January 7, 2026

Dentsply Sirona Inc
℅ Deepthi Paknikar
Senior Manager, Regulatory Affairs
221 West Philadelphia St.
YORK, PA 17401

Re: K253009
Trade/Device Name: DS Core Detect
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: December 5, 2025
Received: December 5, 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 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,

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic 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)*
K253009

Device Name
DS Core Detect

Indications for Use *(Describe)*
DS Core Detect is a concurrent read, computer assisted detection software intended to aid the dentist in the incidental detection of permanent teeth that may be associated with periapical radiolucencies in CBCT images. The device is not intended as a replacement for a complete dentist's review or a replacement of their clinical judgment. The device is to be used by licensed dentists. The device is designed for patients who already have CBCT data obtained for other reasons. DS Core Detect does not generate X-ray images and does not provide an indication for taking such images.
The device is intended for adults aged 22 years and older with permanent teeth.

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) #: K253009

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: DS Core Detect
Common Name: Medical image analyzer
Classification Name: Medical Image Analyzer
Regulation Number: 21 CFR 892.2070
Product Code(s): MYN

Predicate Device: Videa Dental Assist (K232384)
Common Name: Medical image analyzer
Classification Name: Medical Image Analyzer
Regulation Number: 21 CFR 892.2070
Product Code(s): MYN

Device Description Summary

The DS Core Detect device is a cloud-based SaMD that is a Computer Aided Detection “CADe” Machine Learning “ML” enabled device for the aid in incidental detection of permanent teeth that may have periapical radiolucency "PARL" on a CBCT image. The device is designed for patients who already have CBCT data obtained from a CBCT imaging system for other reasons. DS Core Detect does not generate X-ray images and does not provide an indication for taking such images.

The device itself is accessed by the dental practitioner through their dental image viewer. From within the dental viewer the user can view the CBCT with results from the subject device. The device will provide a list of teeth that may potentially have PARL and a corresponding PARL "map" to visualize where the PARL is detected. The user has completely autonomy to confirm or reject a tooth that is flagged by the device as potentially PARL positive.

The intended users of the device are trained and licensed dentists. The intended patient population for the device is adult patients with permanent teeth at least age 22.

Intended Use/Indications for Use

DS Core Detect is a concurrent read, computer assisted detection software intended to aid the dentist in the incidental detection of permanent teeth that may be associated with periapical radiolucencies in CBCT images. The device is not intended as a replacement for a complete dentist’s review or a replacement of their clinical judgment. The device is to be used by licensed dentists. The device is designed for patients who already have CBCT data obtained for other

reasons. DS Core Detect does not generate X-ray images and does not provide an indication for taking such images.

The device is intended for adults aged 22 years and older with permanent teeth.

Indications for Use Comparison

The minor differences in indications for use between the subject and predicate do not constitute a new intended use. Both devices are diagnostic aids for detection of PARL. The primary predicate device provides PARL findings for 2D periapical images whereas the subject device detects PARL positive teeth on a CBCT image. The predicate is indicated for bitewing, periapical, and panoramic radiographs and detects multiple pathologies, restorations, and normal anatomy, whereas the subject device is indicated only for incidental detection of PARL on CBCT. The subject device is also specific with regards to being used with CBCTs that have already been taken for other reasons, for aiding with incidental detection of PARL only. Both devices are SaMD and AI/ML enabled. Both devices are diagnostic aids only, not a replacement for standard of care diagnosis.

Technological Comparison

The main technological difference is that the predicate device provides PARL detection, as well as multiple other detections (anatomy, caries, etc.) for 2D dental radiographs, whereas the subject device provides PARL detection on 3D CBCT images. The predicate device spans a large age range and permanent and primary teeth findings, whereas the subject device is limited to permanent teeth for patients 22 and older. The subject device input is CBCT's taken for other reasons for the incidental detection of PARL, whereas the predicate device has 2D bitewing, periapical, and panoramic images as the input. The subject device will provide a list of teeth that may potentially have PARL which the user must confirm or reject and a corresponding PARL "map" to visualize where the PARL is detected. The predicate device outputs a set of bounding boxes for each finding, including PARL. The minor difference in technological characteristics do not raise a concern of substantial equivalence as demonstrated by the performance testing of the subject device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

The DS Core Detect device underwent comprehensive performance testing including standalone testing and a Multi-Reader Multi-Case Reader Study (MRMC). Software verification and validation testing was completed per applicable standards and agency guidance.

