October 30, 2026

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

Re: K261072
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: September 28, 2026
Received: September 28, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP), Pre-Determined Change Control Plan V1.0. Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively. 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261072

Please provide the device trade name(s).

DS Core Detect

Please provide your Indications for Use below.

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. This device includes an authorized Predetermined Change Control Plan (PCCP) V1.0.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

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: DS Core Detect (K253009)
Common Name: Medical image analyzer
Classification Name: Analyzer, Medical Image
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 complete 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.

This device includes an authorized Predetermined Change Control Plan (PCCP) V1.0.

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. This device includes an authorized Predetermined Change Control Plan (PCCP) V1.0.

Indications for Use Comparison

There is no difference in the indications for use between the subject and predicate devices. The DS Core Detect predicate device cleared under K253009 and the subject DS Core Detect device are identical, with the exception that the subject device incorporates a Predetermined Change Control Plan (PCCP). Device functionality, incorporated algorithms/models, indications for use, intended patient population, and all other device characteristics remain identical. The inclusion of the PCCP is the sole distinguishing feature between the subject and predicate devices.

Technological Comparison

The inclusion of the PCCP for the subject device is the only technological difference to the predicate device.

The PCCP describes the structured approach for assessing and implementing future modifications. All modifications will be deployed through a manual (non-automated) process and applied consistently across all devices. This approach ensures that any changes improve the device's clinical performance and reliability while remaining aligned with the original intended use and established performance.

The PCCP contains a detailed modification protocol that defines the activities required to support proposed modifications. The modification protocol includes information on data management practices, retraining practices, performance evaluation methods, and update procedures, including verification and validation methods. An impact assessment was also created to assess the individual and cumulative impact of the PCCP on the device. If a modification does not meet the defined performance requirements, the issues will be documented within the Software Development Life Cycle (SDLC) as a controlled report, and the modification will not be implemented. A summary of the PCCP and the associated modification protocol is provided in the list below:

PCCP Summary

1. Planned Modifications: The PCCP includes a single planned modification: expansion of device compatibility to CBCT images acquired from additional CBCT imaging systems beyond those supported by the originally cleared device (K253009). Implementation of this modification requires new data from the additional CBCT imaging system(s) and may include retraining of the PARL Detector ML model on that data. The modification does not change the intended use, indications for use, intended user, intended patient population, or the fundamental scientific technology of the device. Modifications that require retraining

the models will not be done more than 1 time a year and a maximum of 3 times in a 5 year period.

2. Testing Methods: Each modified model is evaluated through standalone performance testing using the same test methodology and statistical analysis plan applied to the originally cleared device. Testing is performed on an independent test dataset that includes images from the newly supported CBCT imaging system(s).
3. Validation Activities and Performance Requirements: Predetermined acceptance criteria are defined prior to the execution of testing and are referenced to the performance of the originally cleared device. Validation includes standalone performance testing, subgroup analyses (including analysis by CBCT imaging system and by relevant patient demographic characteristics), and software verification and validation in accordance with the established Software Development Life Cycle (SDLC). A modification is implemented only if all predetermined acceptance criteria are met and the associated risk management activities demonstrate that residual risk remains acceptable. If the predetermined performance requirements are not met, the issues are documented within the SDLC as a controlled report and the modification is not implemented.
4. PCCP Modification Implementation: Modifications are deployed through a manual (non-automated) process and applied consistently across all commercially distributed devices as a global update. The PCCP does not provide for the deployment of adaptive or continuously learning algorithms in the field. All algorithm updates are developed, trained, tuned, and fixed prior to software release, ensuring that no learning or adaptation occurs post-deployment.
5. Means by Which Users Will Be Informed of Implemented Modifications: Users are informed of each modification implemented under the authorized PCCP prior to or at the time the updated version becomes available. Release notes are created with each version released under the PCCP and identify the version number and release date, the modification implemented and the reason for it, the specific CBCT imaging systems newly supported, the summary performance of the updated version, and any changes to limitations, warnings, or precautions. The user manual is updated at each release to describe the performance of the current version, the composition of the dataset used to validate it, subgroup performance results, and the limitations applicable to that version, including the CBCT imaging systems for which performance has been established.

Non-Clinical and/or Clinical Tests Summary & Conclusions

The subject device is identical to the predicate device cleared under K253009. No additional performance testing was conducted, as the sole difference between the devices is the inclusion of a Predetermined Change Control Plan (PCCP).

The subject and predicate devices have the same intended use and indications for use. The inclusion of the PCCP represents a minor technological difference and does not impact the substantial equivalence of the devices.

Conclusion

The subject and predicate devices share the same intended purpose. Minor differences in technological features do not raise concerns regarding substantial equivalence. In summary, following the information reviewed as part of this 510k, it can be concluded that the subject device is substantially equivalent to the predicate device.