January 7, 2026

Kerr Corporation
Maria Rao
Principal Specialist, Regulatory Affairs
1889 W. Mission Blvd.
Pomona, California 91766

Re: K252890
Trade/Device Name: ZenSeal Pro
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: December 5, 2025
Received: December 8, 2025

Dear Maria Rao:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K252890

Device Name

ZenSeal Pro

Indications for Use *(Describe)*

Permanent obturation of the root canal.
ZenSeal Pro is intended for root canal sealing after the removal of infected or necrotic pulp tissue.

ZenSeal Pro is suitable for use in the warm vertical condensation, single cone, cold lateral condensation and gutta-percha carrier obturator 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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K252890
510(k) Summary

Submitter Information:

Kerr Corporation
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USA

Contact Person: Maria Rao
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Email: maria.rao@envistaco.com

Date Prepared: October 15, 2025

Device Name:

Proprietary Name: ZenSeal Pro
Manufacturer: Kerr Corporation
Common Name: Resin, Root Canal Filling
Classification Name: Resin, Root Canal Filling
CFR Number: 21 CFR 872.3820
Device Class: II
Product Code: KIF

Predicate Device:

Proprietary Name:	CeraSeal (K190503) iRoot SP (K080917)
Manufacturer:	Meta Biomed Co., Ltd. Innovative BioCeramix Inc
Common Name:	Resin, Root Canal Filling
Classification Name:	Resin, Root Canal Filling
CFR Number:	21 CFR 872.3820
Device Class:	II
Product Code:	KIF

Description of Device:

ZenSeal Pro is a Bioceramic root canal sealer based of calcium silicate making it a bioceramic material. The device is a single syringe barrel, insoluble, radiopaque material, which requires the presence of water to set and harden. It is delivered into the canal with the use of disposable tips provided in the package or it can be delivered via the gutta-percha paper point or file method. ZenSeal Pro is used for permanent obturation of the root canal space with the aid of obturating points.

It is suitable for use in the warm vertical condensation, single cone, cold lateral condensation and gutta-percha carrier obturator technique.

ZenSeal Pro consists of one (1) syringe with 1.8 grams of paste and twenty (20) single use ZenSeal Pro Trimmable Tips also known as disposable delivery tips. Tips are also offered separately as an accessory.

The product is intended for use by a dental professional in a general patient population in need of an endodontic treatment due to infection of the pulp tissue.

Principle of Operation / Mechanism of Action:

ZenSeal Pro is a convenient premixed ready to-use injectable white cement paste developed for permanent root canal filling and sealing applications. ZenSeal Pro is an insoluble, radiopaque material which requires the presence of water to set and harden.

It can be placed into the root canal by directly injecting the material into the canal or by manually coating a gutta percha point with the sealer paste and then slowly transferring the material to the root canal by insertion of the gutta percha point. For the first approach, a delivery tip must be attached on the orifice of the syringe delivery system. Packaged in a pre-loaded syringe and supplied with disposable tips.

Intended Use:

ZenSeal Pro, a Bioceramic sealer intended for use as a permanent endodontic sealer after removal of infected or necrotic pulp tissue.

Indications for Use:

Permanent obturation of the root canal

ZenSeal Pro is intended for root canal sealing after the removal of infected or necrotic pulp tissue. ZenSeal Pro is suitable for use in the warm vertical condensation, single cone, cold lateral condensation and gutta-percha carrier obturator technique.

Description of Substantial Equivalence:

Table 5-1 below compares the ZenSeal Pro to the Predicate devices (CeraSeal (K190503) and iRoot SP (K180917) with respect to intended use, technological characteristics, and performance testing.

Details of the Similarities between the Subject and Predicate Devices:

ZenSeal Pro and predicate devices have the same or similar intended use and indications for use, delivery system, principle of operation, and technological characteristics such as packaging, shelf life, and performance values (Flowability, Set Time, Film Thickness, Solubility, Radiopacity, Ph, and Heat Compatibility).

Details of the differences between the Subject and Predicate Devices:

There are no major differences between the subject device (ZenSeal Pro) and predicate devices (CeraSeal, K190503 and iRoot SP, K080917), however there are some minor differences between the two devices. The chemical composition and product configuration are slightly different between the two devices.