DS Core Detect indications detections in two operating points: Standard sensitivity and High sensitivity, whereby sensitivity describes the portion of detected teeth with evidence of periapical radiolucency. The standalone study assessed the performance of the device compared to a consensus ground truth. The MRMC study evaluated reader performance with and without the assistance of the device, in a fully crossed study design.

Depending on the operating point, these teeth are detected with the following standalone study accuracy with 95% CI's:

1. Sensitivity: High sensitivity 0.78 [0.74; 0.81], Standard sensitivity 0.66 [0.62; 0.70]

2. Specificity: High sensitivity 0.93 [0.92; 0.94], Standard sensitivity 0.97 [0.97; 0.98]

Standalone Study Subgroup performance testing subjects included patients 22 and older from various clinical sites across the U.S., with permanent teeth, with CBCT images. Subgroup reporting included lesion size, age, device, gender, and endodontic treatment status, with results as follows:

Operating point	Group		Sensitivity[1]	95% confi-dence interval	Specificity[1]	95% confi-dence interval
High sensitivity	Lesion	> 8 mm^3	0.82	[0.79; 0.86]	0.93	[0.92; 0.94]
		≤ 8 mm^3	0.65	[0.59; 0.71]	0.93	[0.92; 0.94]
	Age	> 52 years	0.76	[0.71; 0.80]	0.95	[0.94; 0.96]
		≤ 52 years	0.8	[0.75; 0.84]	0.92	[0.91; 0.93]
	Device	Orthophos S/ SL	0.76	[0.72; 0.81]	0.93	[0.91; 0.94]
		Axeos	0.80	[0.75;0.84]	0.94	[0.91; 0.94]
	Gender	Male	0.78	[0.73;0.83]	0.93	[0.92; 0.95]
		Female	0.79	[0.74; 0.85]	0.93	[0.91; 0.95]
	Endodontic treatment	Tooth treated	0.82	[0.78; 0.86]	0.82	[0.77; 0.87]
		Tooth un-treated	0.72	[0.67; 0.78]	0.94	[0.93; 0.95]
Standard sensitivity	Lesion	> 8 mm^3	0.73	[0.68; 0.77]	0.97	[0.97; 0.98]
		≤ 8 mm^3	0.50	[0.43; 0.57]	0.97	[0.97; 0.98]
	Age	> 52 years	0.64	[0.58; 0.70]	0.98	[0.97; 0.98]
		≤ 52 years	0.68	[0.62; 0.74]	0.97	[0.96; 0.98]
	Device	Orthophos S/ SL	0.64	[0.58; 0.69]	0.97	[0.96; 0.98]
		Axeos	0.70	[0.64; 0.76]	0.98	[0.97; 0.98]
	Gender	Male	0.67	[0.60; 0.73]	0.97	[0.96; 0.98]
		Female	0.70	[0.64; 0.76]	0.97	[0.96; 0.98]
	Endodontic treatment	Tooth treated	0.75	[0.70; 0.80]	0.90	[0.86; 0.94]
		Tooth un-treated	0.56	[0.50; 0.62]	0.98	[0.97; 0.98]
1 Result of a representative standalone study with 306 CBCTs						

The MRMC Tooth Level AUC results are as follows:

Number of U.S. readers = 11	Unaided	Aided	Difference
	OR Model-Based AUC Estimates (95% CIs)		
	0.415 (0.279, 0.550)	0.639 (0.529, 0.749)	0.224 (0.124, 0.324)
	Tooth Level Sensitivity (95% CIs)		
	0.421 (0.281, 0.562)	0.649 (0.535, 0.763)	0.227 (0.124, 0.330)
	Tooth Level Specificity (95% CIs)		
	0.962 (0.928, 0.995)	0.946 (0.915, 0.976)	-0.016 (-0.034, 0.002)

Conclusion

The standalone and MRMC study results collectively demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.