October 8, 2019

Kuraray Noritake Dental Inc.
Yasujiro Ohara
Manager, Quality Assurance Department
Ote Center Bldg. 7F
Chiyoda-ku, 100-0004 JAPAN

Re: K191133
Trade/Device Name: KATANA Cleaner, KATANA Cleaner (Trial)
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: PME, LBH
Dated: September 6, 2019
Received: September 12, 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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.


For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha

-S

for Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental Devices
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): K191133

Device Name: KATANA Cleaner

Indications for Use:

[1] Cleaning of contaminated glass ceramic, zirconia, resin restorations, metal restorations and fiber post after intraoral try-in.

[2] Cleaning for contaminated prepared tooth (cavity, root canal and tooth abutment), and implant abutment

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) Summary

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
Manager
Quality Assurance Department
Knd.Regist@kuraray.com

4) Contact person in US
Manabu Suzuki
Director
Dental Material Division
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

2. Date:
7th October, 2019

3. Name of Device

1) Trade / Proprietary name
KATANA Cleaner

2) Classification Name
External Cleaning Solution
21 CFR 872.3260
PME
Subsequent Product Code: LBH
(Cavity Varnish)

3) Common Name
Dental Cleaning Agent
4. Predicate Device

1) CONSEPSIS

- 510(k) Number: K925375
- Classification: Cavity Varnish
- Product Code: LBH
- 21 CFR: 872.3260
- Applicant: ULTRADENT PRODUCTS, INC.

5. Reference Devices

1) Zirclean

- 510(k) Number: K163171
- Classification: External Cleaning Solution
- Product Code: PME
- 21 CFR: 872.3260
- Applicant: Bisco, Inc.

2) CLEARFIL SE BOND

- 510(k) Number: K990040
- Classification: Agent, Tooth Bonding, Resin
- Product Code: KLE
- 21 CFR: 872.3200
- Applicant: Kuraray Noritake Dental Inc.

3) CLEARFIL TRI-S BOND

- 510(k) Number: K042913
- Classification: Agent, Tooth Bonding, Resin
- Product Code: KLE
- 21 CFR: 872.3200
- Applicant: Kuraray Noritake Dental Inc.

4) K-ETCHANT Syringe

- 510(k) Number: K133078
- Classification: Agent, Tooth Bonding, Resin
- Product Code: KLE
- 21 CFR: 872.3200
- Applicant: Kuraray Noritake Dental Inc.

5) CLEARFILSE Protect

- 510(k) Number: K033938
- Classification: Agent, Tooth Bonding, Resin
- Product Code: KLE
- 21 CFR: 872.3200
- Applicant: Kuraray Noritake Dental Inc.

6. Device Description

This subject device is a dental cleaning agent suitable for non-abrasive cleaning of the bonding surfaces of prosthetic restorations after intraoral try-in.

It is also suitable for cleaning a contaminated prepared cavity, root canal, and tooth/implant abutment. It is used in helping to achieve optimal adhesive results.

7. Statement of Indication for Use

The subject device is indicated for the following uses:

[1] Cleaning of contaminated glass ceramic, zirconia, resin restorations, metal restorations and fiber post after intraoral try-in.

[2] Cleaning for contaminated prepared tooth (cavity, root canal and tooth abutment), and implant abutment.
8. Substantial Equivalence Discussion

- Indication for Use

Indication for Use of the subject device, the predicate device and the reference device listed on the following table.

Table: Indication for Use of the subject device, the predicate device and the reference device

<table>
<thead>
<tr>
<th>Subject device</th>
<th>Trade name</th>
<th>Indication for Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>KATANA Cleaner</td>
<td>[1] Cleaning of contaminated glass ceramic, zirconia, resin restorations, metal restorations and fiber post after intraoral try-in.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>[2] Cleaning for contaminated prepared tooth (cavity, root canal and tooth abutment), and implant abutment.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Predicate device</th>
<th>Trade name</th>
<th>Indication for Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONSEPSIS (K925375)</td>
<td>Consepsis liquid is used before crown cementation (temporary and/or permanent) and for restorative preparation of crowns, inlays, and composite.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consepsis is a demonstrated, quality wetting agent for bonding, and increasing bond strength.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consepsis recommended for procedural endodontic disinfection, as a final endodontic rinse prior to canal obturation and as an antimicrobial prior to pulp capping.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consepsis helps prevent the influx of micro-organisms into dentinal tubules.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>A clinician can reduce potential post-op pulpitis and sensitivity by thoroughly cleaning and disinfecting preparations with Consepsis before sealing and restoring.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reference device</th>
<th>Trade name</th>
<th>Indication for Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZirClean (K163171)</td>
<td>This device is an extra oral cleaner of pre-treated ceramic, zirconia and metal restoration surfaces which have been contaminated during intraoral try-in.</td>
<td></td>
</tr>
</tbody>
</table>

The subject device is substantially equivalent to CONSEPSIS (Predicate device) in that it can be used not only extra-orally for prior to cementation but also intra-orally for prior to sealing and restoring.

