February 5, 2026

Dentsply Sirona
℅ Deepthi Paknikar
Sr Manager Regulatory Affairs
221 W. Philadelphia St.
Suite 60w
YORK, PA 17401

Re: K253959
Trade/Device Name: Primevision 3D
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: December 10, 2025
Received: December 10, 2025

Dear Deepthi Paknikar:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253959

Device Name
Primevision 3D

Indications for Use *(Describe)*

The X-ray system creates data for digital exposures in the maxillofacial area and in sub-areas for dentistry and pediatric dentistry and for hard tissue diagnostics within ENT medicine.

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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510(k) Summary

510(k) #: K253959

Applicant Name: Dentsply Sirona Inc
Applicant Address: 221 West Philadelphia St. York PA 17401 United States
Applicant Contact Telephone: 630-201-1612
Applicant Contact: Dr. Deepthi Paknikar
Applicant Contact Email: Deepthi.Paknikar@dentsplysirona.com

Device Trade Name: Primevision 3D
Common Name: Computed tomography x-ray system
Classification Name:Computed tomography x-ray system
Regulation Number: 21 CFR 892.1750
Product Code(s): OAS
Device Class: 2

Predicate Device: Axeos (K201140)
Common Name: Computed tomography x-ray system
Classification Name: Computed tomography x-ray system
Regulation Number: 21 CFR 892.1750
Product Code(s): OAS
Device Class: 2

Reference Device(s): Planmeca Viso (K230985), Planmeca Viso (K181576), Trophy CS 9600 (K181136), Planmeca ProMax 3D Max (K160506), Orthopantomograph™ OP 3D LX (K230505)
Common Name: Computed tomography x-ray system
Classification Name:Computed tomography x-ray system
Regulation Number: 21 CFR 892.1750
Product Code(s): OAS
Device Class: 2

1. Device Description Summary

Primevision 3D is a digital panoramic and cone beam computed tomography (CBCT) x-ray device. A Computed tomography x-ray system (21 CFR 892.1750) is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. The subject Primevision 3D uses just one imaging detector to collect data for both 2D and 3D modes of operation. Additionally, the Primevision 3D does not offer a cephalometric mode.

1.1 Intended Use/Indications for Use

The X-ray system creates data for digital exposures in the maxillofacial area and in sub-areas for dentistry and pediatric dentistry and for hard tissue diagnostics within ENT medicine.

1.2 Indications for Use Comparison

The subject device is substantially equivalent to the predicate device in terms of intended use, fundamental design, and core functionality. Both devices are intended for dental imaging

applications and support panoramic and 3D imaging. Although the subject device does not include cephalometric imaging, this omission does not alter the intended use or raise new questions of safety or effectiveness. Performance testing and documentation provided in this submission demonstrate that the subject device meets applicable standards and performs as safely and effectively as the predicate.

2. Technological Comparison

The subject device introduces several technological updates compared to the predicate. It utilizes a single sensor for both 2D and 3D imaging, whereas the predicate used separate sensors. The subject device also incorporates cloud-based acquisition software accessed via a standard internet browser, replacing the predicate's on-premise software. Additional enhancements include motion and spine artifact compensation, and a revised hardware interface with simplified controls. These differences reflect advancements in technology and workflow efficiency, and do not impact the device's safety or effectiveness.

3. Non-Clinical and/or Clinical Tests

Testing to verify the performance requirements of the subject device was conducted and included in this premarket notification. The results of the performance testing support substantial equivalence. Tests included in this premarket notification verify the conformity of the proposed device with the requirements of:

• IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020: Medical electrical equipment Part 1: General requirements for basic safety and essential performance.

• IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

• IEC 60825-1:2014: Safety of laser products – Part 1: Equipment classification and requirements.

• IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013, IEC 60601-1-3:2008/AMD2:2021 for use in conjunction with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020: Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment.

• IEC 62366-1:2015/AMD1:2020: Medical devices – Application of usability engineering to medical devices.

• IEC 62304:2006 (First Edition) + A1:2015 (or IEC 62304:2015 CSV): Medical device software – Software life cycle processes.

