February 12, 2021

Essential Dental Systems
Jason Guzman
R&D Manager
89 Leuning Street
South Hackensack, New Jersey 07606

Re: K202281
Trade/Device Name: EDS Bioceramic Sealer (Bioseal)
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: December 21, 2020
Received: December 22, 2020

Dear Jason Guzman:

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,

Michael E. Adjodha, M.ChE.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202281

Device Name
EDS Bioceramic Sealer (Bioseal)

Indications for Use *(Describe)*

– Permanent obturation of the root canal following vital pulp-extirpation.
– Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings.
– Suitable for use in single cone and lateral condensation 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.

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Section 5 - 510(k) Summary

[21 CFR 807.92 (c)]

1. Application Information: [807.92 (a)(1)]

Date Prepared: July 6, 2020

Company Name and Address: Essential Dental Systems
89 Leuning Street, South Hackensack, NJ 07606

Contact:	Mr. Jason Guzman	**OR**	Ms. Shamal Kadam
Designation:	R&D Manager		Regulatory Affairs Specialist
Email:	jguzman@edsdental.com		skadam@edsdental.com
Phone #:	201-487-9090 (ext.119)		201-487-9090 (ext.114)
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List of devices for which clearance is requested: Root canal sealing material called EDS Bioceramic Sealer (Bioseal)

2. Name of the Device: [807.92 (a)(2)]

Trade name: EDS Bioceramic Sealer (Bioseal)
Device Type: Resin, Root Canal Filling
Regulation Description: Root Canal Filling Resin
Review Panel: Dental
Regulation Number: 21 CFR 872.3820
Device class: Class II
Product Code: KIF

3. Predicate Device Information: [807.92 (a)(3)]

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

Table 5A – Predicate Devices

	Device	Manufacturer	510K number
1.	EndoSequence BC Sealer	Brasseler	K120048
2.	ProSmart Root Canal Obturation System	DRFP	K100248

4. Device Description: [807.92 (a)(4)]

EDS Bioceramic sealer (Bioseal) is a ready-to-use injectable bioceramic cement paste developed for permanent root canal filling and sealing applications. **EDS Bioceramic Sealer (Bioseal)** is an insoluble, radiopaque material based on a calcium silicate and calcium phosphate composition, which requires the presence of water to set and harden. **EDS Bioceramic Sealer (Bioseal)** does

not shrink during setting. **EDS Bioceramic Sealer (Bioseal)** is packaged in a pre-loaded syringe and is supplied with disposable Intra Canal Tips.

5. Device Configuration: [807.92 (a)(4)]

It consists of two component pastes that are combined in a dual barrel syringe for ease of dispensing and consistent dosage. It is used in combination with gutta-percha points during root canal obturation. It is packaged in the familiar double-barrel syringe configuration used by numerous other dental materials. The steps required to properly express the cement are: remove cap, attach mixer, attach dispensing top, press plunger. After use, the mixer / dispensing tip should be discarded and the cap replaced. The device is provided non-sterile.

6. Device Composition:

- Calcium Silicates
- Zirconium Oxide
- Calcium Hydroxide
- Halloysite clay
- Polyacrylic acid
- Bioactive Glass (45S5)
- Calcium Phosphate Monobasic
- β-Tricalcium Phosphate
- Silica thickening Agents
- Chlorhexidine
- Polyethylene glycol (MW 300)

7. Intended Use: [807.92 (a)(5)]

The **EDS Bioceramic Sealer (Bioseal)** is indicated for permanent sealing of root canals following established endodontic procedures. Permanent obturation of the root canal following vital pulp-extirpation or removal of infected or necrotic pulp followed by the placement of intra-canal dressings. The **EDS Bioceramic Sealer (Bioseal)** is suitable for use in single cone and lateral condensation technique.

8. Indications for Use: [807.92 (a)(5)]

- Permanent obturation of the root canal following vital pulp-extirpation.
- Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings.
- Suitable for use in single cone and lateral condensation technique.

9. Substantial Equivalence Discussion: [807.92 (a)(6)]

A comparison of **EDS Bioceramic Sealer (Bioseal)** and the predicate devices indicates the following similarities and differences to the devices which received 510(k) clearance:

Table 5C - Comparison of Characteristics

	Proposed Device	Primary Predicate Device	Reference Predicate Device
Device Name	EDS Bioceramic Sealer (Bioseal)	EndoSequence BC Sealer	ProSmart Root Canal Obturation System
510(k) Number	K202281	K120048	K100248
Manufacturer	Essential Dental Systems	Brasseler	DRFP
Indications for Use	– Permanent obturation of the root canal following vital pulp-extirpation. – Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings. – Suitable for use in single cone and lateral condensation technique.	– Permanent obturation of the root canal following vital pulp-extirpation. – Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings. – Suitable for use in single cone and lateral condensation technique.	– Permanent obturation of the root canal following vital pulp-extirpation. – Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings. – Suitable for use in single cone and lateral condensation technique.
Composition	Calcium Silicates, Calcium Phosphate monobasic, β-Tricalcium Phosphate, Zirconium Oxide, Polyethylene glycol (MW 300), Calcium Hydroxide, silica thickening agents. Bioactive Glass (45S5), Polyacrylic acid, Chlorhexidine, Halloysite clay.	Calcium Silicates, Calcium Phosphates, Zirconium Oxide, Polyethylene glycol, Calcium Hydroxide, Filler and Silica Thickening Agents.	Epoxy-Amine Resin, Hydrophilic Polymers, Calcium Hydroxide, Metal Oxides, Filler and Thickening Agents.

