K111980

Date: July 6, 2011

OCT 14 2011

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 US	Kiyoyuki Arikawa KURARAY AMERICA INC. 600 Lexington Avenue, 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 TRI-S BOND PLUS
2) Classification name	Resin Tooth Bonding Agent (21 CFR section 872.3690. Product code: KLE)
3) Common name	Dental bonding agent

3-3. Predicate device

1) CLEARFIL TRI-S BOND	510(k) Number:	K042913
	Product Code:	KLE
	21 CFR Section:	872.3690
	Applicant:	KURARAY MEDICAL INC.
2) CLEARFIL DC BOND	510(k) Number:	K062382
	Product Code:	KLE
	21 CFR Section:	872.3200
	Applicant:	KURARAY MEDICAL INC.
3) PANAVIA F 2.0	510(k) Number:	K032455
	Product Code:	EMA
	21 CFR Section:	872.3275
	Applicant:	KURARAY MEDICAL INC.
4) CLEARFIL MAJESTY Flow	510(k) Number:	K063593
	Product Code:	EBF
	21 CFR Section:	872.3690
	Applicant:	KURARAY MEDICAL INC.

3-4. Device Description

The subject device is a single-component, light-cured bonding agent that allows simultaneous treatment of both dentin and enamel.

3-5. Substantial Equivalence Discussion

1) Intended uses

The intended uses of the subject device were written up based on those of CLEARFIL TRI-S BOND and CLEARFIL DC BOND, the predicate devices.
Therefore, the intended uses of the subject device are substantially equivalent to those of the predicate devices.

2) Chemical ingredients / Safety

Except for 2 new chemical ingredients, all ingredients in the subject device 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.
And 2 new ingredients have been evaluated referring to ISO 10993 series and ISO 7405. As the result, it was confirmed that these substances were biocompatible.
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, in comparison with the predicate device and it was confirmed that this device was substantially equivalent to the predicate device in terms of the effectiveness and performance.
Tensile bond strength test and Fluoride releasing property were performed to validate the substantial equivalence of the subject device with the predicate device in terms of effectiveness and performance for the intended uses. The test has exhibited almost the same results for the subject device indicating that the subject device was as effective as and performs as good as or better than the predicate device.

3-6. Biocompatibility

Except for 2 new chemical ingredients, all ingredients in the subject device 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.
And 2 new ingredients have been evaluated referring to ISO 10993 series and ISO 7405. As the result, it was confirmed that these substances were biocompatible.
In conclusion, it was concluded that the biocompatibility of the subject device could be assured.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OCT 14 2011

Kuraray Medical, Incorporated
C/O Mr. Kiyoyuki Arikawa
General Manger
Kuraray America, Incorporated
600 Lexington Avenue, 26th Floor
New York, NY 10022

Re: K111980
Trade/Device Name: Clearfil Tri-S Bond Plus
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: July 6, 2011
Received: July 12, 2011

Dear Mr. Arikawa:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Anthony D. Watson, B.S., M.S., M.B.A.
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): K111980

Device Name: CLEARFIL TRI-S BOND PLUS

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] Intraoral repairs of fractured restorations made of porcelain, ceramic or composite resin

[5] Surface treatment of prosthetic restorations made of porcelain, ceramic or composite resin

[6] Surface treatment of dental posts

[7] Post cementation and core build-ups using dual-cured composite resin CLEARFIL DC CORE PLUS

[8] Core build-ups using light-cured composite resin

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)

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

510(k) Number: K111980