KURARAY CO., LTD.
12-39, 1-Chome, Umeda, Kita-ku, Osaka 530, JAPAN
Phone : +81-6-348-2603
Facsimile: +81-6-348-2552

JAN 29 1998

K974486

510(k) SUMMARY

1. Submitter

1)	Name	Kuraray Co., Ltd.
2)	Address	1-12-39, Umeda, Kita-ku, Osaka 530, Japan
3)	Telephone	81(Japan)6-348-2603
4)	Facsimile	81(Japan)6-348-2552
5)	Contact person	Yoshinori Nagase Dental Material Department Medical Products Division
6)	Date	December 2, 1997

2. Representing (Subsidiary of Kuraray Co., Ltd.)

1)	Name	Kuraray America, Inc.
2)	Address	30th Fl. Metlife Buiding, 200 Park Avenue, New York, NY 10166
3)	Telephone	(212)986-2230
4)	Facsimile	(212)876-3543
5)	Contact person	Koji Fujita President

3. Name of Device

1)	Proprietary Name	CLEARFIL LINER BOND 2V
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 2 by Kuraray Co., Ltd.	(K943170)
2)	CLEARFIL PORCELAIN BOND by Kuraray Co., Ltd.	(K871636)
3)	CLEARFIL PHOTO BOND by Kuraray Co., Ltd.	(K943165)
4)	CLEARFIL NEW BOND by Kuraray Co., Ltd.	(K943167)
5)	SCOTCHBOND MULTI-PURPOSE PLUS DENTAL ADHESIVE SYSTEM by 3M COMPANY	(K942493)
6)	PRIME & BOND 2.1 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT WITH ACTIVATOR by DENTSPLY	(K964525)
7)	ALL-BOND 2 by BISCO, INC.	(K910860)
8)	PROBOND by LD CAULK/DENTSPLY	unknown
9)	OPTIBOND by KERR MFG.CO	(K934690)

5. Description for the premarket notification

CLEARFIL LINER BOND 2V 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. PROTECT LINER F is classified into tooth shade resin material, CFR 21 Section 872.3690, because it is a device composed of material such as bisphenol A glycidylmethacrylate (Bis-GMA) intended to restore carious or structural defects in teeth. CLEARFIL PORCELAIN BOND ACTIVATOR was permitted to marketed under its 510 (k) notification submission.

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 as that of similar products.

1) Direct filling restorations using light-cure or chemical-cure composite resin

a)	CLEARFIL LINER BOND 2 by Kuraray Co., Ltd.	(K943170)
b)	CLEARFIL PHOTO BOND by Kuraray Co., Ltd.	(K943165)
c)	CLEARFIL NEW BOND by Kuraray Co., Ltd.	(K943167)
d)	SCOTCHBOND MULTI-PURPOSE PLUS DENTAL ADHESIVE SYSTEM by 3M COMPANY.	(K942493)
e)	PRIME & BOND 2.1 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT WITH ACTIVATOR by DENTSPLY	(K964525)
f)	ALL-BOND 2 by BISCO, INC.	(K910860)
g)	PROBOND by LD CAULK/DENTSPLY	unknown
h)	OPTIBOND by KERR MFG.CO	(K934690)

2) Bonded amalgam restorations

a)	CLEARFIL LINER BOND 2 by Kuraray Co., Ltd.	(K943170)
b)	CLEARFIL PHOTO BOND by Kuraray Co., Ltd.	(K943165)
c)	CLEARFIL NEW BOND by Kuraray Co., Ltd.	(K943167)
d)	ALL-BOND 2 by BISCO, INC.	(K910860)
e)	PROBOND by LD CAULK/DENTSPLY	unknown
f)	OPTIBOND by KERR MFG.CO	(K934690)

3) Treatment of hypersensitive and/or exposed root surfaces

a)	CLEARFIL LINER BOND 2 by Kuraray Co., Ltd.	(K943170)
b)	ALL-BOND 2 by BISCO, INC.	(K910860)

4) Cavity sealing as a pretreatment for indirect restorations

a)	ALL-BOND 2 by BISCO, INC.	(K910860)
b)	OPTIBOND by KERR MFG.CO	(K934690)

5) Intraoral repairs of facing crowns using light-cure composite resin

a) CLEARFIL PORCELAIN BOND by Kuraray Co., Ltd. (K871636)
b) SCOTCHBOND MULTI-PURPOSE PLUS DENTAL ADHESIVE SYSTEM by 3M COMPANY. (K942493)
c) PRIME & BOND 2.1 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT WITH ACTIVATOR by DENTSPLY (K964525)
d) PROBOND by LD CAULK/DENTSPLY unknown
e) ALL-BOND 2 by BISCO, INC. (K910860)
f) OPTIBOND by KERR MFG.CO (K934690)

