May 3, 2019

Kuraray Noritake Dental Inc.
Yasujiro Ohara
Manager
Ote Center Bldg. 7F, 1-1-3, Otemachi
Chiyoda-ku, Tokyo 100-0004
JAPAN

Re: K182430
Trade/Device Name: CLEARFIL MAJESTY IC
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: January 31, 2019
Received: February 4, 2019

Dear Yasujiro Ohara:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S
for Malvina Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known): K182430

Device Name: CLEARFIL MAJESTY IC

Indications for Use:

[1] Direct restorations for all cavity classes in anterior and posterior teeth

[2] Direct veneers

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

[4] Intraoral repairs of fractured restorations

Prescription Use ✓ AND/OR Over-The-Counter Use N/A

(Part 21 CFR 801 Subpart D) (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)
510(k) number: K182340

510(k) Summary

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

1) Name: Kuraray Noritake Dental Inc.
2) Address: 1621 Sakazu, Kurashiki, Okayama 710-0801, Japan
3) Contact person: Yasujiro Ohara
   Quality Assurance Department
4) Contact person in US: Manabu Suzuki
   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 IC
2) Regulation Number: 21 CFR 872.3690
3) Product Code: EBF
4) Common Name: Dental light-cured restorative composite

3-3. Primary Predicate Device

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

3-4. Reference Devices

CLEARFIL MAJESTY ES Flow
510(k) Number: K130371
Classification: Tooth shade resin material
Product Code: EBF
21 CFR: 872.3690
Applicant: Kuraray Noritake Dental Inc.

ESTENIA C&B
510(k) Number: K042929
Classification: Tooth shade resin material
Product Code: EBF
21 CFR: 872.3690
Applicant: Kuraray Noritake Dental Inc.

Filtek One Bulk Fill Restorative
510(k) Number: K163207
Classification: Tooth shade resin material
Product Code: EBF
21 CFR: 872.3690
Applicant: 3M Company

CLEARFIL MAJESTY Posterior PLT
510(k) Number: K092281
Classification: Tooth shade resin material
Product Code: EBF
21 CFR: 872.3690
3-4. Device Description
CLEARFIL MAJESTY IC is an intra-oral, light-cured restorative composite that is available direct injection method into preparations with its syringe and replaceable tips. It is the radiopaque equivalent of 1mm aluminium and classified as a Type 1 and Class 2 (Group 1) material by ISO 4049. It is indicated for both anterior and posterior restorations and provides accurate color matching, high polishability and excellent physical properties.

3-5. Indications for Use Statement
The subject device is indicated for the following uses:
[1] Direct restorations for all cavity classes in anterior and posterior teeth
[2] Direct veneers
[3] Correction of tooth position and tooth shape (e.g. diastema closure, dwarfed tooth, etc.)
[4] Intraoral repairs of fractured restorations

3-6. Substantial Equivalence Discussion
1) Indications for Use
The Indications for Use of the subject device is identical to the primary predicate device. Therefore, the Indications for Use of the subject device is substantially equivalent to that of the primary predicate device.

The indications of the subject device and the primary predicate device are as listed on the following table.

<table>
<thead>
<tr>
<th>Trade name</th>
<th>Subject device</th>
<th>Primary predicate device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for Use</td>
<td>[1] Direct restorations for all cavity classes in anterior and posterior teeth</td>
<td>[1] Direct restorations for all cavity classes in anterior and posterior teeth</td>
</tr>
<tr>
<td></td>
<td>(e.g. diastema closure, dwarfed tooth, etc.)</td>
<td>(e.g. diastema closure, dwarfed tooth, etc.)</td>
</tr>
</tbody>
</table>

2) Chemical ingredients
All ingredients in the subject device and its accessories have been used in the primary predicate device and the reference devices.
Regarding the primary predicate device and the reference devices, there have not been any reported problems or recalls according to the post-market adverse event reporting requirements in the US.
The chemical ingredients of the subject device and its accessories are equivalent to those of the primary predicate device and the reference devices.
3) Technological characteristics/ Non-Clinical Testing

Physical and mechanical properties of the subject device were evaluated according to ISO 4049: 2009 (Dentistry - Polymer-based restorative and materials). According to ISO 4049: 2009, the subject device is classified into the following:

- Type 1: Polymer-based restorative materials;
- Class 2: materials whose setting is effected by light;
- Group 1: materials whose use requires the energy to be applied intra-orally.

In addition, we examined the subject device concerning the Physical Properties described in the “Dental Composite Resin Devices – Premarket Notification [510(k)] Submissions – Guidance for Industry and FDA Staff”.

