DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 21, 2015

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

Re: K150704
Trade/Device Name: Panavia V5
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: July 21, 2015
Received: July 23, 2015

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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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 Erin I. Keith, M.S.
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): K150704

Device Name: PANAVIA V5

Indications for Use:
[1] Cementation of crowns, bridges, inlays and onlays

[2] Cementation of veneers

[3] Cementation of adhesion bridges and splints

[4] Cementation of prosthetic restorations on implant abutments and frames

[5] Cementation of posts and cores

[6] Amalgam bonding

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)

K150704

Date: August 13, 2015

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	Michio Takigawa Quality Assurance Department
4) Contact person in US	Shinichi Sato 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	PANAVIA V5
2) Classification name	Dental cement (21 CFR section 872.3275. Product code: EMA)
3) Common name	Adhesive resin cement system

3-3. Predicate devices

1)	PANAVIA F 2.0 (Primary predicate)	510(k) Number Classification: Product Code: 21 CFR Section: Applicant:	K032455 Dental cement EMA 872.3275 Kuraray Noritake Dental Inc.
2)	PANAVIA SA Cement Plus Automix	510(k) Number: Classification: Product Code: 21 CFR Section: Applicant:	K142625 Dental cement EMA 872.3275 Kuraray Noritake Dental Inc.
3)	CLEARFIL AP-X	510(k) Number: Classification: Product Code: 21 CFR Section: Applicant:	K012740 Tooth shade resin material EBF 872.3690 Kuraray Noritake Dental Inc.
4)	CLEARFIL ESTHETIC CEMENT EX	510(k) Number: Classification: Product Code: 21 CFR Section: Applicant:	K062410 Dental cement EMA 872.3275 Kuraray Noritake Dental Inc.
5)	ESTENIA C&B	510(k) Number: Classification: Product Code: 21 CFR Section: Applicant:	K042929 Tooth shade resin material EBF 872.3690 Kuraray Noritake Dental Inc.

6) CLEARFIL SE Protect	510(k) Number:	K033938
	Classification:	Resin Tooth Bonding Agent
	Product Code:	KLE
	21 CFR Section:	872.3200
	Applicant:	Kuraray Noritake Dental Inc.

3-4. Device Description

The subject device is an adhesive resin cement system. It consists of the cement paste (Paste), Try-in Paste, Tooth Primer, CLEARFIL CERAMIC PRIMER PLUS and K-ETCHANT Syringe. The Paste is a dual-cure (light- and/or self-cure), fluoride-releasing, radiopaque resin cement for ceramics (lithium disilicate, zirconia, etc.), hybrid ceramics, composite resins, and metal restorations. It is supplied in an automix delivery system which mixes equal amounts of two components. It is available in the following 5 shades; Universal (A2), Clear, Brown (A4), White, and Opaque. The Opaque shade should be self-cured for final curing due to its strong opacity. The Try-in Paste is a shade matching material which has approximate color and transparency as the hardened mixture of Paste. The Tooth Primer is a self-etching primer to tooth structures that accelerates the polymerization of the Paste.

This is the new registration application for the subject device.

Concerning CLEARFIL CERAMIC PRIMER PLUS and K-ETCHANT Syringe, the specification of those 2 components were omitted for the reasons set forth below.

We already have had 510(k) clearance of K-ETCHANT Syringe (510(k) Number: 133078).

And we submit the application for CLEARFIL CERAMIC PRIMER PLUS as separate application at the same time.

3-5. Statement of Intended Use

The subject device is indicated for the following uses:

[1] Cementation of crowns, bridges, inlays and onlays
[2] Cementation of veneers
[3] Cementation of adhesion bridges and splints
[4] Cementation of prosthetic restorations on implant abutments and frames
[5] Cementation of posts and cores
[6] Amalgam bonding

3-6. Substantial Equivalence Discussion

1) Intended uses

The INDICATIONS of the subject device and predicate devices, PANAVIA F2.0 which is dental resin cement and PANAVIA SA Cement Plus Automix which is self-adhesive resin cement, are as listed on the following table.

	Trade name	Intended use
Subject device	PANAVIA V5	[1] Cementation of crowns, bridges, inlays and onlays [2] Cementation of veneers [3] Cementation of adhesion bridges and splints [4] Cementation of prosthetic restorations on implant abutments and frames [5] Cementation of posts and cores [6] Amalgam bonding
Predicate devices	PANAVIA F2.0 (Primary predicate)	[1] Cementation of metal crowns and bridges, inlays and onlays [2] Cementation of porcelain crowns, inlays, onlays and veneers [3] Cementation of composite resin crowns, inlays, and onlays [4] Cementation of adhesion bridges [5] Cementation of endodontic cores and prefabricated posts [6] Amalgam bonding
	PANAVIA SA Cement Plus Automix	[1] Cementation of crowns, bridges, inlays and onlays [2] Cementation of prosthetic restorations on implant abutments and frames [3] Cementation of adhesion bridges and splints [4] Cementation of posts and cores [5] Amalgam bonding

The intended use of the subject device was written up based on those of the predicate devices.
Therefore, the intended use of the subject device is substantially equivalent to those of the predicate devices

2) Chemical ingredients

Except for 5 chemical ingredients, all ingredients in the Paste and Tooth Primer are identical and have been used in the following predicate devices: K032455 Panivia 2.0, K142625 Panavia SACement, K012740 Clearfil AP-X, K062410 Clearfil Esthetic Cement and DC Bond, K033938 Clearfil Protect Bond and K042929 Estenia C&B.

