August 21, 2026

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

Re: K262127
Trade/Device Name: DS Core CBCT Anatomy
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: June 24, 2026
Received: June 24, 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.

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 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
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

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.	K262127

Please provide the device trade name(s).

DS Core CBCT Anatomy

Please provide your Indications for Use below.

"DS Core CBCT Anatomy" is a cloud-based AI/ML enabled software as a medical device. The device is available as a back end service via an API (Application Programming Interface). The device is intended to be used by dental professionals when reviewing Digital Impression (DI) scans and CBCT (DX) scans during standard of care diagnostic review and treatment planning. DS Core CBCT Anatomy analyses CBCT scans and Digital Impression (DI) scans to identify anatomical structures, propose a panoramic curve, segmentation of teeth, jaws, and the inferior alveolar nerve canal (IAN), as well as to perform image registration to support the review of CBCT dental images and DI scans.

This device is intended to be used with patients aged 12 and older with permanent dentition.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #: K262127

510(k) Summary

Prepared on: 2026-08-21

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Dentsply Sirona
Applicant Address	221 West Philadelphia St. York PA 17401 United States
Applicant Contact Telephone	6302011612
Applicant Contact	Dr. Deepthi Paknikar
Applicant Contact Email	Deepthi.Paknikar@dentsplysirona.com
Correspondent Name	Dentsply Sirona
Correspondent Address	221 West Philadelphia St. York PA 17401 United States
Correspondent Contact Telephone	6302011612
Correspondent Contact	Dr. Deepthi Paknikar
Correspondent Contact Email	Deepthi.Paknikar@dentsplysirona.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	DS Core CBCT Anatomy
Common Name	Medical image management and processing system
Classification Name	Medical image management and processing system
Regulation Number	892.2050
Product Code(s)	QIH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K260785	DS Core CBCT Anatomy	QIH

Device Description Summary

21 CFR 807.92(a)(4)

"DS Core CBCT Anatomy" is a cloud-based, AI/ML-enabled software as a medical device (SaMD) that operates as a backend service accessible through an Application Programming Interface (API). The software is designed to support dental professionals during routine diagnostic review and treatment planning by analyzing Digital Impression (DI) scans (also referred to as "IOS" intra oral scans) and cone-beam computed tomography (CBCT) (DX) scans. Using automated algorithms, DS Core CBCT Anatomy identifies key anatomical structures, proposes a panoramic curve, segments teeth, jaws, and the inferior alveolar nerve canal (IAN), and performs image registration to assist in comprehensive interpretation of CBCT and DI data. The device provides automatic comparison of two different DI Scans. The device is intended to integrate seamlessly into clinical workflows, providing supplementary visualizations and structural information while preserving clinician oversight and decision-making. This device is intended to be used with patients aged 12 years and older who have permanent dentition.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

"DS Core CBCT Anatomy" is a cloud-based AI/ML enabled software as a medical device. The device is available as a back end service via an API (Application Programming Interface). The device is intended to be used by dental professionals when reviewing Digital Impression (DI) scans and CBCT (DX) scans during standard of care diagnostic review and treatment planning. DS Core CBCT Anatomy analyses CBCT scans and Digital Impression (DI) scans to identify anatomical structures, propose a panoramic curve, segmentation of teeth, jaws, and the inferior alveolar nerve canal (IAN), as well as to perform image registration to support the review of CBCT dental images and DI scans.

This device is intended to be used with patients aged 12 and older with permanent dentition.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the Subject Device is identical to that of the predicate (DS Core CBCT Anatomy, K260785). Both devices are intended to assist dental professionals in reviewing CBCT (DX) and Digital Impression (DI/IOS) scans for clinical assessment, communication, and treatment planning during standard-of-care diagnostic review. Like the predicate, the Subject Device performs automated analysis of CBCT and DI data to identify anatomical structures, propose a panoramic curve, segment the teeth, jaws, and inferior alveolar nerve canal (IAN), and perform image registration, for patients aged 12 and older with permanent dentition. The Subject Device adds two additional algorithms:
1. DI Scan Comparison - enables clinicians to view and compare two intraoral scans from a patient and observe any potential differences.
2. DI Segmentation – identifies and marks specific features in a DI scan:
• A specific tooth (with its associated tooth number)
• Brackets
• Attachments

This addition does not alter the fundamental intended use, which remains an assistive software function that provides supplementary anatomical information under clinician oversight while retaining full clinical autonomy. Consistent with the predicate, the Subject Device does not provide diagnostic conclusions and does not direct treatment. Therefore, the additional capabilities do not constitute a new intended use.

