February 13, 2020

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

Re: K192158
Trade/Device Name: DiaTemp
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: October 1, 2020
Received: October 1, 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)*
K192158

Device Name
DiaTemp

Indications for Use *(Describe)*
All types of temporary fillings, temporary protection in inlay and onlay technique.

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."

5.0 510(k) Summary

5.1 Application Information

Date Prepared	February 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	Material, Tooth Shade, Resin
Regulation Description	Tooth shade resin material.
Review Panel	Dental
Regulation Number	21 CFR 872.3690
Product Code	EBF
Device Class	II
Device Name	DiaTemp

5.3 Predicate Devices

The legally marketed device to which substantial equivalence is being claimed is:

510(k) Number	K111666
Applicant	NEO DENTAL CHEMICAL PRODUCTS CO., LTD.
Device Name	EVADYNE TEMPORARY CROWN AND BRIDGE RESIN
Regulation Number	21 CFR 872.3770
Product Code	EBG
Device Class	II

5.4 Device Description

DiaTemp is a temporary filling material that sets with curing light. In case the cavity is not permanently restored, Diatemp can be used as a temporary restoration until the next appointment. DiaTemp has four models and packaged with syringe and protective cap.

Model Name	Color	Weight
DiaTemp Yellow 3g	Yellow	3g
DiaTemp Blue 3g	Blue	3g
DiaTemp Yellow Intro kit 1g	Yellow	1g
DiaTemp Blue Intro kit 1g	Blue	1g

5.5 Indications for Use

All types of temporary fillings, temporary protection in inlay and onlay technique.

5.6 Clinical Performance Data

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

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:

- ISO 4049:2009, Dentistry – Polymer-based restorative materials
- ISO 7405:2009, Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
- ISO 10993-1:2009, 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

5.8 Technological Characteristics

The technological comparison of the subject device to the predicate device is as follows.

	Subject Device	Primary Predicate Device	Discuss
510(k) Number	-	K111666	
Device code	EBF	EBG	
Applicant	DiaDent Group International	NEO DENTAL CHEMICAL PRODUCTS CO., LTD.	
Device Name	DiaTemp	EVADYNE TEMPORARY CROWN AND BRIDGE RESIN	
Indications for Use	All types of temporary fillings, temporary protection in inlay and onlay technique.	Evadyne is a light cured single-component material for the temporary restoration of crowns, bridges, or similar dental prostheses. Evadyne is intended for the general dental patient population.	Equivalent The indications for use of the subjective device and predicate device is the temporary filling, sealing, restoration.
Description	DiaTemp is a temporary filling material that sets with curing light. In case the cavity is not permanently restored, DiaTemp can be used as a temporary restoration until the next appointment.	Evadyne is a yellowish translucent, lower viscosity, light-cured temporary restoration material for direct filling. After curing, Evadyne can be removed in one piece when the permanent restoration is to be placed.	Equivalent
Package Contents	-Syringe -Protective Cap	-Syringe -Disposable tips	Equivalent
Composition	-Ethyl 4-(N,Ndimethylamino) benzoate -Silica amorphous,fumed -Urethane acrylate -BHT -Camphorquinone	-Ethyl-4-dimethylamino benzoate -Fluoroaluminosilicate glass -Polyester urethane dimethacrylat-	The main ingredients are similar. Also, biocompatibility and performance tests demonstrate that DiaTemp and the predicate device

			are substantially equivalent.
Performance Standard Conformance	ISO4049	ISO4049	Equivalent
Physical and Mechanical Properties	-Sensitivity to ambient light -Depth of cure -Curing time -Water sorption and solubility -Shade & Colour stability	-Sensitivity to ambient light -Depth of cure -Curing time	Equivalent
Period of Use	Prolonged exposure(B) (exceed 24 hours but not 30 days)	Prolonged exposure(B) (exceed 24 hours but not 30 days)	Equivalent
Bio-compatibility	Biocompatible	Biocompatible	Equivalent
Use	Prescription/Hospital	Prescription/Hospital	Equivalent
Standards	ISO7405	ISO7405	Equivalent

There are similarities between the subject device and predicate device.
The indications for use of the subject device and predicate device is the temporary filling, sealing and restoration. Also, the subject device has similar physical properties to the predicate device.

Physical characteristics	**Subject Device**	**Predicate Device**
Sensitivity to ambient light	homogeneous	homogeneous
Depth of cure	More than 1.5mm (average: 2.9 mm)	2.5 mm
Curing Time	20 ~ 30 seconds	20 seconds

However, the composition of the subject device is slightly different from the predicate device. However, the main ingredients are similar. Also, the biocompatibility and performance tests were confirmed.

5.9 Conclusions

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