In terms of being used for dental prostheses, since CONSEPSIS (Predicate device) is used before crown cementation and for restorative preparation of crowns, inlays, and composite, Indication for Use [1] of the subject device is substantially equivalent to CONSEPSIS.

In addition, Indication for Use [1] is substantially equivalent to that of Zirclean due to clean pre-treated ceramic, zirconia and metal restoration surfaces.

In terms of being used for the tooth structure intra-orally, since CONSEPSIS (Predicate device) is used to thoroughly clean and disinfect the preparation prior to sealing and restoring, Indication for Use [2] of the subject device is substantially equivalent to CONSEPSIS.

The subject device is NOT used to disinfect.

Therefore, Indication for Use of the subject device is substantially equivalent to that of the predicate device.

- Chemical ingredients

The subject device is categorized into the external communicating device (tissue/ bone/ dentin) and limited exposure device (contact to teeth less than 24 hours).

All chemical ingredients of the subject device have been proven to be blended with our own reference devices. However, the chemical material percentage of the subject device differs from the reference devices. Thus, we evaluated whether this change result in an adverse biological response.

In addition, the manufacturing process of the subject device is substantially equivalent to those of the
reference devices in point of view of equipment, temperature, pressure and time.

Furthermore, these manufacturing processes do not include sterilization processes.

Regarding the reference devices (In-house device), there have not been any reported problems or recalls according to the post market adverse event reporting requirements in the US.

Since the contact site of the subject device is identical to those of the reference devices (contact to dentin), and the contact duration of the subject device is shorter than those of reference devices, we concluded that the risks by the ingredients of the subject is lower and safer than reference devices.

From the above, it was concluded that the subject device is substantially equivalent to the reference devices.
Comparison of Technological Characteristics
Comparison of Technological characteristics table is shown below:

Table Comparison of Technological characteristics

<table>
<thead>
<tr>
<th></th>
<th>KATANA Cleaner K191133</th>
<th>Predicate device (CONSEPSIS) (K925375)</th>
<th>Reference device (ZirClean) (K163171)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Active ingredient</strong></td>
<td>MDP * ammonium salt</td>
<td>Chlorohexidine</td>
<td>Potassium Hydroxide</td>
</tr>
<tr>
<td><strong>Operating principle for the cleaning ability to the contaminated adherent</strong></td>
<td>Micelle</td>
<td>Bactericidal</td>
<td>Alkaline cleaning effect</td>
</tr>
<tr>
<td><strong>Physical /Mechanical Properties</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Shear Bond Strength</strong> (modified ISO/TS 11405:2015)</td>
<td>Removes saliva contamination</td>
<td>Removes saliva contamination</td>
<td>Removes saliva contamination</td>
</tr>
<tr>
<td><strong>Method of Application</strong></td>
<td>Brush</td>
<td>Syringe or Dispenser</td>
<td>Syringe tip or brush</td>
</tr>
<tr>
<td><strong>Method of Cleaning</strong></td>
<td>Abrasive</td>
<td>Non-abrasive</td>
<td>Non-abrasive</td>
</tr>
<tr>
<td><strong>Device Geometry</strong></td>
<td>Liquid</td>
<td>Liquid</td>
<td>Gel</td>
</tr>
<tr>
<td><strong>Method of Removal</strong></td>
<td>Water rinsed &amp; air dried</td>
<td>Air dry</td>
<td>Water spray &amp; air dried</td>
</tr>
<tr>
<td><strong>Delivery configuration</strong></td>
<td>Bottle</td>
<td>Syringe or Dispenser</td>
<td>Syringe or Bottle</td>
</tr>
<tr>
<td><strong>Removal</strong></td>
<td>Water Soluble</td>
<td>Water Soluble</td>
<td>Water Soluble</td>
</tr>
<tr>
<td><strong>Chemical Composition</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Composition</strong></td>
<td>Water based liquid</td>
<td>Water based liquid</td>
<td>Water based gel</td>
</tr>
<tr>
<td><strong>Viscosity modifier</strong></td>
<td>Polyethylene glycol</td>
<td>—</td>
<td>Xanthum Gum</td>
</tr>
<tr>
<td><strong>pH after rinsing</strong></td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
</tr>
<tr>
<td><strong>Water Solubility</strong></td>
<td>Water Soluble</td>
<td>Water Soluble</td>
<td>Water Soluble</td>
</tr>
<tr>
<td><strong>Pigmented</strong></td>
<td>Yes-Purple</td>
<td>Yes-Blue</td>
<td>Yes-Blue</td>
</tr>
</tbody>
</table>

