March 25, 2021

Diadent Group International
Kab Lee
Quality Assurance Manager
16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu
Cheongju-si, Chungcheongbuk-do 28161
SOUTH KOREA

Re: K210333
Trade/Device Name: DiaPaste
Regulation Number: 21 CFR 872.3820
Regulation Name: Root canal filling resin
Regulatory Class: Class II
Product Code: KIF
Dated: February 25, 2021
Received: February 26, 2021

Dear Kab Lee:

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.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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, M.ChE.
Assistant 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210333

Device Name
DiaPaste

Indications for Use *(Describe)*
Aqueous ointment material that temporarily fills the root canal for the following indications:
Apexification
Temporary root filling
Root canal filling for primary teeth
Vital pulpotomy
Temporary pulp capping

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Special 510(k) Summary

1 Application Information

Date Prepared:	01 Feb, 2021
Company Name and Address:	DiaDent Group International 16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea
Contact Person:	Kab Sun, Lee Quality Assurance Manager Phone: +82-43-266-2315 FAX: +82-43-235-2315 Email: diadent32@diadent.co.kr

2 Device Information

Device Type:	Root Canal Filling Resin
Regulation Description:	Root Canal Filling Resin
Review Panel:	Dental
Regulation Number:	21 CFR 872.3820
Product Code:	KIF
Device Class:	II
Device Name:	DIAPASTE

3 Predicate Devices

The legally marketed devices to which substantial equivalence is being claimed are:

	Primary Predicate Device
510(k) Number:	K190091
Applicant:	DiaDent Group International
Device Name:	DiaPaste
Regulation Number:	21 CFR 872.3820
Product Code:	KIF
Device Class:	II

4 Device Configuration

Each model configurations of subject device are described as following:

Model Name	**Contents**
DiaPaste Type A	1 syringe(2g), 20 disposable tips, 1silicone cap
DiaPaste Type B	1 syringe(2g), 10 disposable tips, 1silicone cap
DiaPaste Type C	1 syringe(2g), 4 disposable tips, 1silicone cap
DiaPaste Refill Kit	1 syringe(2g)
DiaPaste Intro Kit	1 syringe(0.5g), 4 disposable tips 1silicone cap

5 Device Description

Diapaste is a calcium hydroxide paste with barium sulfate, used as a temporary root canal filling material.

6 Intended Use/Indications for Use

Aqueous ointment material that temporarily fills the root canal for the following indications:

- Apexification
- Temporary root filling
- Root canal filling for primary teeth
- Vital pulpotomy
- Temporary pulp capping

7 Comparison Table and Discussion

This device compares to the legally marketed devices as follows:

	Reference Predicate Device	Subject Device	
	DiaPaste	**DiaPaste(Special 510k)**	**Discussion**
Regulation Number:	21 CFR 872.3820	21 CFR 872.3820	-
510(k) Number	**K190091**	**K210333**	-
Indication for Use	Aqueous ointment material that temporarily fills the root canal for the following indications: ·○ Apexification ·○ Temporary root filling ·○ Root canal filling for primary teeth ·○ Vital pulpotomy ·○ Temporary pulp capping	Aqueous ointment material that temporarily fills the root canal for the following indications: ·○ Apexification ·○ Temporary root filling ·○ Root canal filling for primary teeth ·○ Vital pulpotomy ·○ Temporary pulp capping	equivalent
Composition	-. Polyoxymethylene sorbitan monooleate -. Polyethylene glycol -. Distilled water -. Barium sulfate -. Zinc oxide -. Calcium hydroxide -. Calcium carbonate	-. Calcium hydroxide -. Titanium dioxide -. Zinc oxide -. Barium sulfate -. Water -. Polyether Polyol -. Polysorbate (Tween80)	
Period of Use	Temporary (remains in the body for 29 days or less)	Temporary (remains in the body for 29 days or less)	equivalent
Physical properties	Conformed to ISO 6876 - Flowability - Film Thickness - Radio-opacity	Conformed to ISO 6876 - Flowability - Film Thickness - Radio-opacity	equivalent
Biocompatibility	Biocompatible - Cytotoxicity - Sensitization - Acute Systemic toxicity - Oral Mucosa irritation - Genetoxicity-Bacterial Reverse Mutation - Genetoxicity- Micronucleus test	Biocompatible - Cytotoxicity - Sensitization - Irritation Test - Genotoxicity Test - Acute Systemic Toxicity Test - Sub chronic Toxicity test - Implantation Test	equivalent
Package Contents	•Syringe •Disposable Tip •Silicone Cap	•Syringe •Disposable Tip •Silicone Cap	-

Differences

-Composition

Reference Predicate Device	Subject Device	Discussion
-. Polyoxymethylene sorbitan monooleate -. Polyethylene glycol -. Distilled water -. Barium sulfate -. Zinc oxide -. Calcium hydroxide -. Calcium carbonate	-. Calcium hydroxide -. Titanium dioxide -. Zinc oxide -. Barium sulfate -. Water -. Polyether Polyol -. Polysorbate (Tween80)	Raw materials except Titanium dioxide is the same as the before medical device. The reason for this change is product improvement due to consumer request. and the biocompatibility of subject device was confirmed by biological safety study.

8. Non-Clinical performance data

This device has demonstrated conformance with non-clinical performance requirements through evaluation and testing in accordance with the following harmonized standards:

-ISO 6876	Root Canal Sealing materials
-ISO 7405	Dentistry - Evaluation Of Biocompatibility Of Medical Devices Used In Dentistry [Including: Amendment 1 (2013)]
-ISO 10993-1	Biological evaluation of medical devices - Part 1:Evaluation and testing within a risk management process
-ISO 10993-3	Biological Evaluation of Medical Devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
-ISO 10993-5	Biological evaluation of medical devices - Part 5. Tests for in vitro Cytotoxicity
-ISO 10993-10	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
-ISO 10993-11	10993-11 – Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity

The following Performance tests were conducted.

- Flowability
- Film thickness
- Radiopacity
- Biocompatibility test

Performance test (Physical properties):

Test	Requirement	Result	Pass/Fail
Flowability	Each disc to have a diameter of not less than 17mm	18mm (mean value)	Pass
Film thickness	No more than 50µm	23µm (mean value)	Pass
Radiopacity	Equivalent to not less than 3mm of Aluminum	Not less than 3mm of Aluminum (approx. 4.1mm)	Pass

9. Conclusion

"Root Canal Filling Materials (model name: DiaPaste)" was compared to "Root Canal Filling Materials (model name: Diapaste) which has similar purpose of use, principle of action, method of use and test specifications. The purpose of use, principle of action, test standard, and method of use were the same as the comparison product, but there were differences in performance, and the raw materials were similar except for some components. In addition, there were no cases of biological side effects reported so far for the licensed product, and the biological safety test results for the applied product were judged as “suitable” for all items. DiaPaste is determined to have a level of biological safety that satisfies risk-benefit analysis based on the clinical use history of similar market products when used according to the intended use and methods of use.