K111982 NOV 17 2011

510(k) Summary

Date: July 6, 2011

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 DC CORE PLUS
2) Classification name	Tooth shade resin material (21 CFR section 872.3690. Product code: EBF)
3) Common name	Dual-cured core build-up material

3-3. Predicate device

1) CLEARFIL DC CORE AUTOMIX	510(k) Number: K043177 Product Code: EBF 21 CFR Section: 872.3690 Applicant: KURARAY MEDICAL INC.
2) CLEARFIL SA CEMENT	510(k) Number: K081583 Product Code: EMA 21 CFR Section: 872.3275 Applicant: KURARAY MEDICAL INC.
3) CLEARFIL ESTHETIC CEMENT EX	510(k) Number: K062410 Product Code: EMA 21 CFR Section: 872.3275(b) Applicant: KURARAY MEDICAL INC.
4) CLEARFIL MAJESTY Flow	510(k) Number: K063593 Product Code: EBF 21 CFR Section: 872.3690 Applicant: KURARAY MEDICAL INC.
5) CLEARFIL AP-X	510(k) Number: K012740 Product Code: EBF 21 CFR Section: 872.3690 Applicant: KURARAY MEDICAL INC.
6) ESTENIA C&B	510(k) Number: K042929 Product Code: EBF and EBG 21 CFR Section: 872.3690 Applicant: KURARAY MEDICAL INC.

3-4. Device Description

The subject device is a dual-cured (light-cured with self-curing property), radiopaque two-component core build-up material supplied in an automix delivery system which can mix equal amount of two components, and is available in two shades, Dentin and White.

3-5. Substantial Equivalence Discussion

1) Intended use

The Intended use of the subject device was written up based on that of CLEARFIL DC CORE AUTOMIX. Therefore, the intended use of the subject device is substantially same as that of the predicate device.

2) Chemical ingredients / Safety

Except for a new ingredient, 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 regions where they have been sold.

And the new ingredient has been widely used for many years in the food industry as a food addictive. There have already been many reports that show its biological safety. As the result, it was concluded that the new ingredient was biologically safe.

In conclusion, it can be said that the safety of the subject device is substantially equivalent to that of the predicate devices.

3) Effectiveness / Performance

Physical and mechanical properties of the subject device have been evaluated according to the applicable FDA recognized consensus standard, ISO 4049: 2009 (Dentistry - Polymer-based restorative materials) which is applicable to dental composite resin. The predicate device devoted for the comparative study was CLEARFIL DC CORE AUTOMIX that had the same structure and application as the subject device.

The study results indicate that the subject device and the predicate device comply with the requirements of ISO 4049: 2009. From this, it can be said that the subject device is effective as well as the predicate device.

3-6. Biocompatibility

Except for a new ingredient, all ingredients in the subject device have been used in the predicate devices as listed on the tables of *"7-4 Chemical ingredients"*: in *"Section 7: Substantial Equivalence Discussion"*. Regarding the predicate devices, there have not been any reported problems or recalls according to the post market adverse event reporting requirements in regions where they have been sold.

And the new ingredient has been widely used for many years in the food industry as a food addictive. There have already been many reports that show its biological safety. As the result, it was concluded that the new ingredient was biologically safe.

Therefore, it was concluded that the biological safety 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

KURARARY MEDICAL Incorporated
C/O Mr. Kiyoyuki Arikawa
General Manager
Dental Material Division
600 Lexington Avenue, 26th Floor
New York, New York 10022

NOV 17 2011

Re: K111982
Trade/Device Name: CLEARFIL DC CORE PLUS
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: October 24, 2011
Received: October 24, 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,

for

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): K111982

Device Name: CLEARFIL DC CORE PLUS

Indications for Use:

Post cementation and core build-up

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)

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

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