	Proposed Device	Primary Predicate Device	Reference Predicate Device
Shades	White	White	White
Tissue Contacting Device Material(s)	Calcium Silicates, Calcium Phosphate monobasic, β-Tricalcium Phosphate, Zirconium Oxide, Polyethylene glycol (MW 300), Calcium Hydroxide, Silica thickening agents. Bioactive Glass (45S5), Polyacrylic acid, Chlorhexidine, Halloysite clay.	Zirconium Oxide, Calcium Phosphates, Tricalcium Silicate, Dicalcium Silicate, Calcium Hydroxide, Polyethylene glycol, Silica Filler, and Silica Thickening Agents.	Calcium Phosphate, Epoxy - Amine Resin, Silica Filler, and Thickening Agents.
Device Description	**EDS Bioceramic sealer (Bioseal)** is a ready-to-use injectable bioceramic cement paste developed for permanent root canal lling and sealing applications. **EDS Bioceramic Sealer (Bioseal)** is an insoluble, radiopaque material based on a calcium silicate and calcium phosphate composition, which requires the presence of water to set and harden. **EDS Bioceramic Sealer (Bioseal)** does not shrink during setting. **EDS Bioceramic Sealer (Bioseal)** is packaged in a pre-loaded syringe and is supplied with disposable Intra Canal Tips.	Premixed ready-to-use injectable white hydraulic cement paste developed for permanent root canal filling and sealing applications. It is based on a primarily calcium silicate/calcium phosphate composition and requires the presence of water to set and harden. Supplied in a single barrel syringe.	The ProSmart uses hydrophylic polymers which allows the material to expand into irregularities and tubules of the root canal to assure a tight mechanical seal with the dentin.

	Proposed Device	Primary Predicate Device	Reference Predicate Device
Picture of Device			
Intended Use	Endsequence BC Sealer is intended for permanent sealing of root canals following established endodontic procedures by qualified healthcare professionals.	Endsequence BC Sealer is intended for permanent sealing of root canals following established endodontic procedures by qualified healthcare professionals.	The ProSmart is designed for the permanent sealing of root canals following established endodontic procedures by qualified healthcare professionals.
Technology Comparison	**EDS Bioceramic Sealer (Bioseal)** uses a dual syringe system to ensure an equal 1:1 mixing of the two hydraulic paste composition. The composition contains absorbant halloysite clays in order to ensure hydration / efficient setting of the cement. The subject device, contains further agents that serve as additional ion sources. These include bioactive glass (45S5) as well as different forms of calcium phosphates (monobasic calcium phosphate, β Tri-calcium phosphate). As these ion rich components become hydrated in the root canal, they further	The EndoSequence comes Pre-mixed and ready-to-use injectable white hydraulic cement paste in a single barrel syringe. The EndoSequence bioceramic sealer is based on a calcium silicate / calcium phosphate composition and requires water to set and harden.	The DRFP ProSmart comes with its two - component catalyst paste based on epoxy-amine resin chemistry. The paste additionally comes with an “active powder” that must be mixed to provide the paste with its hydrophilic properties to allow the mixture to expand into crevices and dentine tubules.

	Proposed Device	Primary Predicate Device	Reference Predicate Device
	contribute to the precipitation/formation of a hard mineral phase that structurally reinforces the endodontically treated tooth over time. The addition of trace amounts of chlorhexidine and poly acrylic acid aid in the stabilization and coordination of precipitated calcium and other ions via electrostatic interactions. These stabilized / precipitated ions aid in the sealing of the root canal system.		
Differences	The **EDS Bioceramic Sealer (Bioseal)** is supplied with a two barrel syringe delivery system in order to ensure proper mixing. The composition contains absorbant halloysite clays in order to ensure hydration / efficient setting of the cement. The subject device, contains further agents that serve as additional ion sources. These include bioactive glass (45S5) as well as different forms of calcium	Delivered in a single barrel syringe delivery system.	Two-component catalyst paste based on epoxy-amine resin chemistry. The paste additionally comes with an “active powder” that must be mixed by hand and applied.

	phosphates (monobasic calcium phosphate, β Tri-calcium phosphate). As these ion rich components become hydrated in the root canal, they further contribute to the precipitation/formation of a hard mineral phase that structurally reinforces the endodontically treated tooth over time. The addition of trace amounts of chlorhexidine and poly acrylic acid aid in the stabilization and coordination of precipitated calcium and other ions via electrostatic interactions. These stabilized/precipitated ions aid in the sealing of the root canal system.		