Therefore, we considered sensitivity to ambient light, Depth of cure, flexural strength, water sorption and solubility, shade, filling and restorative materials, color stability after irradiation and water sorption, radio-opacity, compressive strength, elastic modulus, intensity for curing, wavelength for curing, filler particle size distribution, surface hardness and curing time as physical properties when testing the subject device. The subject device doesn’t contain chemical ingredients which are corresponded releasable agents “such as fluoride or nitrate ions”. The compared test items and the evaluation results are described as follows.
<table>
<thead>
<tr>
<th>Test item</th>
<th>For comparison: Primary Predicate device or Reference device</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity to ambient light</td>
<td>Primary Predicate device</td>
<td>The result demonstrated substantial equivalence.</td>
</tr>
<tr>
<td>Depth of cure</td>
<td>Primary Predicate device</td>
<td>The result demonstrated substantial equivalence.</td>
</tr>
<tr>
<td>Flexural strength</td>
<td>Primary Predicate device</td>
<td>The result demonstrated substantial equivalence.</td>
</tr>
<tr>
<td>Water sorption and solubility</td>
<td>Primary Predicate device</td>
<td>The result demonstrated substantial equivalence.</td>
</tr>
<tr>
<td>Shade, filling and restorative</td>
<td>Primary Predicate device</td>
<td>The result demonstrated substantial equivalence.</td>
</tr>
<tr>
<td>materials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Color stability after irradiation and</td>
<td>Primary Predicate device</td>
<td>The result demonstrated substantial equivalence.</td>
</tr>
<tr>
<td>water sorption</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radio-opacity</td>
<td>Primary Predicate device</td>
<td>The result demonstrated substantial equivalence.</td>
</tr>
<tr>
<td>Compressive strength</td>
<td>Primary Predicate device</td>
<td>The result demonstrated substantial equivalence.</td>
</tr>
<tr>
<td>Elastic modulus</td>
<td>Primary Predicate device Reference device</td>
<td>The result demonstrated substantial equivalence.</td>
</tr>
<tr>
<td>Intensity for curing</td>
<td>Primary Predicate device</td>
<td>The result demonstrated substantial equivalence.</td>
</tr>
<tr>
<td>Wavelength for curing</td>
<td>Primary Predicate device</td>
<td>The result demonstrated substantial equivalence.</td>
</tr>
<tr>
<td>Filler particle size distribution</td>
<td>Primary Predicate device</td>
<td>The result demonstrated substantial equivalence.</td>
</tr>
<tr>
<td>Surface hardness</td>
<td>Primary Predicate device</td>
<td>The result demonstrated substantial equivalence.</td>
</tr>
<tr>
<td>Curing time</td>
<td>Primary Predicate device</td>
<td>The result demonstrated substantial equivalence.</td>
</tr>
</tbody>
</table>

So we conducted the comparative tests for above test items. And all of tests results demonstrated that each characteristic of the subject device is substantially equivalent to that of the primary predicate device or the reference devices.
< Non-Clinical Testing >

The subject device is categorized into the external communicating device (dentin) and permanent contact device.

All the chemical ingredients of the subject device are equivalent to those of the primary predicate device and the reference devices.

Contacting information about the accessories of the subject device is as follows:

<table>
<thead>
<tr>
<th>Item</th>
<th>Human contacting information</th>
<th>The reference device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syringe</td>
<td>Indirect</td>
<td>CLEARFIL MAJESTY ES Flow</td>
</tr>
<tr>
<td>Dispensing tip</td>
<td>Direct</td>
<td>510(k) Number; K130371</td>
</tr>
<tr>
<td>Dispensing tip cap</td>
<td>Indirect</td>
<td>CLEARFIL MAJESTY Posterior PLT</td>
</tr>
<tr>
<td></td>
<td></td>
<td>510(k) Number; K092281</td>
</tr>
</tbody>
</table>

All the chemical ingredients of accessories about the subject device are equivalent to those of the reference device.

And biological evaluation was conducted according to ISO10993-1:2009. Concerning the track records of the ingredients, Indications for Use, manufacturing process, contact part and contact duration, all of these are substantially equivalent to those of the primary predicate device and the reference devices. Therefore, the subject device and its accessories are substantially equivalent in biocompatibility to the primary predicate device and the reference devices.

Concerning Shelf Life, the subject device was evaluated by using temperature accelerated samples. And the properties of them which are equivalent to storing at 25°C/77 °F more than 48 months were complied with ISO 4049: 2009. So the Shelf Life of the subject device was determined to be 48 months at 2-25 °C/36-77 °F.

3-7. Conclusion

The comparison for Indications for Use, chemical ingredients and performance data shows that the subject device is substantially equivalent to the primary predicate device and the reference devices.