June 25, 2020

Diadent Group International
Kab Sun Lee
Quality Assurance Manager
16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu
Cheongju-si, Chungcheongbuk-do, 28161
Republic of Korea

Re: K200175
Trade/Device Name: DIA-ROOT BIO Sealer
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: March 25, 2020
Received: March 27, 2020

Dear Kab Sun 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)*
K200175

Device Name
DIA-ROOT BIO Sealer

Indications for Use *(Describe)*
DIA-ROOT BIO Sealer is a MTA (mineral trioxide aggregate) based root canal sealer that provides complete and permanent sealing of root canals. It can be used with or without root canal obturation materials.

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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510(k) Summary (K200175)

This summary of 510(k) substantial equivalence information is submitted in accordance with the requirements of 21 CFR 807.92.

1. Application Information

Date Prepared	Jun 24, 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

2. Device Information

510(k) Number	K200175
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 Sealer

3. Primary Predicate Device

510(k) Number	K170950
Applicant	Vericom Co., Ltd.
Device Name	Well-Root ST
Regulation Number	21 CFR 872.3820
Product Code	KIF
Device Class	II

4. Device Description

DIA-ROOT BIO Sealer is a hydraulic material, and a premixed form that does not require mixing. It blocks the root canal by hardening by reacting with water in the oral cavity. It is contained in a water-blocked syringe and corresponds to ISO 6876:2012, Dentistry-Root canal sealing materials. DIA-ROOT BIO Sealer has two models and they are packaged with components; Disposable tip, Silicone cap.

Model Name	Composition
DIA-ROOT BIO Sealer 2.0g	2.0g syringe 1ea + Disposable tip 20ea + Silicone cap 1ea
DIA-ROOT BIO Sealer 0.5g	0.5g syringe 1ea + Disposable tip 4ea + Silicone cap 1ea

5. Indications for Use
DIA-ROOT BIO Sealer is a MTA (mineral trioxide aggregate) based root canal sealer that provides complete and permanent sealing of root canals. It can be used with or without root canal obturation materials.

6. Clinical Performance Data
No clinical data was collected or provided to support substantial equivalence between the subject and primary predicate device.

7. Non-Clinical Performance Data
The performance and biological tests were conducted on the subject device; DIA-ROOT BIO Sealer according to the following 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

The test results corresponded the requirements of standards. Therefore, the subject device is substantially equivalent to the primary predicate device.

8. Technological Characteristics
The subject device, DIA-ROOT BIO Sealer has similar characteristics to the primary predicate device, Well-Root ST.

First, the indications for use of the subject device and primary predicate device is to seal root canal permanently. Our indications for use is more detailed than the predicate device, but it does not contain new indications.

Second, both the subject device and primary predicate device are premixed hydraulic materials, and to seal the root canal by hardening with water in the oral cavity. Also, they are contained in a syringe and supplied with disposable tips.

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

Finally, they are supplied non-sterile state and have 2 years shelf-life.

The raw materials composition of the subject device is slightly different from the primary predicate device. However, the main material, Calcium silicate of the subject device is similar to Calcium aluminosilicate compound of the primary predicate device. Also, Zirconium Oxide and Polyethylene glycol are contained in both subject device and primary predicate device. Through the results of bench and biocompatibility tests, this difference does not affect substantial equivalance.

[Comparison table]

	Subject Device	Primary Predicate Device	Discuss
510(k) Number	K200175	K170950	-
Product Code	KIF	KIF	Equivalent
Device Class	II	II	Equivalent

Manufacturer	DiaDent Group International	Vericom Co., Ltd.	-
Device Name	DIA-ROOT BIO Sealer	Well-Root ST	-
Indications for Use	DIA-ROOT BIO Sealer is a MTA (mineral trioxide aggregate) based root canal sealer that provides complete and permanent sealing of root canals. It can be used with or without root canal obturation materials.	Permanent sealing of root canal	Equivalent
Description	DIA-ROOT BIO Sealer is a hydraulic material, and a premixed form that does not require mixing. It blocks the root canal by hardening by reacting with water in the oral cavity. It is contained in a water-blocked syringe and corresponds to ISO 6876:2012, Dentistry-Root canal sealing materials.	Well-Root ST is a convenient premixed ready-to use composition which requires the presence of water to set and harden. The device is contained in a plastic syringe and the system includes a plunger, disposable tips, and a holder.	Equivalent
Package Contents	-Syringe -Disposable tip -Silicone Cap	-Syringe -Disposable tip -Holder	Equivalent
Raw Materials	- Calcium Silicate - Calcium Aluminate - Ytterbium Trifluoride - Zirconium Oxide - Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica - Hydroxypropyl Methylcellulose - Polyethylene glycol 400 - Polyethylene glycol 200 - Sorbitan - White Mineral Oil-	-Calcium aluminosilicate compound - Calcium Sulfate dihydrate - Calcium sodium phosphosilicate - Zirconium Oxide - Titanium Dioxide - Polyethylene glycol - Polypropylene glycol - Propylene glycol	The main material, calcium silicate of the subject device is similar to calcium aluminosilicate compound of the primary predicate device. Also, zirconium oxide and polyethylene glycol are contained in both subject device and primary predicate device. Through the results of bench and biocompatibility tests, this difference does not affect substantial equivalence.

Principle of operation	DIA-ROOT BIO Sealer is a premixed form that does not require mixing, and a hydraulic material that hardens by reacting water. Also, it blocks the root canal by hardening by reacting with water in the oral cavity. It is contained in a water-blocked syringe and is supplied with disposable tips and silicone caps.	Well-Root ST is a convenient premixed ready-to-use injectable white hydraulic cement paste developed for permanent root canal filling and sealing applications. Well-Root ST is an insoluble, radiopaque material which sets and hardens with moisture providing from dentin tubules during hydration reaction. Well-Root ST is packaged in a pre-loaded syringe and is supplied with disposable tips.	Equivalent
Performance Standard Conformance	Conformed ISO 6876	Conformed ISO 6876	Equivalent
Physical and Mechanical properties	-Flow: Not less than 17 mm -Film thickness: Not more than 50 μm -Solubility: Not more than 3 % -Radio-opacity: Not less than 3 mm	-Flow: Not less than 17 mm -Film thickness: Not more than 50 μm -Solubility: Not more than 3 % -Radio-opacity: Not less than 3mm	Equivalent
Biocompatibility	Biocompatible	Biocompatible	Equivalent
Use	Prescription / Hospital	Prescription / Hospital	Equivalent
Period of use	Permanent	Permanent	Equivalent
Sterility	Non-sterile	Non-sterile	Equivalent
Shelf-life	2 years	2 years	Equivalent

9. Conclusions

Based on the above information and all data provided in this submission, the subject device is substantially equivalent to the legally marketed device identified in this submission.