Table 5-1 Device Comparison Table:

Descriptive Information	Subject Device ZenSeal Pro	Predicate Device CeraSeal K190503	Predicate Device iRoot SP (HiFlow) K080917	Comparison
Product Image				N/A
Regulation Number	21 CFR 872.3820	21 CFR 872.3820	21 CFR 872.3820	Same as Predicate
Regulation Title	Root canal filling resin	Root canal filling resin	Root canal filling resin	Same as Predicate
Regulation Class	Class II	Class II	Class II	Same as Predicate
Product Code	KIF	KIF	KIF	Same as Predicate
Intended Use/Purpose	ZenSeal Pro, a bioceramic sealer intended for use as a permanent endodontic sealer after removal of infected or necrotic pulp tissue.	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 CeraSeal is suitable for use in the single cone and lateral condensation techniques.	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. iRoot SP is suitable for use in the single cone and lateral condensation technique.	Same Intended Use as Predicate but expressed through a similar choice of words.

Indications for Use	Permanent obturation of the root canal. ZenSeal Pro is intended for root canal sealing after the removal of infected or necrotic pulp tissue. ZenSeal Pro is suitable for use in the warm vertical condensation, single cone, cold lateral condensation and gutta-percha carrier obturator 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 CeraSeal is suitable for use in the 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. iRoot SP is suitable for use in the single cone and lateral condensation technique.	Same Indications for Use as Predicate but expressed through a similar choice of words.
Composition	Insoluble, radiopaque material based on calcium silicate compound containing: Zirconia oxide, polyethylene glycol, inorganic salts, and ionic acrylic stabilizer	Insoluble, radiopaque material based on a calcium silicate compound containing: Thickening agent, Zirconium dioxide, Calcium silicates, 1, 3 Propanediol	Insoluble, radiopaque, and aluminum-free material based on a calcium silicate containing: Zirconium oxide, calcium silicates, calcium hydroxide, calcium phosphate monobasic and filler agents.	Similar to Predicate
Delivery System	One (1) syringe with 1.8 grams of pre-mixed paste and twenty (20) single use ZenSeal Pro Tips also known as disposable delivery tips. Tips are also offered separately as an accessory.	One (1) syringe with 2.0 grams of pre-mixed paste and ten (10) single use disposable delivery tips.	One (1) syringe with 2.0 grams of pre-mixed paste and ten (15) single use disposable delivery tips.	Similar to Predicate
Single Use	ZenSeal Pro is not for single use. Delivery tips are single-use and disposable	CeraSeal is not for single use. Delivery tips are single-use and disposable	iRoot SP is not for single use. Delivery tips are single-use and disposable	Same as Predicate

Principle of Operation	ZenSeal Pro is a convenient premixed ready to-use injectable white cement paste developed for permanent root canal filling and sealing applications. ZenSeal Pro is an insoluble, radiopaque material which requires the presence of water to set and harden. It can be placed into the root canal by directly injecting the material into the canal or by manually coating a gutta percha point with sealer paste and slowly transferring material to the root canal by insertion of a gutta percha point. For the first approach, a delivery tip must be attached to the syringe. ZenSeal Pro is packaged in a pre-loaded syringe and is supplied with disposable tips.	CeraSeal is a convenient premixed ready to-use injectable white hydraulic cement paste developed for permanent root canal filling and sealing applications. CeraSeal is an insoluble, radiopaque material which requires the presence of water to set and harden. CeraSeal is packaged in a pre-loaded syringe and is supplied with disposable tips.	iRoot SP Injectable Root Canal Sealer (iRoot SP) is a convenient premixed ready-to-use, injectable white hydraulic cement paste developed for permanent root canal filling and sealing applications. iRoot SP is an insoluble, radiopaque and aluminum-free material based on a calcium silicate composition, which requires the presence of water to set and harden. iRoot SP does not shrink during setting and demonstrates excellent physical properties. iRoot SP is packaged in a pre-loaded syringe and is supplied with disposable Intra Canal tips	Similar to Predicate but expressed through a similar choice of words

Technological Characteristics	**Subject Device ZenSeal Pro**	**Predicate Device CeraSeal K190503**	**Predicate Device iRoot SP (HiFlow) K080917**	**Comparison**
Packaging	Packaged in a sealed aluminum pouch and placed in a paper box.	Packaged in a sealed aluminum pouch and placed in a paper box.	Packaged in a sealed aluminum pouch and placed in a paper box.	Same as Predicate
Sterilization	Non-Sterile	Non-Sterile	Non-Sterile	Same as Predicate
Shelf life	2 years	2 Years	18 months	Same/Similar to Predicate
MR Compatibility	None	None	None	Same as Predicate

