Date: June. 12, 2013

K131432

510(k) Summary

AUG 2 2 2013

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

1) Name	Kuraray Noritake Dental Inc.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-0801, Japan
3) Contact person	Michio Takigawa Quality Assurance Department
4) Contact person in US	Goro Asanuma KURARAY AMERICA INC. 33 Maiden Lane, 6th Floor, New York, NY 10038 Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676 Fax: (212)-867-3543

3-2. Name of Device

1) Trade / Proprietary name	CLEARFIL SE BOND 2
2) Classification name	Agent, Tooth Bonding, Resin (21 CFR section 872.3200. Product code: KLE)
3) Common name	Dental bonding agent

3-3. Predicate devices

1) CLEARFIL SE BOND	510(k) Number	K012442
	Classification:	Agent, Tooth Bonding, Resin
	Product Code:	KLE
	21 CFR Section:	872.3200
	Applicant:	Kuraray Noritake Dental Inc.
2) CLERFIL DC BOND	510(k) Number:	K062382
	Classification:	Agent, Tooth Bonding, Resin
	Product Code:	KLE
	21 CFR Section:	872.3200
	Applicant:	Kuraray Noritake Dental Inc.
3) Optibond XTR	510(k) Number:	K101423
	Classification:	Agent, Tooth Bonding, Resin
	Product Code:	KLE
	21 CFR Section:	872.3200
	Applicant:	KERR CORPORATION
4) CLEARFIL TRI-S BOND PLUS	510(k) Number:	K111980
	Classification:	Agent, Tooth Bonding, Resin
	Product Code:	KLE
	21 CFR Section:	872.3200
	Applicant:	Kuraray Noritake Dental Inc.
5) CLEARFIL DC CORE AUTOMIX	510(k) Number:	K043177
	Classification:	Material, Tooth Shade, Resin
	Product Code:	EBF
	21 CFR Section:	872.3690
	Applicant:	Kuraray Noritake Dental Inc.

3-4. Device Description

The subject device is a two component, self-etch, light-cured bonding agent, which is intended for universal use for both direct and indirect restorations. The PRIMER allows simultaneous treatment of both dentin and enamel using one liquid. The product is activated by a dual-cure mechanism when the BOND is mixed with CLEARFIL DC Activator. This allows it to be used with dual-cure or self-cure composite filling materials, cements, or core build-up materials.

This is the new registration application for the subject device and there have not been any prior submissions regarding the subject device.

3-5. Statement of Intended Use

The subject device is indicated for the following restorative applications:
[1] Direct restorations using light-cured composite resin
[2] Cavity sealing as a pretreatment for indirect restorations
[3] Treatment of exposed root surfaces
[4] Treatment of hypersensitive teeth
[5] Intraoral repairs of fractured restorations
[6] Post cementation using a dual or self-cured composite resin
[7] Core build-ups using a light-, dual or self-cured core material
[8] Cementing inlays, onlays, crowns, bridges and veneers using a composite resin cement

3-6. Substantial Equivalence Discussion

1) Intended uses
The intended uses of the subject device were written up based on those of the predicate devices. Therefore, the intended uses of the subject device are substantially equivalent to those of the predicate devices.

2) Chemical ingredients/ Safety
All ingredients in the subject have been used in the predicate devices.
Regarding the predicate devices, there have not been any reported problems or recalls according to the post market adverse event reporting requirements in the US.
In conclusion, it can be said that the safety of the subject device is substantially equivalent to that of the predicate devices.

3) Technological characteristics/ Effectiveness and Performance
Since there have not been any international standards concerning performance of this type of device, certain tests were performed on this device considering its intended uses, in comparison with the predicate device.
As the result of the testing, it was confirmed that each tensile bond strength of the subject device was not significantly different or not less than that of the predicate devices.
Therefore, it was considered that the subject device was as effective as and performs as good as the predicate device.
In conclusion, it can be said that the effectiveness and performance of the subject device are substantially equivalent to those of the predicate device.

3-7. Biocompatibility

The subject device is categorized into the external communicating device (tissue/ bone/ dentin) and permanent contact device.
All the chemical ingredients of the subject device are equivalent to those of the predicate devices.
Regarding the predicate devices, there have not been any reported problems or recalls according to the post-market adverse event reporting requirements in the US.
Accordingly, it was considered that the subject device was substantially equivalent in safety to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 22, 2013

Kuraray Noritake Dental, Inc.
C/O Mr. Goro Asanuma
General Manger, Dental Materials Division
Kuraray America, Incorporated
33 Maiden Lane, 6th Floor
New York, NY 10038

Re: K131432
Trade/Device Name: Clearfil SE Bond 2
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Codes: KLE, EMA, EBF
Dated: June 12, 2013
Received: June 14, 2013

Dear Mr. Asanuma:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131432

Device Name: CLEARFIL SE BOND 2

Indications for Use:

[1] Direct restorations using light-cured composite resin
[2] Cavity sealing as a pretreatment for indirect restorations
[3] Treatment of exposed root surfaces
[4] Treatment of hypersensitive teeth
[5] Intraoral repairs of fractured restorations
[6] Post cementation using a dual- or self-cured composite resin
[7] Core build-ups using a light-, dual- or self-cured core material
[8] Cementing inlays, onlays, crowns, bridges and veneers using a composite resin cement

Prescription Use ✓
(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)

Andrew I. Steen -S
2013.08.20 14:10:21 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K131432