April 25, 2019

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

Re: K183537
Trade/Device Name: PANAVIA SA Cement Universal
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA, KLE
Dated: January 24, 2019
Received: January 28, 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,

Srinivas Nandkumar -S

for Tina Kiang, Ph.D.
Acting 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): K183537

Device Name: PANAVIA SA Cement Universal

Indications for Use:

PANAVIA SA Cement Universal is indicated for the following uses:

[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

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)

Date: January 24th, 2019

K183537

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	PANAVIA SA Cement Universal
2) Classification name	Dental cement (21 CFR section 872.3275. Product code: EMA)
3) Common name	Dental adhesive resin cement

3-3. Predicate device

1) PANAVIA SA Cement Plus Automix	510(k) Number	K142625
	Classification:	Dental cement
	Product Code:	EMA
	21 CFR Section:	872.3275
	Applicant:	Kuraray Noritake Dental Inc.

3-4. Reference devices

1) CLEARFIL MAJESTY ES Flow	510(k) Number:	K130371
	Classification:	Tooth shade resin material
	Product Code:	EBF
	21 CFR Section:	872.3690
	Applicant:	Kuraray Noritake Dental Inc.
2) PANAVIA SA Cement Plus Handmix	510(k) Number	K142623
	Classification:	Dental cement
	Product Code:	EMA
	21 CFR Section:	872.3275
	Applicant:	Kuraray Noritake Dental Inc.

3-5. Device Description

PANAVIA SA Cement Universal is a dual-cure (light- and/or self-cure), fluoride releasing, radiopaque self-adhesive resin cement for ceramic (porcelain, lithium disilicate, zirconia, etc.), composite resin, and metal restorations. It has a choice of Automix delivery (equal amounts of two components are combined through a mixing tip) or Handmix (equal amount of two components are combined on a mixing pad). This is the new registration application for the subject device and there have not been any prior submissions regarding the subject device.

3-6. Statement of Intended Use

PANAVIA SA Cement Universal is indicated for the following uses:
[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

3-7. Substantial Equivalence Discussion

1) Intended uses

Intended uses of the subject device and predicate devices, PANAVIA SA Cement Plus Automix which is self-adhesive resin cement which is dental resin cement, is as listed on the following table.

	Trade name	Intended use
Subject device	PANAVIA SA Cement Universal	[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
Predicate device	PANAVIA SA Cement Plus Automix	

The intended use of the subject device is the same as that of the predicate device.
Therefore, the intended use of the subject device is substantially equivalent to that of the predicate device.

2) Chemical ingredients/ Safety

All ingredients in the subject device have been used in the predicate device and reference devices.
Regarding the predicate device and reference devices, there have not been any reported problems or recalls according to the post market adverse event reporting requirements in the US.
From the above, it was concluded that the subject device is substantially equivalent in biological safety to the predicate device and reference 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).

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

Section		PANAVIA SA Cement Universal (Handmix) (Subject device)		PANAVIA SA Cement Plus Automix (Predicate device)	
		Shade type: Universal (A2)	Shade type: White	Shade type: Universal (A2)	Shade type: White
5.2.2 Film thickness, luting materials		***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.2.4 Working time, Class 1 and Class 3 luting materials		***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.2.6 Setting time, Class 3 materials		***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.2.9 Flexural strength		***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.2.10 Water sorption and solubility	Water sorption	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
	Solubility	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.4 Color stability after irradiation and water sorption		***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.5 Radio-opacity		***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***

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 result of Bond strength test

Adherend surface (Material composition)	Criteria	Subject device (Handmix)	Predicate device	
Tooth dentin	In-house standard	***COMPLIES***	***COMPLIES***	PANAVIA SA Cement Plus Automix
Tooth enamel		***COMPLIES***	***COMPLIES***	
Ceramic		***COMPLIES***	***COMPLIES***	
Metal		***COMPLIES***	***COMPLIES***	
Titan		***COMPLIES***	***COMPLIES***	
Composite resin		***COMPLIES***	***COMPLIES***	
Amalgam		***COMPLIES***	***COMPLIES***	

The bond strengths to all substrates of the subject device were not statistically (P>0.05) different from that of the predicate device.
Therefore, it was concluded that the bonding performance to all substrates of the subject device was equivalent to that of the predicate device.

Released fluorine ion test was performed to validate the substantial equivalence of the subject device with the predicate device.
It was concluded that amount of released fluorine ion from the subject device is substantially equivalent to that of the predicate device.

3-8. Biocompatibility

The subject device is classified according to ISO 7405:2008 and ISO 10993-1:2009 as an external communicating device that will have permanent (> 30 days) contact with tissues.
All ingredients in the subject device have been used in the predicate device and the reference devices as listed on the *"Table 7-5-1.and 7-5-2."* in *"Section 7: Substantial Equivalence Discussion".* And those devices are also classified as an external communicating device that will have permanent (> 30 days) contact with tissues.
Regarding the 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.
Concerning the track records of the ingredients, intended use, manufacturing process, contact part and contact duration, all of them are substantially equivalent to those of the predicate device and the reference devices.
These facts lead us to conclude that the subject device is substantially equivalent in biocompatibility to the predicate device and the reference devices without performing additional biological tests.

3-9. Conclusion

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