Biocompatibility Testing	Biocompatible per ISO 10993-1, ISO 10993-3, ISO 10993-5, ISO 10993-6, ISO 10993-10, ISO 10993-11, ISO 10993-23, ISO 7405	Biocompatible per ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11	Biocompatible per ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11
Performance Testing – Bench	Flowability ≥ 17 mm **Actual 23 mm** Setting Time ≤ 48 hrs **Actual 24 hrs** Film Thickness ≤ 50 µm **Actual 31.3µm** Solubility ≤ 3% **Actual 2.6%** Radiopacity ≥3 mm (Al) **Actual 536 mm** Ph ≥ 9 **Actual 11.02** Heat Compatibility ≤ 4.5% at 200°C **Actual 3.318%** Shelf Life: 2 years	Flowability: 23 mm Setting Time: 3.5 hrs Film Thickness: 9 µm Solubility: 1.1% Radiopacity: 8 mm Ph: 12.73 Shelf Life: 2 Years	Flowability: 28 ± 1 mm Setting Time: 24 - 46 hours Film Thickness: 29.2 ± 4.8 µm Solubility: 4.72 – 4.99% Radiopacity: 499 ± 16 Ph: 11.6 Shelf Life: 18 months
Clinical Testing	In-Vivo Clinical Study. DC-DHF-006373 Design Validation Protocol DC-DHF-006621 Design Validation Report	None	None

Non-Clinical Test Data:
Performance testing was performed per ISO 6876:2012 to ensure that the ZenSeal Pro meets specifications for its intended use. All test results met their acceptance criteria and support that the ZenSeal Pro is appropriately designed for their intended use.
Test results on Flowability, Setting time, Film thickness, Solubility, pH, and radiopacity of the subject device are very similar to predicate device.
Biocompatibility testing was performed to verify the equivalent safety of the materials.

- ISO 6876: 2012, Dentistry - Root canal sealing materials
- Shelf-life testing conducted per ISO 6876: 2012

Flowability

The flowability test was performed on three (3) samples according to ISO 6876:2012 test method described in ISO 6876:2012 and TM-Patch-001. The paste's flowability was verified and all samples met the required flowability specification of ≥ 17mm when tested.

Setting Time

Setting time was performed on three (3) samples using gypsum mold as stated in ISO 6876:2012 section 5.4 as Zenseal Pro is an endo sealer that requires moisture for setting. The paste's setting time was verified, and all samples met the required setting time of ≤ 48 hours when tested.

Setting time was tested at various time intervals. The time interval to test setting time is as follows: 8 hours after start of sample preparation, 24 hours after start of sample preparation, 32 hours after start of sample preparation and 48 hours after start of sample preparation.

Film thickness

The film thickness was performed on three (3) samples according to ISO 6876:2012. The paste's film thickness was verified, and all samples met the required film thickness of ≤ 50 μm when tested.

Radiopacity

Radiopacity was performed according to TI 920.013, and it was verified to be ≥ 3mm aluminum (300%Al) when tested. TI 920.013 refers to radiopacity measurement based on the gray scale of the 1 mm thick sample as correlated to the gray scale of standard aluminum step wedge with known thickness. This is similar to the described test method in ISO 13116:2014 using digital equipment and currently is implemented for radiopacity measurement of restorative dental materials per ISO 4049:2019.

The test method in ISO 6876:2012 is based on radiopacity determination by optical density comparison of the 1 mm thick sample versus a standard aluminum step wedge with known thickness. This is similar to the described test method in ISO 13116:2014 using analogue equipment.

Therefore it can be concluded that the digital radiopacity test method TI 920.013 is equivalent to the analog radiopacity test method listed in ISO 6876:2012.

Solubility

Solubility was tested per ISO6876:2012 on three (3) samples. The paste's solubility was verified, and all samples met the required solubility specification of ≤ 3% and showed no visible disintegration.

pH

pH was performed following TI905.002 on five (5) samples with a 10mm diameter and 1mm thickness. Samples were immersed in 25 mL distilled/MilliQ water. Results indicated an average of 11.02 pH.

The 24 hours of storage was conducted at 37°C oven to mimic oral/root canal environment. One-sample t-analysis shows that the product is able to increase the pH of water to reach pH ≥ 9 after 24 hours immersion.

Heat Compatibility

Heat compatibility was tested on ten (10) samples via TGA analysis, and it was verified to have a mass % loss $\leq$ 4.5% at 200°C when tested with an average of 3.32% at 200°C.

