February 13, 2025

Dentsply Sirona Inc.
Rebecca Sporer
Principle Regulatory Affairs Specialist
221 W Philadelphia Street,
Suite 60W
York, Pennsylvania 17401

Re: K243546
Trade/Device Name: AH Plus Endodontic Sealer
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: November 15, 2024
Received: November 15, 2024

Dear Rebecca Sporer:

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 Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
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Respiratory, ENT, and Dental Devices
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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)*

K243546

Device Name

AH Plus Endodontic Sealer

Indications for Use *(Describe)*

Permanent obturation of root canals of teeth of the secondary dentition in combination with root canal 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.

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."

Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401

510(k) SUMMARY
for
AH Plus Endodontic Sealer (K243546)

1. Submitter Information:

Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17404

Contact Person: Rebecca Sporer
Telephone Number: 717-849-4793
Email address: Rebecca.sporer@dentsplysirona.com

Date Prepared: 15 November 2024

2. Device Name:

Proprietary Name:	AH Plus Endodontics Sealer
Common Name:	Root canal filling resin
Classification Name:	Resin, Root Canal Filling
CFR Number:	872.3820
Device Class:	2
Product Code:	KIF

3. Predicate Device:

Table FS.1: Predicate device information

Primary Predicate Device Name	510(k)	Company Name
AH Plus Root Canal Sealer	K960548	Dentsply Intl.

4. Description of Device:

AH Plus Endodontic Sealer is a two-component paste-paste permanent root canal sealer based on epoxy-amine resin. It is available in two delivery forms: AH Plus Endodontic Sealer in tubes, for an easy manual mix, or as AH Plus Jet Endodontic Sealer double-barrel syringe with a disposable mixing tip for intraoral use, offering a more precise, convenient, and faster procedure. It functions as part of the endodontic treatment, allowing for restoration of tooth integrity. It adapts closely to the walls of the prepared root canal and presents permanent sealing ability and radiopacity. AH Plus Endodontic Sealer does not stain teeth.

5. Indications for Use:

Permanent obturation of root canals of teeth of the secondary dentition in combination with root canal points.

6. Comparison of Technological Characteristics:

The proposed AH Plus Endodontic Sealer has a similar intended use and the same Indications for Use as compared to the predicate, AH Plus Root Canal Sealer (K960548). The proposed AH Plus Endodontic Sealer and the predicate, AH Plus Root Canal Sealer (K960548), are similar in design, principles of operation and composition. The proposed and predicate devices are both epoxide and amine pastes. The composition differences are due to market availability of the raw materials and added modifiers for added physical paste stability. The proposed device is offered in two delivery systems: tubes for manual mixing on a mixing pad and dual-barrel syringe with mixing tips that mixes the pastes as extruded from the syringe. Table FS.2 compares the technological characteristics of the proposed and predicate devices.

Table FS.2-Comparison of the proposed and predicate devices			
Item of Comparison	**Proposed device AH Plus Endodontic Sealer (K243546)**	**Predicate device AH Plus Root Canal Sealer (K960548)**	**Discussion**
Manufacturer	Dentsply DeTrey GmbH	Dentsply DeTrey GmbH	Same
Product Code	KIF	KIF	Same
Site of Application	Root Canal	Root Canal	Same
Sterile	Non-sterile	Non-sterile	Same
Shelf-Life	2 years	2 years	Same
Packaging / Delivery System	• AH Plus® in tubes for manual mixing of Paste 1 and Paste 2  • AH Plus Jet® Dual-barrel syringe with mixing tip  	• AH Plus® in tubes for manual mixing of Paste A and Paste B  	The proposed AH Plus Endodontic Sealer in the tubes are for manual mixing and are similar to the predicate with the exception of the color layout of the tubes. The proposed AH Plus Jet Endodontic Sealer contains the same sealer material (Paste 1 and Paste 2) as the tubes but packaged in a dual-barrel syringe with an intraoral mixing tip. The mixing tip attached to the syringe mixes the sealer when extruded whereas the tubes are manually mixed on a mixing pad.
Mode of Action	The final product consists of two components, the epoxy resin paste and the amine paste, that are mixed prior to insertion into the root canal.	The final product consists of two components, the epoxy resin paste and the amine paste, that are mixed prior to insertion into the root canal.	Same

