September 26, 2019

Diadent Group International
Myung Sub Kim
Quality Assurance Manager
16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu
Cheongji-si, 28161 KOREA

Re: K182009
Trade/Device Name: DIA-PROSEAL
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: August 30, 2019
Received: August 30, 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/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 Nandkumar, PhD
Acting 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)*

K182009

Device Name
DIA-PROSEAL

Indications for Use *(Describe)*
DIA-PROSEAL is used for permanent sealing of root canals in secondary dentition with gutta percha points.

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.

510(k) Summary

5.0 Application Information

Date Prepared:	26th Sep, 2019
Company Name and Address:	DiaDent Group International 16, Osongsaengmyeong 4-ro, Osong-eup, Heundeok-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

5.1 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:	DIA-PROSEAL

5.2 Predicate Devices

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

510(k) Number:	K960548
Applicant:	Dentsply International
Device Name:	AH Plus Root Canal Sealer
Regulation Number:	21 CFR 872.3820
Product Code:	KIF
Device Class:	II

5.3 Device Description

DIA-PROSEAL Root Canal Sealer is two-component systems that react via an epoxide/amine chemical reaction to case setting.

5.4 Intended Use/Indications for Use

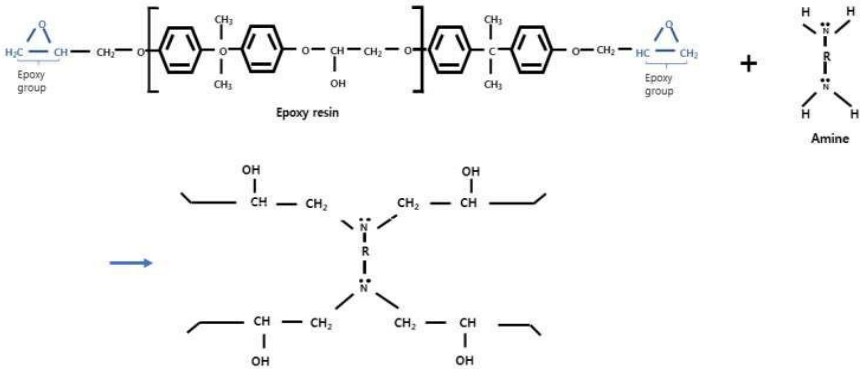
- DIA-PROSEAL is used for permanent sealing of root canals in secondary dentition with gutta percha points.

5.5 Technological Characteristics

This device compares to the legally marketed devices as follows:

	Subject Device	**Primary Predicate Device**	**Discuss**
Product name	**Dia-ProSeal**	AH Plus	
Manufacturer	DiaDent Group International	Dentsply	
510K Number	K182009	K960548	
Product Code	KIF	KIF	
Intended use	DIA-PROSEAL is used for permanent sealing of root canals in secondary dentition with gutta percha points.	AH Plus Root Canal Sealer is used for permanent sealing of root canals following established endodontic procedures.	Equivalent
Image			
Main ingredient	Base Bisphenol A epoxy resin Bisphenol F epoxy resin Zirconium dioxide Iron oxide silica Calcium tungstate Catalyst amine-containing paste	Paste A Bisphenol A epoxy resin Bisphenol F epoxy resin zirconium oxide Iron oxide Pigments silica Calcium tungstate Paste B amine-containing paste	The main ingredients of AH Plus and of Dia-Proseal are similar. They are both two-component system that use epoxide/ amine reaction to cause setting.
Resin Sealer Type	Epoxy resin based sealers	Epoxy resin based sealers	equivalent
Device description	DiaProSeal Root Canal Sealer consists of two components, the epoxy resin paste(Base) and the amine-containing paste(Catalyst) portions which are mixed prior to insertion into the root canal. DiaProSeal Root Canal Sealer is two-component systems that react via an **epoxide/amine chemical reaction** to cause setting.	AH Plus Root Canal sealer is a two-component paste: paste root canal sealer based on epoxy-amine rein chemistry. This is easy-to-mix sealer adapts closely to the walls of the prepared root canal and provides outstanding long-term dimensional stability with minimal shrinkage upon setting. The final product consists of two components, the epoxy resin paste(PasteA) and the amine-containing paste(PasteB) portions which are mixed prior to insertion into the root canal	equivalent
Direction for	**Application Method**	**Preparation**	equivalent

