K023842

FEB 11 2003

KURARAY MEDICAL INC.

Dental Material Department
3-1-6 Nihonbashi, Chuo-ku, Tokyo 103-8254, Japan
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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	November 11, 2002
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 SE BOND PLUS
2) Classification Name	Resin tooth bonding agent (21CFR 872.3200)
3) Common/Usual Name	Resin-based dental adhesive system

3. Predicate device:

The predicate products are;

a) Resin Tooth Bonding Agent

1. CLEARFIL SE BOND	by Kuraray Medical Inc.	(K012442)
2. CLEARFIL LINER BOND 2V	by Kuraray Medical Inc.	(K012440)
3. TOKUYAMA ONE-UP-BOND F	by Tokuyama America Inc.	(K993917)
4. IMPERVA FLUORO BOND	by Shofu Dental Corp.	(K953612)
5. PRIME & BOND NT DUAL CURE UNIVERSAL DENTAL ADHESIVE SYSTEM	by Dentsply Intl.	(K982394)
6. OPTIBOND SOLO PLUS 4	by KERR DENTAL MATERIALS CENTER.	(K014027)

b) Other dental materials

1. PANAVIA F	by Kuraray Medical Inc.	(K012441)
2. SEAL & PROTECT PROTECTIVE SEALANT	by Dentsply Intl.	(K021805)
3. PANAVIA EX	by Kuraray Co., Ltd.	(K855211)
4. ESTENIA	by Kuraray Medical Inc.	(K012707)

4. Description for the premarket notification

CLEARFIL SE BOND PLUS 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.

5 Statement of the intended use

This device has the following indications for use which are substantially equivalent to the legally marketed predicate devices.

Indications for use	Predicate device
1) Direct restorations using light-cured composite resin 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 crowns/bridges made of porcelain, hybrid ceramics or composite resin using light-cured composite resin 5) Surface treatment of prosthetic appliances made of porcelain, hybrid ceramics and cured composite resin	CLEARFIL SE BOND (K012442)
6) Core build-ups using light- or dual-cured composite resin	OPTIBOND SOLO PLUS 4 (K014027)
7) Cavity sealing under amalgam restorations	PRIME & BOND NT DUAL CURE UNIVERSAL DENTAL ADHESIVE SYSTEM (K982394)

6. Statement of the technological characteristics and safety

6-1 Design/Components

This device consists of the primer, the bond and the accessories, and is substantially equivalent in design to CLEARFIL SE BOND.

6-2 Material and chemical ingredients

The ingredients other than MDPB are used in the legally marketed predicate devices; CLEARFIL SE BOND etc. The biocompatibilities of the new ingredient, MDPB, and this device were evaluated according to ISO 7405: 1997 and ISO 10993-1: 1997. As to the results, this device is judged that it is substantially equivalent in safety to the legally marketed predicate devices.

6-3 Mechanical properties

The bond strengths between bovine tooth and a composite resin and a fresh amalgam were evaluated in comparison with the legally marketed predicate devices; CLEARFIL SE BOND etc. The bond strengths between composite resin and various substances were evaluated when used as intra-oral repairs of fractured crowns/bridges. The marginal sealing was also evaluated when used as direct filling and cavity sealing under amalgam restoration. As to the result, this device is substantially equivalent to the legally marketed predicate devices in effectiveness.

6-4 Physical properties

The amount of fluorine ion from the cured material immersed in water was evaluated in comparison with the legally marketed predicate devices; TOKUYAMA ONE UP-BOND F, IMPERVA FLUORO BOND and PANAVIA F. The changes in mechanical strength due to fluorine releasing were also evaluated. As to the result, this device is substantially equivalent in the fluoride releasing property including the change of mechanical strength to the legally

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K023842
Trade/Device Name: CLEARFIL SE BOND PLUS
Regulation Number: 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: November 12, 2002
Received: November 18, 2002

Dear Ms. 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), please contact the Office of Compliance at (301) 594-4613. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K023842

Indications for Use

CLEARFIL SE BOND PLUS is indicated for the following applications:

1) Direct restorations using light-cured composite resin 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 crowns/bridges made of porcelain, hybrid ceramics or composite resin using light-cured composite resin
5) Surface treatment of prosthetic appliances made of porcelain, hybrid ceramics and cured composite resin
6) Core build-ups using light- or dual-cured composite resin
7) Cavity sealing under amalgam restorations

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Part 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)

Kevin Mulvey for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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