Table FS.2-Comparison of the proposed and predicate devices			
Item of Comparison	**Proposed device AH Plus Endodontic Sealer (K243546)**	**Predicate device AH Plus Root Canal Sealer (K960548)**	**Discussion**
Biocompatibility	Meets ISO 10993-1:2018 requirements	Meets ISO 10993 requirements	The proposed device conforms to the most recent FDA recognized version of the standard.
Performance	Meets ISO 6876:2012 *Dentistry-Root Canal Sealing Materials*	Meets ISO 6876:1996 *Dentistry-Root Canal Sealing Materials*	Same ISO standard applied for testing using the version recognized at the time the testing was performed. Performance results according to ISO 6876are acceptable.

7. Non-Clinical Performance Data

Performance Testing:
The proposed AH Plus Endodontic Sealer was tested and conforms to:

- ISO 6876:2012 *Dentistry-Root canal sealing materials*

The performance results of the proposed AH Plus Endodontic Sealer satisfactorily met the requirements of the non-clinical bench testing conducted to support substantial equivalence. Table FS.3 summarizes the bench testing conducted on the proposed device according to ISO 6872:2012.

Table FS.3- Performance Bench Testing according to ISO 6876:2012

Test Performed	Test method / Applicable Standard	Results
Radiopacity	ISO 6876:2012 *Dentistry-Root Canal Sealing Materials*	Pass
Solubility		Pass
Setting Time		Pass
Film Thickness		Pass
Flow		Pass

Biocompatibility Testing:

A biological risk assessment was conducted on the proposed AH Plus Endodontic Sealer. Review of available information on raw materials, manufacturing processes, chemical characterization tests concludes that the test results meet the requirements of the following ISO 10993 standard series.

The following tests were conducted:

- ISO 7405: 2018 *Dentistry-Evaluation of biocompatibility of medical device used in dentistry*
- ISO 10993-1:2018 *Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process*
- ISO 10993-18:2020 *Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process*
- ISO 10993-5: 2009 *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-10: 2021 *Biological evaluation of medical devices - Part 10: Tests for skin sensitization*
- ISO 10993-23: 2021 *Biological evaluation of medical devices - Part 23: Tests for irritation*
- ISO 10993-3: 2014 *Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
- ISO 10993-6: 2016 *Biological evaluation of medical devices - Part 6: Tests for local effects after implantation*
- USP <151> *Pyrogen Test (USP Rabbit Test)*

Conclusion:

Minor differences in the technological characteristics between the proposed and predicate (K960548) devices were evaluated through appropriate performance bench testing and biocompatibility testing which demonstrated that the proposed device, when compared to the predicate device (K960548), does not raise new questions regarding safety and effectiveness. Therefore, the nonclinical testing data supports the conclusion that the proposed device performs as well as the predicate device (K960548).

8. Clinical Performance Data

No data from human clinical studies has been included to support the substantial equivalence of the proposed AH Plus Endodontic Sealer.

9. Conclusion Regarding Substantial Equivalence

The proposed AH Plus Endodontic Sealer is a root canal sealer which is intended for permanent sealing of root canals following established endodontic procedures. The proposed AH Plus Endodontic Sealer has a similar intended use, incorporates similar fundamental technologies, and has the same Indications for Use as the predicate AH Plus Root Canal Sealer (K960548). Test data is included in this premarket notification to verify the safety and performance requirements of the proposed AH Plus Endodontic Sealer and the results support a conclusion of substantial equivalence.