K061906

KURARAY MEDICAL INC.
Quality Assurance Department
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SEP 28 2006

Date: June 30, 2006

510(k) Summary

3-1. 510(k) owner (submitter)

1) Name	KURARAY MEDICAL INC.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-0801, Japan
3) Contact person	Michio Takigawa Quality Assurance Department
4) Contact person in U.S.	Koji Nishida KURARAY AMERICA INC. 101 East 52nd Street, 26th Floor New York, NY 10022 Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676 Fax: (212)-867-3543

3-2. Name of Device

1) Trade / Proprietary name	CLEARFIL CERAMIC PRIMER
2) Classification name	Resin tooth bonding agent (21 CFR section 872.3200. Product code: KLE)
3) Common name	Silane coupling agent

3-3. Predicate device

1) CLEARFIL PORCELAIN BOND ACTIVATOR	510(k) Number: Product Code: 21 CFR Section: Applicant:	K012730 KLE 872.3200 KURARAY MEDICAL INC.
2) CLEARFIL SE BOND	510(k) Number: Product Code: 21 CFR Section: Applicant:	K012442 KLE 872.3200 KURARAY AMERICA, INC.
3) CLEARFIL TRI-S BOND	510(k) Number: Product Code: 21 CFR Section: Applicant:	K042913 KLE 872.3200 KURARAY COMPANY, LTD.
4) MONOBOND S	510(k) Number: Product Code: 21 CFR Section: Applicant:	K905220 EBF 872.3690 IVOCLAR NORTH AMERICA, INC.

3-4. Description of device

CLEARFIL CERAMIC PRIMER is a silane-coupling agent that provides an enhanced adhesive surface to porcelain, ceramics, hybrid ceramics or composite resin.

It is intended to be used for the indications listed in the right hand column of the below table that are equivalent to the predicate devices.

Table 3: Indications for Use and predicate devices

Indications for Use	Predicate devices
1) Surface treatment of porcelain, ceramics, hybrid ceramics or composite resin	- MONOBOND S - CLEARFIL SE BOND (not indicating ceramics) - CLEARFIL TRI-S BOND and CLEARFIL PORCELAIN BOND ACTIVATOR (not indicating ceramics or hybrid ceramics)
2) Intraoral repairs of fractured crowns/bridges made of porcelain, ceramics, hybrid ceramics or composite resin	- MONOBOND S - CLEARFIL SE BOND (not indicating ceramics) - CLEARFIL TRI-S BOND and CLEARFIL PORCELAIN BOND ACTIVATOR (not indicating ceramics or hybrid ceramics)

3-5. Technological characteristics of device

It can be said that the applicant device is as safe as, as effective, and performs as well as or better than the predicate devices with the followings:

1) Chemical ingredients

All the chemical ingredients of the applicant device have been used in the predicate devices indicating that the safety of the applicant device is substantially equivalent to the predicate devices.

2) Effectiveness / Performance

Tensile bond strength tests on the applicant device in comparison to the predicate devices demonstrate that the applicant device is as effective and performs as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 28 2006

Kuraray Medical, Incorporated
C/O Mr. Koji Nishida
General Manager
Kuraray America, Incorporated
101 East 52nd Street, 26th Floor
New York, New York 10022

Re: K061906
Trade/Device Name: Clearfil Ceramic Primer
Regulation Number: 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: EBF
Dated: June 30, 2006
Received: July 11, 2006

Dear Mr. Nishida:

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.

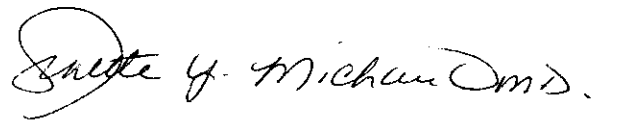
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061906

Device Name: CLEARFIL CERAMIC PRIMER

Indications for Use:

1) Surface treatment of porcelain, ceramics, hybrid ceramics or composite resin
2) Intraoral repairs of fractured crowns/bridges made of porcelain, ceramics, hybrid ceramics or composite resin

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use N/A (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

...n Sign-Off)
...n of Anesthesiology, General Hospital,
...on Control, Dental Devices

...Number: K061906