Technological Comparison

21 CFR 807.92(a)(6)

The Subject Device and the predicate share the same fundamental technological principle: automated, machine-learning-based image analysis using computer-vision neural network (CNN) algorithms to identify and display dental anatomy for clinical use. Both are cloud-based AI/ML-enabled software as a medical device, delivered as a back-end service via an API, and both fall under the same regulation (892.2050), product code (QIH), and device class (II). The devices are technologically equivalent in that they process CBCT and DI scans and apply CNN-based algorithms for detection, segmentation, and registration. The only difference is that the Subject Device includes two additional algorithms, one for DI Scan Comparison and one for DI Segmentation. These algorithms rely on the same fundamental technological principles as the predicate and do not introduce any new principles of operation. Like the predicate, the Subject Device is software-based, uses machine learning algorithms, and produces results intended to support, rather than replace, clinician review. Accordingly, the devices are considered technologically comparable.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The device uses several locked, machine-learning–based convolutional neural network (CNN) models that were independently evaluated through standalone testing. These models support anatomical segmentation (for DI and CBCT "DX" scans), keypoint detection (tooth and root tip detection), and automatic scan orientation (ASO) with their performance assessed against expert ground truth created by U.S. licensed dentists. The DI/DX Matching algorithm incorporates ML components, such as the Keypoint & Automatic Scan Orientation (ASO) model, and was evaluated through clinical expert evaluation of the output registration. The DI Comparison algorithm also incorporates an ML component, DI Segmentation, and was evaluated through a clinical expert evaluation of the output registration (scan comparison). Other than the DI Segmentation and DI Comparison algorithms, all others were cleared in the previous version of the device and were not retested for this subject device submission.

The device uses locked, machine learning–based convolutional neural network (CNN) models to assist dental professionals in reviewing intraoral (Digital Impression, or DI) scan data. These models do not adapt or change once deployed. The performance of the previously cleared algorithms under K260785 remains unchanged. The two new algorithms for the subject device are addressed here: DI Segmentation, which is an ML-based CNN algorithm evaluated against a consensus ground truth from U.S.-licensed dentists in a standalone study, and DI Comparison, which compares two different DI scans. DI Comparison is not itself ML-enabled, but its pipeline incorporates the DI Segmentation model, and it was evaluated through expert clinical evaluation by U.S.-licensed, experienced dentists who reviewed the final comparison output for clinical acceptability.
Standalone testing used generalizable datasets with expert ground truth. The datasets included patients aged 12 years and older with permanent dentition and reflected diverse demographics and imaging characteristics. All algorithms were tested against predefined

acceptance criteria, and all evaluations met their prespecified success criteria.

Primary endpoint results

DI Segmentation met all three co-primary endpoints. Tooth detection sensitivity was 99.37%, with a 95% confidence interval of (98.97%, 99.70%). Tooth numbering classification accuracy was likewise 99.37%, with a 95% confidence interval of (98.89%, 99.74%). The tooth segmentation Dice score had a mean of 0.9806 (about 98%), with a 95% confidence interval of (0.9791, 0.9820). All lower bounds met or exceeded their thresholds.

DI Comparison met its primary acceptance criteria for both jaws. The mandibular (lower) full-arch pass rate was 85.86%, with a 95% confidence interval of (81.82%, 89.70%), and the maxillary (upper) pass rate was 88.89%, with a 95% confidence interval of (86.06%, 91.32%); the acceptance criterion was met or exceeded in each case.

Subgroup performance

Subgroup analyses supported generalizability across patient and imaging factors.

For DI Segmentation, tooth detection and numbering remained high across subgroups. By sex, sensitivity was 100% (female), about 99% (male), and 99% (unknown), with tooth numbering accuracy near 99–100% across the same groups. Across patient age bands (from 11–20 through 71+), sensitivity stayed roughly 99–100% and numbering accuracy roughly 98–100%. By U.S. region, sensitivity ranged from about 99% to 100%, same for tooth numbering accuracy. By arch type, lower-arch and upper-arch sensitivities were about 99% each, with numbering accuracy of roughly 99% (lower) and 100% (upper). Across scanner types, sensitivity was about 99% for Primescan, 100% for Primescan 2, and 100% for the unknown group. Tooth-level Dice scores were consistently around 0.98, including roughly 0.98 across age bands, 0.98–0.99 by sex, about 0.98 across U.S. regions, 0.98 for both arches, and 0.97–0.99 across scanner types.

For DI Comparison, the sextant pass rates were 95.35% (lower anterior), 92.32% (upper anterior), 96.58% (lower posterior right), 97.65% (upper posterior right), and 97.90% for both lower and upper posterior left. At the overall jaw level, subgroup pass rates by sex were about 84% (lower) and 89% (upper) for female, 88% and 89% for male, and 89% and 89% for the unknown group. Across age bands the lower-arch rates ranged from roughly 82% to 88% and the upper-arch rates ranged roughly 87–93%. Across U.S. regions, lower-arch rates ranged from about 81% (South) to 88% (West) and upper-arch rates from about 85% (Northeast) to 93% (Midwest and West).

All performance evaluations met their pre specified success criteria.

Results collectively demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.