Biocompatibility

Biocompatibility assessments were conducted in accordance with ISO-10993-1:2018, "Biological evaluation of medical devices – part 1: Evaluation and testing within a risk management process". U.S. Food and Drug Administration (FDA) Guidance Document for the Use of ISO 10993-1 (issued 09/04/2020) guidelines and ISO 7405:2018 "Dentistry - Evaluation of biocompatibility of medical devices used in dentistry" as guidance. Kerr performed the biocompatibility testing of the finished product according to the following parts of the ISO 10993 and ISO 7405 standard.

- ISO 7405:2018, "Dentistry - Evaluation of biocompatibility of medical devices used in dentistry"
- ISO 10993-2:2006, "Biological evaluation of medical devices – Part 2: Animal welfare requirements"
- ISO 10993-3:2014, "Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive"
- ISO 10993-5:2009, "Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity"
- ISO 10993-6:2016, "Biological evaluation of medical devices – Part 6: Tests for local effects after implantation"
- ISO 10993-10:2021, "Biological evaluation of medical devices – Part 10: Tests for skin sensitization"
- ISO 10993-11:2017, "Biological evaluation of medical devices - Part 11: Tests for systemic toxicity"
- ISO 10993-12:2021, "Biological evaluation of medical devices- part 12: Sample preparation and reference materials"
- ISO 10993-23:2021, "Biological evaluation of medical devices – Part 23: Tests for irritation"

Clinical Performance Data:

The clinical evaluation of ZenSeal Pro was conducted as a prospective, in-vivo study at the Autonomous University of San Luis Potosí, Mexico. The study aimed to validate the safety and efficacy of ZenSeal Pro across three obturation techniques: warm vertical condensation, single cone, cold lateral condensation and gutta-percha carrier obturator technique.

Primary endpoints:

Evaluation of clinical safety and efficacy of ZenSeal Pro on an anterior or a posterior tooth when used following the manufacturer's Instruction For Use.

Secondary endpoints:

Evaluation of ZenSeal Pro when obturating the teeth with cold and warm obturation techniques.
Quality of root canal obturation assessed on periapical radiographic – length and density of the root canal obturation.
Pre-operative pain and post-operative pain – 48h after the procedure.
Post-operative evaluation 6 month and 1 year after the procedure.

A total of 112 teeth in 99 patients were treated by 10 qualified clinicians, exceeding the minimum requirements for sample size and procedural diversity.
ZenSeal Pro demonstrated consistent clinical performance across all techniques. Radiographic assessments showed that over 98% of root canals achieved adequate obturation length, and 100% met the criteria for obturation density and taper.

Clinician satisfaction scores were uniformly high, with average ratings ranging from 4.20 to 4.78 across all evaluated parameters, including flowability, radiopacity, obturation quality, and ease of use.
All three techniques passed the acceptance criteria with no statistically significant differences in performance.
Post-operative outcomes further supported the product's safety profile.
Within 48 hours of treatment, 91% of patients reported minimal or no pain (pain score 0–1), and no patients reported pain above level 4. Only 6.25% of patients required analgesics post-operatively, and all reported effective pain relief. Importantly, no adverse events, serious adverse events, or protocol deviations were reported during the study.
The study also confirmed ZenSeal Pro's adaptability to various clinical scenarios, including cases with periapical radiolucency and complex canal anatomies. The product's high flowability facilitated effective obturation even in accessory and curved canals, and its radiopacity allowed for clear post-operative assessment.
In conclusion, ZenSeal Pro has been clinically validated as a safe, effective, and user-friendly bioceramic sealer suitable for a wide range of endodontic procedures. Its performance across multiple obturation techniques, combined with high clinician satisfaction and excellent patient outcomes, supports its readiness for clinical use and market release. Additionally, all Voice of the Customer (VOC) requirements were successfully met, confirming the product's alignment with key user expectations and clinical demands.
Refer to DC-DHF-006373 Design Validation Protocol and DC-DHF-006621 Design Validation Report.

Conclusion:

Based on a comparison of intended use, indications for use, technological characteristics, principle of operation, features, and performance data, ZenSeal Pro is deemed to be substantially equivalent to predicate devices as it satisfies all criteria of substantial equivalence and does not raise new concerns.
ZenSeal Pro has been clinically validated as a safe, and effective bioceramic sealer suitable for root canal obturation with warm vertical condensation, single cone, cold lateral condensation and gutta-percha carrier obturator technique.