIL LINER BOND 2V by KURARAY CO., LTD. (K974486)
   b) CLEARFIL LINER BOND 2 by KURARAY CO., LTD. (K943170)
   c) PRIME & BOND 2.1 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT WITH ACTIVATOR by DENTSPLY (K964525)
   d) ONE STEP UNIVERSAL DENTAL ADHESIVE SYSTEM by BISCO, INC. (K#unknown)

4) Intraoral repairs of fractured facing crowns made of porcelain, hybrid ceramics or composite resin using light-curing composite
   a) CLEARFIL LINER BOND 2V by KURARAY CO., LTD. (K974486)
   b) PRIME & BOND 2.1 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT WITH ACTIVATOR by DENTSPLY (K964525)

5) Surface treatment of prosthetic appliances made of porcelain, hybrid ceramics and cured composite resin
   a) CLEARFIL LINER BOND 2V by KURARAY CO., LTD. (K974486)
   b) CLEARFIL PHOTO BOND by KURARAY CO., LTD. (K943165)

7. Statement of the technological characteristics and safety

CLEARFIL SE BOND is developed as a simplified system of CLEARFIL LINER BOND 2V permitted to be marketed (K974486). CLEARFIL SE BOND is substantially equivalent to those of products sold in the U.S. market in design, components and functions.

7-1 Components

CLEARFIL SE BOND consists of Primer, Bonding Agent, Etching Agent and accessories. These components are similar to those of the products in the paragraph 4 of this summary.

7-2 Performance

There is no ISO standard applicable to CLEARFIL SE BOND. The bond strengths to human enamel, human dentine, precious metal and porcelain were evaluated in comparison with CLEARFIL LINER BOND 2V. The bonding performances are substantially equivalent to those of CLEARFIL LINER BOND 2V.

7-3 Chemical ingredients and safety

The chemical ingredients have been used in the following products allowed to be sold in U.S. market. The safety of this product is substantially equivalent to the predicated devices.

a) CLEARFIL LINER BOND 2V by KURARAY CO., LTD. (K974486)
b) PANAVIA F by KURARAY CO., LTD. (K983361)
c) ESTENIA by KURARAY CO., LTD. (K982164)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 1999

Kuraray Co., Ltd.
C/O Mr. Koji Fujita
President
Kuraray America, Incorporated
30th FI Metlife Building
200 Park Avenue
New York, New York 10166-3098

Re: K990040
Trade Name: CLEARFIL SE BOND
Regulatory Class: II
Product Code: KLE
Dated: January 6, 1999
Received: January 6, 1999

Dear Mr. Fujita:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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

K990040

[CLEARFIL SE BOND, Kuraray]

510(k) Number (if known): K990040

Device Name: CLERFIL SE BOND

Indications For Use

CLEARFIL SE BOND is indicated for the following applications:

1) Direct filling restorations using light-curing composite or compomer
2) Cavity sealing as a pretreatment for indirect restorations
3) Treatment of hypersensitive and/or exposed root surfaces
4) Intraoral repairs of fractured facing crowns made of porcelain, hybrid ceramics and cured composite resin
5) Surface treatment of prosthetic appliances made of porcelain, hybrid ceramics and cured composite resin

(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)

(Division Sign-Off)
Division of [illegible] and General Hospital Devices
510(k) Number K990040