K012440

KURARAY MEDICAL INC.
Dental Material Department
12-39, 1-Chome, Umeda, Kita-ku, Osaka 530-8611, JAPAN
Phone : +81-6-348-2603
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510(k) SUMMARY

1. Submitter

1)	KURARAY MEDICAL INC.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-8622, Japan
3) Contact person	Koji Nishida DENTAL MATERIAL DEPARTMENT
4) Date	July 23, 2001
5) Contact person in U.S.A.	Masaya Sasaki 30th Fl. Metlife Building, 200 Park Avenue, New York, NY 10166 Telephone : (212)-986-2230 1(800)-879-1676 Facsimile : (212)-867-3543

2. 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

3. Predicate device:

Kuraray Co., Ltd. will transfer the medical device business and the relevant functions including manufacturing facilities to its subsidiary company named Kuraray Medical Inc. on October 1st 2001. The aim of 510(k) submission is to alter the name and address of manufacturer, and not to intend other changes.

The predicate device is as follow.

1. CLEARFIL LINER BOND 2V by Kuraray Co., Ltd. (K974486)

4. 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 market under its 510(k) notification submission.

5. Statement of the intended use

The intended uses of this device are as follows. They are completely the same as CLEARFIL LINER BOND 2V manufactured by Kuraray Co., Ltd. (K974486).

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

6. Statement of the technological characteristics and safety

This device is essentially the same as CLEARFIL LINER BOND 2V manufactured by Kuraray Co., Ltd. (K974486). Therefore the technological characteristics, chemical ingredients and safety of this device are completely the same as CLEARFIL LINER BOND 2V.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2001

Kuraray Medical Incorporated
C/O Ms. Masaya Sasaki
Kuraray America, Incorporated
30th Floor Metlife Building
200 Park Avenue
New York, New York 10166

Re: K012440
Trade/Device Name: Modification To Clearfil Liner Bond 2V
Regulation Number: 872.3200
Regulatory Class: II
Product Code: KLE
Dated: Jul 23, 2001
Received: July 31, 2001

Dear Ms. Sasaki:

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 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). 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 requirements, 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) 594-4613. 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 807.97). Other general information on ycur 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

K012440

510(k) Number (if known): K012440

Device Name: CLEARFIL LINER BOND 2V

Indications for Use

CLEAFIL LINER BOND 2V is indicated for the following applications:

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)

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 K012440