Date: Feb. , 2013.

K130371

510(k) Summary

APR 0 9 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	Kiyoyuki Arikawa 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 MAJESTY ES Flow
2) Classification name	Tooth shade resin material (21 CFR section 872.3690. Product code: EBF)
3) Common name	Dental light-cured restorative composite

3-3. Predicate Device

1) CLEARFIL MAJESTY Flow	510(k) Number:	K063593
	Classification:	Tooth shade resin material
	Product Code:	EBF
	21 CFR Section:	872.3690
	Applicant:	Kuraray Noritake Dental Inc.
2) CLEARFIL MAJESTY ES-2	510(k) Number:	K121583
	Classification:	Tooth shade resin material
	Product Code:	EBF
	21 CFR Section:	872.3690
	Applicant:	Kuraray Noritake Dental Inc.

3-4. Device Description

The subject device, CLEARFIL MAJESTY ES Flow is a light-cure, flowable, radiopaque restorative material which provides accurate color matching, high polishability and excellent physical properties, making it ideal for both anterior and posterior restorations.

It is classified into tooth shade resin material (21 CFR section 872.3690, Product code:EBF) according to 21 CFR§872 since it is composed of materials such as methacrylate monomers.

3-5. Statement of Intended Use

The subjest device is indicated for the following restorative applications:

[1] Direct restorations for all cavity classes, cervical lesions (e.g. root surface caries, v-shape defects), tooth wear, and tooth erosion

[2] Cavity base / liner

[3] Correction of tooth position and tooth shape (e.g. diastema closure, tooth malformation)

[4] Intraoral repair of fractured restorations

3-6. Substantial Equivalence Discussion

1) Intended uses

The INDICATIONS of the subject device were written up based on that of the predicate device. Therefore, the intended purposes of the subject device are substantially the same as those of the predicate devices.

2) Chemical ingredients / Safety

Except for two new ingredients, all ingredients in this product have been used in the predicate devices. Regarding the above predicate devices, there have not been any reported problems or recalls according to the post-market adverse event reporting requirement in the US.

Two new ingredients have been evaluated referring to ISO 10993 series and ISO 7405. As the result, it was confirmed that these substances were 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) Technological characteristics /Effectiveness and Performance

Regarding the comparison with the predicate device according to ISO 4049: 2009, the subject device and the predicate device complied with ISO 4049: 2009 indicating that the subject device was substantially equivalent in effectiveness to the predicate device.

3-7. Biocompatibility

Except for two new ingredients, all ingredients in this product have been used in the predicate devices. Regarding the above predicate devices, there have not been any reported problems or recalls according to the post-market adverse event reporting requirement in the US.

Two new ingredients have been evaluated referring to ISO 10993 series and ISO 7405. As the result, it was confirmed that these substances were biologically safe.

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

Conclusion

The test results exhibited that the subject device was substantially equivalent in effectiveness and biocompatibility 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

April 9, 2013

Kuraray Noritake Dental, Incorporated
C/O Ms. Kiyoyuki Arikawa
Kuraray America, Incorporated
33 Maiden Lane, 6th Floor
NEW YORK NY 10038

Re: K130371
Trade/Device Name: CLEARFIL MAJESTY ES Flow
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: February 6, 2013
Received: February 19, 2013

Dear Ms. 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,

Kwame O. Ulmer -S FDA for

Anthony D. Watson, B.S., M.S., M.B.A.
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): K130371

Device Name: CLEARFIL MAJESTY ES Flow

Indications for Use:

CLEARFIL MAJESTY ES Flow is indicated for the following restorative applications:

[1] Direct restorations for all cavity classes, cervical lesions (e.g. root surface caries, v-shape defects), tooth wear, and tooth erosion

[2] Cavity base / liner

[3] Correction of tooth position and tooth shape (e.g. diastema closure, tooth malformation)

[4] Intraoral repair of fractured restorations

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)

Mary S. Runner -S
2013.04.02
13:13:28 -04'00'

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

510(k) Number: K130371