K122421

Date: Nov. 12, 2012

# 510(k) Summary

DEC 11 2012

**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<br>Quality Assurance Department |
| 4) Contact person in US | Kiyoyuki Arikawa<br>KURARAY AMERICA INC.<br>33 Maiden Lane, 6th Floor, New York, NY 10038<br>Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676<br>Fax: (212)-867-3543 |

**3-2. Name of Device**

| | |
|---|---|
| 1) Trade / Proprietary name | TEETHMATE DESENSITIZER |
| 2) Classification name | Calcium hydroxide cavity liner<br>(21 CFR section 872.3250. Product code: EJK) |
| 3) Common name | Tooth Desensitizer |

**3-3. Predicate Device**

| | | |
|---|---|---|
| 1) SUPER SEAL | 510(k) Number: | K983477 |
| | Classification: | Calcium hydroxide cavity liner |
| | Product Code: | EJK |
| | 21 CFR Section: | 872.3250 |
| | Applicant: | Phoenix Dental Inc. |
| 2) TEETHMATE F-1 | 510(k) Number: | K012742 |
| | Classification: | Pit and Fissure Sealant and Conditioner |
| | Product Code: | EBC |
| | 21 CFR Section: | 872.3765 |
| | Applicant: | Kuraray Noritake Dental Inc. |

**3-4. Device Description**

The subject device consists of POWDER which contains Calcium Phosphate as a major component and LIQUID which mainly contains water. POWDER and LIQUID are mixed to obtain paste. The paste applied to the affected area transforms to a hardened material of hydroxyapatite and it suppresses hypersensitivity by sealing the dentin tubules and microcracks in the enamel.

**3-5. Statement of Intended Use**

TEETHMATE DESENSITIZER is indicated for reduction of tooth hypersensitivity by the following treatments:

[1] Treatment of dentin exposed by toothbrush abrasion, gingival recession, periodontal disease and/or acid erosion
[2] Treatment of dentin after mechanical tooth cleaning, scaling and/or root planing
[3] Treatment of tooth surface after bleaching
[4] Treatment of prepared dentin for fillings and/or prosthetic restorations

### 3-6. Substantial Equivalence Discussion

1) Intended uses

The intended uses of the subject device are substantially equivalent to the predicate device as shown on the following comparative table.

| | Subject device | Predicate device |
|---|---|---|
| | TEETHMATE DESENSITIZER | SUPER SEAL |
| 510(k) Number | TBD | K983477 |
| Applicant | Kuraray Noritake Dental Inc. | Phoenix Dental Inc. |
| Regulation number | 872.3250 | 872.3250 |
| Classification product code | EJK | EJK |
| Classification name | Calcium hydroxide cavity liner | Calcium hydroxide cavity liner |
| Common name | Tooth Desensitizer | Tooth Desensitizer |
| Indications for use | TEETHMATE DESENSITIZER is indicated for reduction of tooth hypersensitivity by the following treatments:<br><br>[1] Treatment of dentin exposed by toothbrush abrasion, gingival recession, periodontal disease and/or acid erosion<br>[2] Treatment of dentin after mechanical tooth cleaning, scaling and/or root planing<br>[3] Treatment of tooth surface after bleaching<br>[4] Treatment of prepared dentin for fillings and/or prosthetic restorations | Application prior to restoration of the tooth surface or for general root sensitivity.<br>• For all crown preparations with eugenol-containing cements and non-eugenol temporary cements.<br>• On root cementum and exposed roots that are sensitive to temperature or air stimuli.<br>• On the dentin of all cavity preparations for amalgam alloys and resin composite restorations.<br>• On all prepared tooth structure (vital dentin), both before and after all prophylaxis treatments (scaling & root planing).<br>• Following all bleaching procedures either in office (power and assisted) or take home systems.<br>• Following periodontal surgery.<br>• As a diagnostic aid to assist in differentiating between reversible pulpitis (hyperemia) and irreversible pulp inflammation. SUPER SEAL will positively affect dentin problems (fluid flow mechanism) by sealing the tubules and preventing fluid flow movement in the tubules. |
| Technological Characteristics | Occlusion of dentinal tubules:<br>The paste mixed POWDER which contains calcium phosphate and LIQUID applied to the affected area transforms to a hardened material of hydroxyapatite and it suppresses hypersensitivity by sealing the dentin tubules and microcracks in the enamel. | Occlusion of dentinal tubules:<br>It demineralizes the organic and mineral debris of the smear layer and the outermost ring of peritubular dentin (the very hard mineralized dentin of each tubule complex) and restructures the demineralized material as a calcium oxalate precipitate. It creates an acid resistant lining layer bound both to the surface as well as into the dentinal tubules. |
| Material composition | Calcium Phosphate, Water | Potassium oxalate, Oxalic Acid |
| Application | Powder/Liquid | Gel |
| Rx/OTC | Rx | Rx |

2) Chemical ingredients / Safety

The subject device contains new ingredients. Therefore, we evaluated the subject device referring to ISO 10993 series and ISO 7405. As the result, its biocompatibility was confirmed. The details concerning the biocompatibility of the subject device are described in "*Section 9: Biocompatibility*".

3) Technological characteristics /Effectiveness and Performance

Since there have not been any international standards concerning performance of this type of device, certain tests were performed on this device, in comparison with the predicate device and it was confirmed that this device was substantially equivalent to the predicate device in terms of the effectiveness and performance.

The brief overview of the non-clinical testing was as follows.

"Occlusion of dentinal tubules", "dentin permeability inhibition" and "tensile bond strength to bovine dentin when used with bonding agent and composite resin" were evaluated to validate the substantial equivalence of the subject device with the predicate device in terms of effectiveness and performance for the intended uses. These test results exhibited that the subject device was substantially equivalent in effectiveness and performance to the predicate device.

**3-7. Biocompatibility**

The safety of the subject device has been evaluated referring to ISO 10993 series and ISO 7405. As the result, it was confirmed that the device was biologically safe.

Accordingly, it was concluded that the subject device was substantially equivalent in biological safety to the predicate device.

**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 20993-002

December 11, 2012

Mr. Michio Takigawa
Manager
Kuraray Noritake Dental Incorporated
Ote Center Building 7F, 1-1-3, Otemachi
Chiyoda-Ku, Tokyo, Japan 100-0004

Re: K122421
Trade/Device Name: TeethMate Desensitizer
Regulation Number: 21 CFR 872.3250
Regulation Name: Calcium Hydroxide Cavity Liner
Regulatory Class: II
Product Code: EJK
Dated: November 12, 2012
Received: November 14, 2012

Dear Mr. Takigawa:

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

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): K122421

Device Name: TEETHMATE DESENSITIZER

Indications for Use:

TEETHMATE DESENSITIZER is indicated for reduction of tooth hypersensitivity by the following treatments:

[1] Treatment of dentin exposed by toothbrush abrasion, gingival recession, periodontal disease and/or acid erosion

[2] Treatment of dentin after mechanical tooth cleaning, scaling and/or root planing

[3] Treatment of tooth surface after bleaching

[4] Treatment of prepared dentin for fillings and/or prosthetic 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)

Susan Runner DDS, MA 2012.12.11 15:03:25 -05'00'

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

**510(k) Number:**