April 23, 2026

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

Re: K260785
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: March 10, 2026
Received: March 10, 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 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, 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)*
K260785

Device Name
DS Core CBCT Anatomy

Indications for Use *(Describe)*
"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.

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.

510(k) #: K260785

510(k) Summary

Prepared on: 2026-03-17

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	630-201-1612
Applicant Contact	Dr. Deepthi Paknikar
Applicant 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
K233925	Relu Creator	QIH
K243989	Second Opinion® 3D	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 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 are consistent with those of the predicates, as all devices are intended to assist dental professionals in reviewing dental imaging for clinical assessment, communication, and treatment planning. The Subject Device, like the predicates, performs automated analysis of CBCT data to identify and mark anatomical structures and support preoperative and pretreatment workflows for patients aged 12 and older with permanent dentition. The Subject Device additionally processes Digital Impression "DI", also referred to as intra oral "IOS", scans (Same as Relu Creator) and provides image registration. The subject device proposes a panoramic curve; however, this feature does not alter the fundamental intended use, which remains an assistive software function that provides supplementary anatomical information under clinician oversight. The Subject Device does not provide diagnostic conclusions and does not direct treatment, which is consistent with the intended use of the predicates. Therefore, any differences in the detailed description of the indications for use do not constitute a new intended use.

Technological Comparison

21 CFR 807.92(a)(6)

The Subject Device and the predicates share the same fundamental technological principle of using automated, machine learning based image analysis to identify and display dental anatomy and image registration for clinical use. The Subject Device and predicates are technologically equivalent in that they process CBCT scans, use CNN based algorithms for detection, marking, and registration of scans, require basic software documentation levels, and pass all verification and validation testing requirements. Any differences identified, such as the Subject Device including a panoramic curve proposal algorithm, are not substantial differences in the operation of the device. Both the Subject Device and Relu Creator predicate device provide 3D modeling (segmentation and registration) for medical images, including CBCT and intraoral scans (IOS). The Second Opinion 3D device also provides identification and marking of dental anatomy on CBCT scans like the Subject Device; however, the Subject Device does not provide marking or identification of the mental foramen, sinus, nasal space, and airway specifically.
All devices process standard dental imaging data and generate assistive outputs such as anatomical segmentations and 3D representations. Minor differences in device features do not change the core purpose or technological method of operation between the subject and predicate devices. Like the predicates, the Subject Device is software based, uses neural network algorithms, and produces results intended to support, rather than replace, clinician review. Any minor differences in deployment method, such as the Subject Device being a back end algorithm without a GUI, or specific features, do not constitute entirely new technological principles, and the devices are considered technologically equivalent.

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, 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 device uses several locked, machine learning–based convolutional neural network (CNN) models designed to assist dental professionals in reviewing CBCT and intraoral scan data. These models do not adapt or change once deployed, and each was evaluated through standalone testing consistent with applicable guidelines and regulatory expectations.

Standalone testing was conducted for each model and algorithmic component using generalizable datasets and expert ground truth from U.S.- licensed dentists. An expert clinical evaluation was conducted for the DI/DX matching algorithm.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.

The Anatomy Segmentation model met all primary endpoints: mean Dice for dentition was 93%, for jaw 94%, and for mandibular canal 78%, with all lower bounds of the 95% confidence intervals meeting or exceeding their success criteria. The Keypoint models achieved high accuracy, with overall tooth center detection sensitivity of 99% and tooth numbering accuracy exceeding 96%, with all lower bounds of the 95% confidence intervals meeting or exceeding their success criteria. DI/DX Matching was evaluated and an expert clinical assessment of CBCT to intra oral scan registration had an overall pass rate of 90% with all lower bounds of the 95% confidence intervals meeting or exceeding their success criteria. The Automatic Scan Orientation (ASO) model also satisfied acceptance criteria, with tooth detection sensitivity of 96% and tooth numbering accuracy of 97%, with all lower bounds of the 95% confidence intervals meeting or exceeding their success criteria.

Subgroup performance supported generalizability across patient and imaging factors.

For Anatomy Segmentation, by sex, female mean Dice scores were 92% (dentition), 94% (jaw), and 75% (canal), while male scores were 94%, 95%, and 80%, respectively. Across device vendors, Dentsply Sirona scans showed 94% (dentition), 94% (jaw), and 78% (canal) versus other vendors at 92%, 94%, and 76%.

For Keypoints subgroup results remained high: by sex, female sensitivity was 99% and male sensitivity 99%. Across device vendors, sensitivities included 99% (Dentsply Sirona), 99% (Planmeca), 99% (Morita), 98% (Carestream), and 99% (Other).

For DI/DX Matching, by sex, pass rates were 90% (female) and 90% (male). Across DI manufacturers, pass rates for DI/DX Matching were consistently high. Align devices (iTero) achieved a 95% pass rate, while Dentsply Sirona scanners showed a 91% pass rate. Planmeca devices performed strongly at 97%, and 3Shape scanners demonstrated an 87% pass rate. An additional "unknown manufacturer" group had a pass rate of 88%. Across CBCT manufacturers, DI/DX Matching pass rates were generally high. Planmeca devices achieved a 100% overall pass rate, and PaloDEx Group Oy devices performed similarly well at 97%. Sirona systems, which represented the largest sample size, showed a strong overall pass rate of 92%. Imaging Sciences International devices demonstrated an 86% pass rate, while Carestream Dental and Carestream Health systems showed pass rates of 91% and 87%, respectively. Smaller sample manufacturers showed more variable results, including Dexis and Vatech at 66%, and HDXWILL at 83%.

For ASO, tooth detection sensitivity subgroups included 95% (female) and 97% (male), with scan coverage at 96% (full) and 96% (partial). Tooth numbering accuracy subgroups included 98% (female) and 97% (male), with 99% (full) and 96% (partial). Examples across scanner vendors showed sensitivity/numbering accuracy of 98%/97% (Omnicam), 96%/97% (Primescan), 94%/98% (TRIOS), and 97%/97% (Unknown).

Collectively, the models met predefined performance criteria and demonstrated consistent results across demographic, regional, vendor, and imaging parameter subgroups, supporting generalizability for use as assistive tools within standard dental imaging workflows.

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