June 3, 2019

Diadent Group International
Myung Sub Kim
Quality Assurance Manager
16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu
Cheongji-si, Chungcheongbuk-do, 28161
Republic of Korea

Re: K182625
Trade/Device Name: Diapex Plus
Regulation Number: 21 CFR 872.3820
Regulation Name: Root canal filling resin
Regulatory Class: Class II
Product Code: KIF
Dated: April 15, 2019
Received: April 19, 2019

Dear Myung Sub Kim:

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,

for Malvina B Eydelman, M.D.
Director
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)*

Device Name
DIAPEX PLUS

Indications for Use *(Describe)*
DIAPEX PLUS is a calcium hydroxide paste with iodoform, used as a temporary root canal filling material.
Application : Root canal filling material/Apexification and hard tissue formation/Apexogensis

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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Food and Drug Administration
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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

5.0 510(k) Summary

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

5.1 Application Information

Date Prepared:	21st September, 2018
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:	Myung Sub Kim Quality Assurance Manager Phone: +82-43-266-2315 FAX: +82-43-235-2315 Email: diadent32@diadent.co.kr

5.2 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:	DIAPEX PLUS

5.3 Predicate Devices

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

510(k) Number:	K973667	K032603
Applicant:	Neo Dental Chemical Products Co, Ltd.	Meta Biomed Co., Ltd.
Device Name:	Vitapex	Metapex
Regulation Number:	21 CFR 872.3820	21 CFR 872.3820
Product Code:	KIF	KIF
Device Class:	II	II

5.4 Device Description

The subject device is packaged with the following:

- Syringe
- Disposable Tip
- Silicon Cap

5.5 Intended Use/Indications for Use

DIAPEX PLUS is a calcium hydroxide paste with iodoform, used as a temporary root canal filling material.
Application : Root canal filling material / Apexification and hard tissue formation/ Apexogensis

5.6 Technological Characteristics

This device compares to the legally marketed devices as follows:

	Proposed Device	Primary predicate device	Reference predicate device	Discussion
	DiaPex Plus	**Vitapex**	**Metapex**	
510(k) Number	-	K973667	K032603	-
Intended Use/Indications for Use	DIAPEX PLUS is a calcium hydroxide paste with iodoform, used as a temporary root canal filling material Application : Root canal filling material / Apexification and hard tissue formation/ Apexogensis	VitaPex can be used as a temporary or permanent root canal filling material. It is ideal for the treatment of infected root canals and for vital pulpotomies In deciduous teeth.	•Exposed pulp in capping and pulpectomy •Leakage canal •Apexification •Formation of hard tissue barrier •Root canal filling material	equivalent
Directions for Use	•Before using Diapex Plus, ensure that the syringe and tip are free of damage(e.g. chips, cracks, deformation, and/or other defects) •Wipe and disinfect the outer syringe and tip with alcohol as tips come unsterilized. •After root canal preparation, the canal is irrigated and dried. •Insert the tip of the Diapex Plus syringe to one fifth of foot canal length from the apex. the tip is bent to obtain easier access to canal. •Slowly and gently press the piston of the syringe to extrude the paste. the paste should reach the periapical tissue and the tip should be pulled out	Extrude VitaPex into the canal. place temporary restoration. At subsequent visits remove VitaPex with sodium hydrochloride and mechanical means.	•Clean and dry it after preparing the root canal •Set up a disposable tip in syringe and insert the ring provided for and easy re-direction of the tip •Disinfect the disposable tip with ethanol •Fill the canal completely by pushing the syringe plunger while withdrawing the tip slowly •Clean any excess paste with a sterilized cotton pellet •Remove the used tip, fix a new one and cover up	equivalent

	Proposed Device	Primary predicate device	Reference predicate device	Discussion
	DiaPex Plus	**Vitapex**	**Metapex**	
	slowly. the paste should reverse back to the pulp chamber. •After placing the paste in the canal and fully removing the syringe, clean off any excess paste. •After each application, the used tip should be discarded and a new tip or the silicon cap put back on			
Package Contents	•Syringe •Disposable Tip •Silicon Cap	•Syringe •Disposable Tip	•Syringe •Disposable Tip •One ring rotator for the direction control of the tip	
Period of Use	Temporary (remains in the body for 29 days or less)	Temporary	Temporary	
Composition	Calcium Hydroxide IODOFORM Polydimethylsiloxane Olive Oil	Calcium Hydroxide IODOFORM Silicone Oil Inert	Calcium Hydroxide IODOFORM Polydimethylsiloxane Silicone Oil	The main ingredients are similar and have some other ingredients. However, biocompatibility and performance tests confirm that DiaPex Plus and similar products are substantially equivalent.
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	equivalent
Delivery forms	Premixed paste	Premixed paste	Premixed paste	equivalent
Standards	ISO 6876	ISO 6876	ISO 6876	equivalent

As demonstrated in the above comparison table, the subject and predicate devices have similar intended uses, contraindications, composition and contents, Base and Catalyst part mixture

design, shelf life, biocompatibility, and conformance with standards.

5.7 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:

Standard	contents	Relevant test	Relevant File
ISO 6876:2012	Dentistry -- Root canal sealing materials	•Flowability •Film Thickness •Radio-opacity	18.0 Performance Testing- Bench
ISO 7405:2008	Dentistry -- Evaluation of biocompatibility of medical devices used in dentistry		15.0 Biocompatibility
ISO 10993-1:2009	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process		15.0 Biocompatibility
ISO 10993-3:2014	Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	•Genotoxicity Bacterial Reverse Mutation •Genotoxicity Mouse Lymphoma Assay	15.0 Biocompatibility
ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity	•Cytotoxicity	15.0 Biocompatibility
ISO 10993-6: 2016	Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation	•4 Week Systemic Toxicity	15.0 Biocompatibility
ISO 10993-10:2010	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	•Sensitization	15.0 Biocompatibility
ISO 10993-11:2017	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity	•Acute Systemic Toxicity •Pyrogenicity •4 Week Systemic Toxicity	15.0 Biocompatibility

Additional non-clinical bench testing demonstrates the substantial equivalence of the subject device.

5.8 Clinical Performance Data

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

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.