K092281

Date: July 24, 2009

510(k) Summary

OCT 2 7 2009

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.	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 MAJESTY Posterior PLT
2) Classification name	Tooth shade resin material (21 CFR section 872.3690. Product code: EBF)
3) Common name	Restorative composite resin
4) Device Listing number	R001413

3-3. Predicate device

1) CLEARFIL MAJESTY Posterior PLT	510(k) Number:	K071169
	Classification:	Tooth shade resin material
	Product Code:	EBF
	21 CFR Section:	872.3690
	Applicant:	KURARAY MEDICAL INC.

Quality Assurance Department
Ote Center Bldg. 7F, 1-1-3 Otemachi, Chiyoda-ku, Tokyo, 100-0004, Japan
Tel : +81.(0)3.6701.1706 Fax : +81.(0)3.6701.1805

3-4. Device Description

CLEARFIL MAJESTY Posterior PLT (PLT:Pre-loaded tip) is a light-cure, radiopaque restorative composite resin which provides accurate color matching, high polish ability and excellent physical properties, making it ideal for both anterior and posterior restorations. It is formulated with optimal viscosity assuring easy handling and placement. CLEARFIL MAJESTY Posterior PLT, with its special dispensing system, can be quickly and conveniently placed directly into the cavity.

In this application, we have precisely defined the amount of dl-Camphorquinone and N,N-Diethanol-p-toluidine (DEPT) contained in CLEARFIL MAJESTY Posterior PLT in range of chemical composition shown in the original application in order to improve its sensitivity to ambient light. Each of the detailed description is as follows.

Chemical ingredient	(weight %)	
	Predicate device	Subject device
dl-Camphorquinone	not more than 0.1	0.02
N,N-Diethanol-p-toluidine (DEPT)	not more than 0.1	0.10

All chemical ingredients of the subject device have been used in the predicate device. And chemical composition of the subject device is very similar to that of the predicate device. Furthermore, physical and mechanical properties of the subject device were evaluated according to ISO 4049 in comparison with the predicate device, in which the substantial equivalence between the subject device and the predicate device was shown in terms of effectiveness/performance. Therefore, it was concluded that the subject device was substantially equivalent to the predicate device.

3-5. Substantial Equivalence Discussion

1) Intended uses

The intended uses of the subject device are the same as those of the predicate device.

(1) Direct restorations for anterior and posterior teeth (Class I – V cavities)
(2) Correction of tooth position and tooth shape (e.g. diastema closure, dwarfed tooth, etc.)
(3) Intraoral repairs of fractured crowns/bridges

2) Chemical ingredients / Safety

The chemical composition of the subject device is very similar to that of the predicate device, suggesting that the safety of the subject device is substantially equivalent to the predicate device. Furthermore, the safety of the predicate device has been shown in the original application. Therefore, it was concluded that the subject device was biologically safe.

3) Effectiveness / Performance

It has been verified that the subject device complies with the requirements of the applicable FDA recognized consensus standard, ISO 4049: 2000 "Dentistry - Polymer-based filling, restorative and luting materials". As to comparison with the predicate device, according to ISO 4049: 2000, both the subject device and the predicate device comply with ISO 4049: 2000, indicating that the subject device is as effective as and performs as well as the predicate device.

3-6. Biocompatibility

All chemical ingredients of the subject device are the same as those of the predicate device as described in 7-4. From this fact, it can be said that the safety of the subject device is substantially equivalent to the predicate device. Furthermore, we have already shown the biocompatibility of the predicate device in the original application. Additionally, the predicate device has been sold for 2 years and there were no reported problems or recalls according to the post market adverse event reporting requirement. Therefore, it was concluded that the subject device was biologically safe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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

OCT 2 7 2009

Re: K092281
Trade/Device Name: CLEARFIL MAJESTY Posterior PLT
Regulation Number: 21CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: July 24, 2009
Received: August 4, 2009

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.

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

Susan Runner, D.D.S., M.A.
Acting 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): K092281

Device Name: CLEARFIL MAJESTY Posterior PLT

Indications for Use:

1) Direct restorations for anterior and posterior teeth (Class I – V cavities)
2) Correction of tooth position and tooth shape (e.g. diastema closure, dwarfed tooth, etc.)
3) Intraoral repairs of fractured crowns/bridges

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)

Kevin Mulby for MSR

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

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