MAR 2 6 2003

K024356

510(k) SUMMARY

1. Submitter

1) Name	KURARAY MEDICAL INC.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-8622, Japan
3) 1. Contact person	Koji Nishida Dental Material Department, Kuraray Medical Inc.
2. 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) 1-(800)-879-1676 Facsimile: (212)-867-3543
4) Date	December 27, 2002

2. Name of Device

1) Proprietary Name	CLEARFIL SILANE KIT
2) Classification Name	Resin tooth bonding agent (21CFR 872.3200)
3) Common/Usual Name	Surface treatment system for porcelain, hybrid ceramics and cured composite resin

3. Predicate device:
The predicate devices are as follows.
1) CLEARFIL SE BOND manufactured by Kuraray Medical Inc. (K012442)
2) CLEARFIL PORCELAIN BOND ACTIVATOR manufactured by Kuraray Medical Inc. (K012730)
3) CLEARFIL PHOTO BOND manufactured by Kuraray Medical Inc. (K012432)

4 Description for the premarket notification
CLEARFIL SILANE KIT 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 paint on the surface of a porcelain, hybrid ceramics and composite resin.

5 Statement of the intended use
The intended uses of this device are as follows. They are included in those of CLEARFIL SE BOND (K012442).
1) Intraoral repairs of fractured facing crowns made of porcelain, hybrid ceramics or composite resin using light-curing composite.
2) Surface treatment of prosthetic appliances made of porcelain, hybrid ceramics and cured composite resin.

6. Statement of the technological characteristics and safety
This device is a kit product that consists of three components, a primer, an etching agent and a silane coupling agent. These three components are same components in the legally marketed predicate devices; CLEARFIL SE BOND, CLEARFIL PORCELAIN BOND ACTIVATOR and CLEARRIL PHOTO BOND. Additionally, the combination use of these components is described in the instructions for use of CLEARFIL SE BOND.

Therefore this device is substantially equivalent of the legally marketed predicate devices in the technological characteristics, chemical ingredients and safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2003

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

Re: K024356
Trade/Device Name: Clearfil Silane Kit
Regulation Number: 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: December 27, 2002
Received: December 30, 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

510(k) Number (if known): K024356

Device Name: CLEARFIL SILANE KIT

Indications for Use

CLEARFIL SILANE KIT is indicated for the following applications:

1) Intraoral repairs of fractured facing crowns made of porcelain, hybrid ceramics or composite resin using light-curing composite.
2) 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 X OR Over-The-Counter Use_____

(Optional Format 1-2-96

Kevin Mulvey for M S K
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K024356