* MDP is abbreviation of 10-methacryloyloxydecyl dihydrogen phosphate.
9. Non-Clinical Performance Testing

<Bench Testing>
Shear bond strength tests to the adherent surfaces were performed on this device considering its intended use, in comparison with the predicate devices and the reference device. Since this subject device is a dental cleaning agent, in order to evaluate its performance, the adherents were contaminated with artificial saliva prior to the shear bond strength test.

Table Comparison with Predicate device and Reference device

<table>
<thead>
<tr>
<th>Evaluation Item</th>
<th>Criteria</th>
<th>Subject Device (KATANA Cleaner)</th>
<th>Predicate device (CONSEPSIS)</th>
<th>Reference device (ZirClean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>In-house standard</td>
<td>COMPLIES</td>
<td>COMPLIES</td>
<td>COMPLIES</td>
</tr>
<tr>
<td>Coating property</td>
<td>In-house standard</td>
<td>COMPLIES</td>
<td>COMPLIES</td>
<td>COMPLIES</td>
</tr>
<tr>
<td>Shear bond strength (contaminated by artificial saliva)</td>
<td>Bovine Dentin In-house standard</td>
<td>COMPLIES</td>
<td>COMPLIES</td>
<td>COMPLIES</td>
</tr>
<tr>
<td></td>
<td>Metal (Titan100) In-house standard</td>
<td>COMPLIES</td>
<td>COMPLIES</td>
<td>COMPLIES</td>
</tr>
<tr>
<td></td>
<td>Ceramics (KATANA Zirconia HT) In-house standard</td>
<td>COMPLIES</td>
<td>COMPLIES</td>
<td>COMPLIES</td>
</tr>
<tr>
<td>pH (before rinse/ after rinse)</td>
<td>In-house Standard</td>
<td>COMPLIES</td>
<td>COMPLIES</td>
<td>COMPLIES</td>
</tr>
<tr>
<td>Water solubility</td>
<td>In-house Standard</td>
<td>COMPLIES</td>
<td>COMPLIES</td>
<td>COMPLIES</td>
</tr>
<tr>
<td>SEM and EDX Surface Comparison</td>
<td>In-house Standard</td>
<td>COMPLIES</td>
<td>COMPLIES</td>
<td>COMPLIES</td>
</tr>
</tbody>
</table>

Regarding “Appearance” and “Coating property”, there are no difference among the subject device, the predicate device and the reference device.

Each shear bond strength of the subject device such as “Just after prepared” and “for 3 weeks at 70 °C/158 °F.” is equal to “Positive control (Without contamination and applying the subject device)”. And shear bond strength of the subject device is higher than that of “Negative control (without the subject device)” where the adherent surface is contaminated by artificial saliva. It indicates that the subject device shows the good performance as cleaning agent. In comparison with the predicate device and reference device, the subject device’s results showed equal to or greater than those of the predicate device and the reference device.

Regarding pH, the value of the subject device is located between the values of predicate device and the reference device. So, it is considered that pH of the subject device is substantially equivalent to those of the predicate device and the reference device.

For “Staining Test”, we confirmed the subject device was colored, and substantially equivalent to the predicate device and the reference device.

Regarding “Water solubility”, the subject device was easily removed from substrate. Also, at “pH (after rinse)”, the value of the subject device showed the same value of control which is not apply any devices.

Finally, at “SEM and EDX Surface Comparison”, peak area ratio of the subject device is the same as the value of control and the predicate device and reference device.

From the above result, the subject device can be easily rinsed with water.
<Biocompatibility Testing>
We evaluated the biocompatibility of the subject device according to “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff” and “ISO 10993-1:2018”. As a conclusion of biological evaluation, we have concluded that the subject device is substantially equivalent to the reference devices.

10. Conclusion
The comparison for Indication for Use, chemical ingredients and performance data shows that the subject device is substantially equivalent to the predicate device and the reference device.