September 18, 2020

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

Re: K200174
Trade/Device Name: Dia-root Bio Mta
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: August 11, 2020
Received: August 19, 2020

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200174

Device Name
DIA-ROOT BIO MTA

Indications for Use *(Describe)*
DIA-ROOT BIO MTA is used for pulp capping (direct pulp capping or partial pulpotomy) and repair of root perforation. Other indications for use include: repair of root resorption, root end filling, apexification and pulpotomy.

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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5.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

5.1 Application Information

Date Prepared:	Aug 11, 2020
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

5.2 Device Information

Device Type:	Resin, Root Canal Filling
Regulation Description:	Root canal filling resin
Review Panel:	Dental
Regulation Number:	21 CFR 872.3820
Product Code:	KIF
Device Class:	II
Device Name:	DIA-ROOT BIO MTA

5.3 Predicate Devices

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

510(k) Number:	K112046
Applicant:	ANGELUS INDUSTRIA DE PRODUCTOS ODONTOLOGICOS
Device Name:	MTA ANGELUS
Regulation Number:	872.3820
Product Code:	KIF
Device Class:	II

5.4 Device Description

Package Composition	Composition
DIA-ROOT BIO MTA 0.5g	0.5g cap & body 1ea + Mixing pad 1ea (5 Sheet/Bundle) + Spatula 1ea

The subject device is packaged with the following:

No.	Component	Description
1	Cap & Body	It stores the contents.
2	Mixing pad	It is a pad used for mixing distilled water and the product.
3	Spatula	It is a spatula used for mixing distilled water and the product.

5.5 Intended Use

DIA-ROOT BIO MTA is used for pulp capping (direct pulp capping or partial pulpotomy) and repair of root perforation. Other indications for use include: repair of root resorption, root end filling, apexification and pulpotomy.

5.6 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 6876:2012, Dentistry - Root canal sealing materials
- ISO 7405:2018, Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
- ISO 10993-1:2018, Evaluation and testing within a risk management process
- ISO 10993-2:2006, Animal welfare requirements
- ISO 10993-3:2014, Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-5:2009, Tests for in vitro cytotoxicity
- ISO 10993-6:2016, Tests for local effects after implantation
- ISO 10993-10:2010, Tests for irritation and skin sensitization
- ISO 10993-11:2017, Tests for systemic toxicity
- ISO 10993-12:2012, Sample preparation and reference materials

Additional non-clinical bench testing demonstrates the safety and effectiveness of the subject device.

5.7 Clinical Performance Data

No clinical data was collected or provided to support substantial equivalence between the subject and predicate devices.

5.8 Technological characteristics

The subject device, DIA-ROOT BIO MTA has similar characteristics to the predicate device, MTA ANGELUS.

First, the intend use of the subject device and predicate device is pulp capping and to repair of root perforation.

Second, both the subject device and predicate device are to react with water.

Third, both the subject device and predicate device confirm to ISO 6876 and have similar physical and mechanical properties; Setting time, Solubility, Radio-opacity. Also, they are biocompatible.

Finally, they are supplied non-sterile state and have 3 years shelf-life.

The raw materials composition of the subject device is slightly different from the predicate device. However, the main material, Calcium silicate of the subject device is similar to Tricalcium silicate, Dicalcium silicate of the predicate device. Through the results of bench and biocompatibility tests, this difference does not raise any issue of safety and effectiveness.

	Subject Device	Primary Predicate Device	Discuss
510(k) Number	-	K112046	-
Product code	KIF	KIF	Equivalent
Device Class	II	II	Equivalent
Applicant	DiaDent Group International	ANGELUS INDUSTRIA DE PRODUCTOS ODONTOLOGICOS	-
Device Name	DIA-ROOT BIO MTA	MTA ANGELUS	-
Indications For Use	DIA-ROOT BIO MTA is used for pulp capping (direct pulp capping or partial pulpotomy) and repair of root perforation. Other indications for use include: repair of root resorption, root end filling, apexification and pulpotomy.	- Treatment of perforations of root canal and furcation caused iatrogenically or by caries lesions - Via canal treatment of root perforation due to internal resorption - Surgical treatment of root perforation due to internal resorption - Periapical surgery with reverse filling - Pulp capping - Pulpotomy(removal of affected coronal pulp to preserve vitality of remaining pulp tissue) - Apexogenesis(induction of root development in vital teeth with an inflamed coronal pulp) - Apexification(induction of formation of a mineralized barrier at the root tip of young	Equivalent

		permanent teeth with incomplete root development and a necrotic pulp)	
Description	DIA-ROOT BIO MTA is a hydraulic product that hardens by reacting with water. It is designed for the protection of pulp such as direct pulp capping, pulpotomy, and perforation.	MTA Angelus is a mineral trioxide aggregate cement used for root repair during endodontic treatment, combining the powder and liquid produces a colloidal gel that solidifies to form a barrier.	Equivalent
Package Contents	● Cap & Body ● Mixing pad ● Spatula	● Cap & Body ● Distilled Water ● Spoon	-
Composition	- Calcium silicate - Zirconium dioxdie - Citric acid - Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-,hydrolysis products with silica -Hydroxypropyl methylcellulose	- Tricalcium silicate - Dicalcium silicate - Tricalcium aluminate - Calcium oxide - Bismuth oxide - Distilled water	The main ingredients are similar, with some different ingredients. However, the results of biocompatibility and performance tests confirm that DIA-ROOT BIO MTA similar products are equivalent.
Physical properties	- Setting time - Solubility - Radiopacity	- Setting time - Solubility - Radiopacity	Equivalent
Use	Prescription / Hospital	Prescription / Hospital	Equivalent
Period of Use	Permanent	Permanent	Equivalent
Sterility	Non-sterile	Non-sterile	Equivalent
Shelf-life	3 years	3 years	Equivalent
Biocompatibility	Biocompatible	Biocompatible	Equivalent
Standards	ISO7405	ISO7405	-

5.9 Conclusions

Based on the above information and all data provided in this submission, the comparison of intended uses, technological characteristics, and non-clinical performance testing demonstrates that the subject device is substantially equivalent to the legally marketed devices identified in this submission.