Use	1. Isolate the site with rubber dam. Prepare and shape the root canal. 2. Remove any debris inside the root canal. Disinfect and clean the root canal thoroughly with Sodium Hypochlorite or EDTA solution and dry it completely. 3) Open the safety cap of DIAPROSEAL and squeeze out the vase material (yellow) and the catalyst material(white) in 1:1 ratio from the dual syringe onto a mixing pad. (Due to the different viscosity of the vase material and the catalyst material, they may be dispensed at a different speed). 4. Using a mixing stick or metal spatula, mix the base material (yellow) and the catalyst material(white) for 10-20 seconds until they are completely mixed together and have turned into an ivory color. 5. Measure the length of the root canal by using an electronic apex locator or a file. Select a gutta percha point accordingly. Apply and coat a small amount of the mixture to the gutta percha point and insert the point towards the apex slowly. alternatively, dentists may choose to apply the mixture with a paper point, a reamer, or Dia-Spiral Filler (Lentulo spiral). In order to Prevent the formation and entrapment of air bubbles and overfilling the canal, the mixture-coated points must be inserted very slowly in a clockwise direction during obturation and withdrawn in a counter clock wise direction. If Lentulo spiral is used, advance and withdraw the Lentulo spiral slowly to the apex at very low speed. 6. Once the procedure is done, take an X-Ray to check the seal.	1. Prior to the application of the material prepare, clean, and dry the root canals to be filled using state-of-the-art endodontic techniques. **Dosage and mixing** 1. Using a metal spatula 2, mix equal volume units (1:1) of paste A (amber color) and paste B (white color) of AH Plus® root canal sealer on a glass slab or the mixing pad supplied with the package. Mix to a homogeneous consistency. 2. Tightly close tubes after use. 3. Do not exchange caps of tubes. The white cap belongs to paste A; the grey cap belongs to paste B. **Master-Point-Technique** 1. Select a gutta-percha point (or alternatively a paper point or a reamer) of the size of the last instrument used during apical preparation. 2. Wet the canal walls with the material through a pumping or simultaneously rotating movement in a counter-clockwise direction of the point/reamer. Alternatively, apply the material onto the tip of a Lentulo spiral. 3. Advance the Lentulo spiral slowly to the apex running at very low speed. Avoid the formation of air bubbles in the material and overfilling of the canal. 4. Withdraw Lentulo very slowly still running at low speed. 5. Dip disinfected and dry master point into the material and insert it into the canal with a slow pumping motion.	

Chemical reaction mechanism			equivalent
Performance Standard Conformance	ISO6876	ISO6876	equivalent
Physical and Mechanical Properties	-. setting time -. Film thickness -. radiopacity -. solubility -. Flow	-. Working time -. film thickness -. radiopacity -. Solubility	equivalent
Biocompatibility	Yes	Yes	equivalent
Use	Prescription/Hospital	Prescription/Hospital	equivalent
Delivery forms (Design)	Manual mixing of Base and Catalyst	Manual mixing of paste A and Paste B	equivalent

As demonstrated in the above comparison table, the subject and predicate devices have similar indication for uses, main ingredients, contents, biocompatibility, and conformance with standards. Also, the subject and predicate devices are using the same chemical reaction and classified as the same resin type (Epoxy resin based sealers) as a two part mixture design.

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 standards:

Standards	Contents	Relevant Tests (Performed)
ISO 7405:2008	Dentistry—Evaluation of biocompatibility of medical devices used in dentistry	-
ISO 10993-1:2009	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	-
ISO 10993-3:2014	Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	•Bacterial Reverse mutation
ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	•Cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	•Sensitization •Irritation/Intracutaneous reactivity
ISO 10993-11:2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	•Acute systemic toxicity
ISO 6876:2012	Dentistry — Root canal sealing materials	•Setting time •Film Thickness •Radio-opacity •Solubility •Flow

5.7 Clinical Performance Data

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

5.8 Conclusions

Based on conclusions drawn from the testing results, the subject device is substantially equivalent to our legally marketed predicate device.