Regarding these predicate devices, there have not been any reported problems or recalls according to the post market adverse event reporting requirements in the US.

5 chemical ingredients in the Paste and Tooth Primer are new ingredients.

Therefore, we evaluated the Paste and Tooth Primer referring to ISO 10993 series and ISO 7405. As a result of the tests, it was concluded that the Paste and Tooth Primer is substantially equivalent in biocompatibility to the predicate devices.

All the chemical ingredients of the Try-in Paste are identical to those of the predicate devices.
Regarding the predicate devices, there have not been any reported problems or recalls according to the post-market adverse event reporting requirements in the US.
Accordingly, it was considered that the Try-in Paste was substantially equivalent to the predicate devices.

3) Technological characteristics/ Effectiveness and Performance

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:

Shade type: Universal (A2), Clear, Brown (A4), White
Class 3: materials that are cured by the application of external energy and also have a self-curing mechanism present

Shade type: Opaque
Class 1: materials whose setting is effected by mixing an initiator and activator.

The results of comparative study performed according to ISO 4049: 2009 were indicated below.

Section		Requirement	PANAVIA V5 (Subject device)			PANAVIA F2.0 (Primary predicate)	
			Shade type: Universal (A2)	Shade type : White	Shade type : Opaque	Shade type: Brown	Shade type: Opaque
			Class 3	Class 3	Class 1	Class 3	Class 1
5.2.2 Film thickness, luting materials		<50μm	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.2.4 Working time, Class 1 and Class 3 luting materials		>60 seconds	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.2.5 Setting time, Class 1 materials or 5.2.6 Setting time, Class 3 materials		<10 min	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.2.9 Flexural strength		≧50 MPa	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.2.10	Water sorption	≦40 μg/mm^3	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
	Solubility	≦7.5 μg/mm^3	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.4 Color stability after irradiation and water sorption		No more than a slight change in color shall be observed	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.5 Radio-opacity		Equal to or greater than that of the same thickness of aluminum	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***

"COMPLIES" means that test values were in the acceptable range to pass the testing in compliance with the requirements of ISO 4049: 2009.

The results indicate that the subject device and the predicate device comply with the requirements of ISO 4049: 2009. From the above, it can be said that comparative study of the subject device is substantially equivalent to that of the predicate device.

The shear bond strengths for the adherent surfaces which are matched to each indication in accordance with ISO/TS 11405: 2003 were indicated below.

Adherent surface (Material composition)	PRIMER	Criteria	Subject device (Universal (A2))	Primary predicate (PANAVIA F 2.0)
Dentin	Tooth Primer	In-house standard	***COMPLIES***	***COMPLIES***
Enamel			***COMPLIES***	***COMPLIES***
Metal			***COMPLIES***	***COMPLIES***
Composite resin			***COMPLIES***	***COMPLIES***
Ceramic	CLEARFIL CERAMIC PRIMER PLUS		***COMPLIES***	***COMPLIES***
Hybrid ceramics			***COMPLIES***	***COMPLIES***
Metal			***COMPLIES***	***COMPLIES***
Composite resin			***COMPLIES***	***COMPLIES***
Dentin	Tooth Primer		***COMPLIES***	***COMPLIES***
Amalgam	N/A			

"COMPLIES" means that test values were in the acceptable range to pass the testing in compliance with the requirements of in-house standard.
It was concluded that the bonding performance to all substrates of the subject device was equivalent to those of the predicate device.

Released fluorine ion test was performed to validate the substantial equivalence of the subject device with the predicate device in terms of performance for the intended uses.
It was confirmed that the released level from the cured one by the subject device was lower than that by PANAVIA F2.0.

3-7. Biocompatibility

Paste and Tooth Primer are categorized into the external communicating device (tissue/ bone/ dentin) and permanent contact device.
Except for 5 chemical ingredients, all ingredients in the Paste and Tooth Primer have been used in the predicate devices.
Regarding these predicate devices, there have not been any reported problems or recalls according to the post market adverse event reporting requirements in the US.

5 chemical ingredients in the Paste and Tooth Primer are new ingredients.
Therefore, we evaluated the Paste and Tooth Primer referring to ISO 10993 series and ISO 7405.
We decided to perform the following tests.

a) Cytotoxicity test
b) Sub-chronic systemic toxicity test
c) Skin irritation and intra-cutaneous reactivity test (oral mucosa irritation test)
d) Sensitization test (skin sensitization test)
e) Genotoxicity test (reverse mutation test, chromosomal aberration test)

As a result of the tests, it was concluded that the Paste and Tooth Primer are substantially equivalent in biocompatibility to the predicate devices.

Try-in Paste is categorized into the external communicating device that may contact dentin and whose duration of contact is less than 24 hours.
All the chemical ingredients of the Try-in Paste are identical to those of the predicate devices.
Regarding the predicate devices, there have not been any reported problems or recalls according to the post-market adverse event reporting requirements in the US.
Accordingly, it was considered that the Try-in Paste was substantially equivalent to the predicate devices.

3-8. Conclusion

The comparison for intended uses, chemical ingredients and performance data shows that the subject device is substantially equivalent to the predicate devices.
This submission information including the nonclinical testing provided supports that the subject device is as safe and as effective as the predicate devices.