• IEC 60601-2-63:2012; IEC60601-2-63:2012/AMD1:2017, IEC 60601-2-63:2012/AMD2:2021 for use in conjunction with IEC 60601-1:2005: Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment

• IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1-6:2010/AMD2:2020 for use in conjunction with IEC 62366-1:2015: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability, (with third edition of 60601-1)

• IEC 61223-3-4:2000: Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests - Imaging performance of dental X-ray equipment

• IEC 61223-3-7:2021: Evaluation and routine testing in medical imaging departments - Part 3-7: Acceptance and constancy tests - Imaging performance of X-ray equipment for dental cone beam computed tomography

Verification activities for confirmation of the image quality of the proposed device have been performed. The results of the image quality review have demonstrated that the device is substantially equivalent to the predicate device.

The subject system Primevision 3D has fundamentally the same hardware as the predicate device, without the inclusion of a Cephalometric imaging feature for the subject device. The remote control has been updated for the subject device to include a hand switch, and the new device HMI (referred to as the "easypad" or "multipad" for prior devices) has a different appearance, yet the same core functionality, as the predicate device. The subject device HMI contains less functionality than the predicate, because some of the functionality has been moved to cloud-based software (e.g. program selection) for the subject device. The EMC testing generated substantially equivalent results results as the predicate. Bench testing for image quality has been performed and the results indicate substantial equivalence to the predicate Axeos, for both 2D and 3D imaging modes (See the tabulated values below for details).

Animal testing was not necessary for this premarket submission. Clinical testing was provided in this submission, and extraoral images were submitted along with an image evaluation report. The Clinical Testing reports indicate device effectiveness.

Software Verification and Validation testing was provided as part of this submission. The predicate device had the option of cephalometric exposures along with panoramic and 3D exposure; the subject device does not have the option of cephalometric exposure. For the subject device, data processing is distributed on the device and the cloud. This is not the case with the predicate; the predicate does not have any cloud-based software component. The 3D reconstruction method (CBCT mode of operation) is the same as the predicate device and is filtered back projection (FBP). The fundamental steps for the user to take an image remain the same, the difference is that the user can use their internet browser with the subject device compared to a downloadable on-premises software with the predicate. All software functions are strongly based on the predicate device.

All cybersecurity testing has been successfully performed per FDA requirements and guidance.

The subject device software includes new features not present in the predicate device, specifically motion artifact compensation and spine artifact compensation. These were evaluated through comprehensive performance testing, including expert clinical evaluation and software verification testing. The metal artifact compensation feature remains the same as in the predicate device and has not been changed. For the motion and spine compensation features, the results of the clinical evaluation testing met prespecified success criteria via a Likert scale-based evaluation. The expert clinical evaluators reported improvements in 3D volume image quality, panoramic image homogeneity, and diagnostic interpretability when reviewing images with the compensation applied.

In summary, a comprehensive set of performance-supporting documents was included in this submission in addition to the software verification and validation reports provided. These materials include information outlined in the FDA guidance for Solid State X-ray Imaging Devices, an image quality assessment report, qualified expert evaluations conducted in accordance with the SSXI FDA guidance, a clinical image validation report, and an overview comparing the subject device's sensor performance to legally marketed predicate devices.

As mentioned above, the imaging performance of the Primevision 3D, subject device has been tested against FDA Recognized Consensus Standards. The standards used are the same with the predicate device Axeos. An additional table has been provided below for information on imaging performance results of the subject and predicate devices:

	Imaging Performance	**CCBCT R1**	**Axeos**	**Comparison**
Panoramic (IEC 61223-3-4)	Low Contrast	At least 1mm low contrast elements	At least 1mm low contrast elements	Same
	Spatial Resolution	At least 2.5 lp/mm	At least 2.5 lp/mm	Same
CBCT (IEC 61223-3-7)	Spatial Resolution	≥ 1 lp/mm (MTF10)	≥ 1 lp/mm (MTF10)	Same
	Homogeneity	≥ 5	≥ 5	Same
	Geometric accuracy	1%	1%	Same
	Acceptance Indicator	≥ 100 / (mGycm2)	≥ 100 / (mGycm2)	Same
CBCT (1020.33)	Spatial Resolution	≥2.6 lp/mm (MTF10) ≥1.3 lp/mm (MTF50)	≥1.0 lp/mm (MTF10) ≥0.7 lp/mm (MTF50)	Improved
	Noise	≤2.1	≤3	Improved

4. Conclusion

The information included in this premarket notification supports the substantial equivalence of the subject device with the identified predicate. The subject device has the identical intended use as the legally marketed predicate device. The subject device also has the identical indications for use and incorporates the same fundamental technology as the predicate device.

Performance data are included in this premarket notification to demonstrate the performance of the subject device against its design, functional, and safety requirements. The results of the testing included in this premarket notification support a determination of substantial equivalence.