6) Cementing laminate veneers, inlays and onlays made of porcelain (or composite resin) using composite resin cement

a) SCOTCHBOND MULTI-PURPOSE PLUS DENTAL ADHESIVE SYSTEM by 3M COMPANY. (K942493)
b) PROBOND by LD CAULK/DENTSPLY unknown
c) ALL-BOND 2 by BISCO, INC. (K910860)
d) OPTIBOND by KERR MFG.CO (K934690)

7. Statement of the technological characteristics and safety

This device is developed as a improved material of CLEARFIL LINER BOND 2 (K943170).

7-1. Components

The new component, BOND Liquid B, is used as a mixture with BOND Liquid A to enable the practitioner to use self-cure or dual-cure techniques. The etching agent and the porcelain primer are introduced to use for special intended purpose. These components are same components in the CLEARFIL PHOTO BOND (K943165) and CLEAFIL PORCELAIN BOND (K871636).

7-2. Chemical ingredients

The chemical ingredients excepting DMABB have been already used in the following devices sold in the U.S. market. All of them are manufactured by Kuraray Co., Ltd.

a) CLEARFIL LINER BOND 2 (K943170)
b) PANAVIA 21(K933030) classified into the dental cement other than zinc oxide-eugenol (21 CFR 872.3275(b))
c) CLEARFIL PHOTO BOND (K943165)
d) CLEARFIL PORCELAIN BOND (K871636)

8. Summary of toxicity study

The chemical ingredients excepting DMABB have been already used in Kuraray's dental material allowed to be sold in US market as described in the paragraph 7-2. The biocompatibility of DMABB was evaluated its acute toxicity (LD50), genotoxicity and sensitization. Additionally The amount of leaching DMABB from cured resin into distilled water is evaluated.

These results suggest that CLEARFIL LINER BOND 2V is a safe dental device.

8-1 Biological evaluation of DMABB

8-1-1 Acute toxicity

1)	Animal	Mouse
2)	Dosing route	Oral
3)	Dosing period	10 days
4)	Results	LD50; not less than 4,000 mg/kg

8-1-2 Genotoxicity test

1)	Method	Ames mutagenicity test
2)	Results	Negative

Bacterial species	Genotoxicity	
	with S-9 mix	without S-9 mix
Salmonella typhimurium TA100	Negative	Negative
Salmonella typhimurium TA1535	Negative	Negative
Escherichia coli WP2 *uvrA*	Negative	Negative
Salmonella typhimurium TA98	Negative	Negative
Salmonella typhimurium TA1537	Negative	Negative

This test was based on ISO 10993-3 (1992-12-15), biological evaluation of medical devices-part 3.

8-1-3 sensitization (maximization test)

1)	Method	Maximization sensitization test
2)	Results	Negative

This test was based on ISO 10993-10 (1995-3-15), biological evaluation on medical devices.

8-2 Leachables

8-2-1 Amount of DMABB leached from cured resin

1)	Sample	Cured resin 10mm ϕ × 5 mm.
2)	Extraction media	Distilled water
3)	Method	Two pieces of cured resin were immersed into 20ml of distilled water and stored at 37℃ or 50℃ for 24 hours. The amount of leached DMABB in measured using high pressure liquid chromatography.
4)	Result	Less than identification limit (0.04ppm) for both conditions

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 1998

Mr. Koji Fujita
President
Kuraray America, Incorporated
200 Park Avenue
New York, New York 10166

Re: K974486
Trade Name: Clearfil Liner Bond 2V
Regulatory Class: II
Product Code: KLE
Dated: November 25, 1997
Received: November 26, 1997

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4618. 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

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510(k) Number(if known): K974486

Device Name: CLEARFIL LINER BOND 2V

Indications For Use

1) Direct filling restorations using light-cure or chemical-cure composite resin
2) Bonded amalgam restorations
3) Treatment of hypersensitive and/or exposed root surfaces
4) Cavity sealing as a pretreatment for indirect restorations
5) Intraoral repairs of facing crowns using light-cure composite resin
6) Cementing laminate veneers, inlays and onlays made of porcelain (or composite resin) using composite resin cement

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K974456

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

(Optional Format 1-2-96)