Similarities and Differences:

The **EDS Bioceramic Sealer (Bioseal)** is similar to the predicate devices EndoSequence BC Sealer (K120048) and ProSmart Root Canal Obturation System (K100248). These are available as radiopaque pastes essentially designed for equivalent dental applications and have comparable physical properties, performance specifications and share specific chemical components. The principal composition of the **EDS Bioceramic Sealer (Bioseal)** is based on EndoSequence BC Sealer (K120048). Both the aforementioned predicate devices contain specific chemical components that are identical or equivalent to those found in the **EDS Bioceramic Sealer (Bioseal)**. The subject device, however, contains further agents that serve as additional ion sources that contribute to the sealing of the root canal. These include bioactive glass (45S5) as well as different forms of calcium phosphates (monobasic calcium phosphate, β Tri-calcium phosphate). As these ion rich components become hydrated in the root canal, they further contribute to the precipitation/formation of a hard mineral phase that structurally reinforces the endodontically treated tooth over time. The addition of trace amounts of chlorhexidine and poly acrylic acid aid in the stabilization and coordination of precipitated calcium and other ions via electrostatic interactions. While these are some of the differences between the subject device and predicate device EndoSequence BC Sealer (K120048), the vast majority of the both compositions are primarily composed of calcium silicates, zirconium oxide, and low molecular weight polyethylene glycol which accounts for well over 90% of the composition. Both compositions, the subject and predicate devices, utilize polyethylene glycol as a nonaqueous liquid carrier where all of the other components are suspended to yield a flowable-injectable paste. Both devices have identical indications for use as root canal sealers. While the subject device has some additional additives, the technological characteristics, mode and mechanism of action for both devices, subject device and predicate device, are identical. All of the components found in the predicate devices have been used in legally marketed devices and were found safe for dental use. We believe that prior use of components in legally marketed devices, the performance and biocompatibility data provided support the safety and effectiveness of the **EDS Bioceramic Sealer (Bioseal)** for the indicated uses.

10. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as Follows:** [807.92 (b)(1)]

The **EDS Bioceramic Sealer (Bioseal)** has undergone extensive bench (ISO 6876:2012) and biocompatibility testing to provide evidence that the physical and chemical properties of the composition are substantially equivalent to EndoSequence BC Sealer (K120048). Bench tests included:

- Flow
- Setting time
- Solubility
- Radiopacity
- Film thickness

The legally marketed and extensively tested EndoSequence BC Sealer (K120048) shows that it is exceptionally biocompatible and safe for the intended use. Since the chemical composition of **EDS Bioceramic Sealer (Bioseal)** is based on EndoSequence BC Sealer (K120048), the biocompatibility test data provides further evidence of biocompatibility and over all safety. The results of the biocompatibility testing shows that the **EDS Bioceramic Sealer (Bioseal)** is non-mutagenic, non-cytotoxic and does not elicit an allergenic response while exhibiting excellent tolerance by the subcutaneous tissue.

Testing of biocompatibility and physical properties were conducted to determine equivalence of *the **EDS Bioceramic Sealer (Bioseal)** [K202281] to the predicate device EndoSequence BC Sealer [K120048].*

Safety:

Equivalence in safety to the predicate device is demonstrated by the results of six biocompatibility tests performed according to ISO 10993, as follows:

- ISO 14971:2007 - *Medical Devices - Application for risk management to medical devices*
- ISO 10993-1:2018 - *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*
- ISO 10993-5:2009 - *Biological evaluation of medical devices - Part 5. Tests for in vitro Cytotoxicity and implantation*
- ISO 10093-6:2016 - *Biological evaluation of medical devices - Part 6: Tests for local effects after implantation*
- ISO 10993-10:2010 - *Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization*
- ISO 10993-11:2017 - *Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity*

Performance:

Testing of physical properties according to the following standards have demonstrated equivalence in performance to the predicate device.

- ISO 6876:2012 - *Dentistry – Root Canal Sealing Materials*
- ISO 7405:2018 - *Dentistry – Evaluation of biocompatibility of medical devices used in dentistry*
- *ANSI / ADA Specification No. 57* - *Endodontic Sealing Materials*

11. **Discussion of Clinical Tests Performed:** [807.92 (b)(2)]

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The verification and validation testing of the device was found to be acceptable and supports the claims of substantial equivalence.

12. **Conclusions:** [807.92 (b)(3)]

The **EDS Bioceramic Sealer (Bioseal)** is substantially equivalent in terms of performance, indications for use, and biocompatibility to the cleared and marketed predicate devices EndoSequence BC Sealer (K120048) and ProSmart Root Canal Obturation System (K100248). Any technological differences between the **EDS Bioceramic Sealer (Bioseal)** and the predicate device(s) do not raise any questions regarding the safety and effectiveness of the subject device.

The information provided in this submission supports the substantial equivalence to the predicate device(s) and that the system is safe and effective for the users/operators.