May 14, 2025

Cube Click, Inc.
℅ Meritxell Martinez
Project Manager and Regulatory Specialist
Innolitics
1101 West 34th St #550
AUSTIN, TX 78705

Re: K242437
Trade/Device Name: Smile Dx®
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN, LLZ
Dated: April 6, 2025
Received: April 7, 2025

Dear Meritxell Martinez:

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

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)*
K242437

Device Name
Smile Dx®

Indications for Use *(Describe)*
Smile Dx® is a computer-assisted detection (CADe) software designed to aid dentists in the review of digital files of bitewing and periapical radiographs of permanent teeth. It is intended to aid in the detection and segmentation of suspected dental findings which include: caries, periapical radiolucencies (PARL), restorations, and dental anatomy.

Smile Dx® is also intended to aid dentists in the measurement (in millimeter and percentage measurements) of mesial and distal bone levels associated with each tooth.

The device is not intended as a replacement for a complete dentist's review or their clinical judgment that takes into account other relevant information from the image, patient history, and actual in vivo clinical assessment.

Smile Dx® supports both digital and phosphor sensors.

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.

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CUBE CLICK	510(k) Summary

1. CONTACT INFORMATION

Company Name	Cube Click, Inc.
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Date Prepared	May 13th, 2025
Documentation Prepared Using	Innolitics Medtech OS Framework

2. DEVICE INFORMATION

Trade Name	Smile Dx®
Common Name	Computer-Assisted Detection Device
Classification Name	Medical Image Analyzer
Primary Product Code	MYN
Primary Regulation Number	21 CFR 892.2070
Secondary Product Code	LLZ

3. PRIMARY PREDICATE DEVICE INFORMATION

Predicate Device Name	Overjet Caries Assist
Predicate Device K Number	K212519

4. REFERENCE DEVICE(S) INFORMATION

Predicate Device Name	Second Opinion

Predicate Device K Number	K210365
Predicate Device Name	Overjet Dental Assist
Predicate Device K Number	K210187

5. DEVICE DESCRIPTION

Smile Dx® is a computer assisted detection (CADe) device indicated for use by licensed dentists as an aid in their assessment of bitewing and periapical radiographs of secondary dentition in adult patients. Smile Dx® utilizes machine learning to produce annotations for the following findings:

- Caries
- Periapical radiolucencies
- Bone level measurements (mesial and distal)
- Normal anatomy (enamel, dentin, pulp, and bone)
- Restorations

6. INDICATIONS FOR USE

Smile Dx® is a computer-assisted detection (CADe) software designed to aid dentists in the review of digital files of bitewing and periapical radiographs of permanent teeth. It is intended to aid in the detection and segmentation of suspected dental findings which include: caries, periapical radiolucencies (PARL), restorations, and dental anatomy.

Smile Dx® is also intended to aid dentists in the measurement (in millimeter and percentage measurements) of mesial and distal bone levels associated with each tooth.

The device is not intended as a replacement for a complete dentist's review or their clinical judgment that takes into account other relevant information from the image, patient history, and actual in vivo clinical assessment.

Smile Dx® supports both digital and phosphor sensors.

7. INTENDED PATIENT POPULATION

The intended patient population of Smile Dx® are patients that have permanent adult dentition and are at least 22 years of age.

8. SUBSTANTIAL EQUIVALENCE SUMMARY

Smile Dx® is similar to the predicate device and reference devices in the following ways:

- **Intended use:** All devices are intended to be used to identify suspected areas of interest in intra-oral radiographs.
- **Technology characteristics:** All devices employ machine learning algorithms to output detections.
- **Safety:** As all devices are CADe and/or SaMD systems, and don't pose any direct safety hazard to the patient.
- **Clinical Performance:** All devices have undergone clinical evaluations which demonstrate statistically significant improvement in aided reader performance.

8.1. Device Comparison Table

For technological characteristics comparison, the following table is provided:

Characteristic	Smile Dx®	Predicate Device: Overjet Caries Assist (K212519)	Reference Device: Second Opinion (K210365)	Reference Device: Overjet Dental Assist (K210187)	Comparison
Manufacturer	Cube Click, Inc.	Overjet, Inc.	Pearl Inc.	Overjet, Inc.	N/A
Regulation Number	892.2070	892.2070	892.2070	892.2050	Smile Dx® falls under the same regulation (892.2070) as primary predicate (Overjet Caries Assist).
Regulation Name	Medical image analyzer	Medical image analyzer	Medical image analyzer	Picture archiving and communications system	Smile Dx® falls under the same regulation (892.2070) as predicate (Overjet Caries Assist).
Regulatory Class	Class II	Class II	Class II	Class II	Same
Product Code	MYN; LLZ	MYN	MYN	LLZ	Smile Dx® has the same primary product MYN as predicate (Overjet Caries Assist) and reference device

Characteristic	Smile Dx®	Predicate Device: Overjet Caries Assist (K212519)	Reference Device: Second Opinion (K210365)	Reference Device: Overjet Dental Assist (K210187)	Comparison
					(Second Opinion). Additionally, Smile Dx®'s secondary product code LLZ is the same as reference device (Overjet Dental Assist). Thus, the subject device has the same product codes as the identified predicate and reference devices.
Device Property	SaMD/CADe	SaMD/CADe	SaMD/CADe	SaMD	Same
Indications for Use	Smile Dx® is a computer-assisted detection (CADe) software designed to aid dentists in the review of digital files of bitewing and periapical radiographs of permanent teeth. It is intended to aid in the detection and segmentation of suspected dental findings which include: caries, periapical radiolucencies (PARL), restorations, and dental anatomy. Smile Dx® is also intended to aid dentists in the measurement (in millimeter and percentage measurements) of mesial and distal bone levels associated with	The Overjet Caries Assist (OCA) is a radiological, automated, concurrent read, computer-assisted detection software intended to aid in the detection and segmentation of caries on bitewing radiographs. The device provides additional information for the dentist to use in their diagnosis of a tooth surface suspected of being carious. The device is not intended as a replacement for a complete dentist's review or their clinical judgment that takes into account other relevant	Second Opinion® is a computer aided detection ("CADe") software to identify and mark regions in relation to suspected dental findings which include Caries, Discrepancy at the margin of an existing restoration, Calculus, Periapical radiolucency, Crown (metal, including zirconia & non-metal), Filling (metal & non-metal), Root canal, Bridge and Implants. It is designed to aid dental health professionals to review bitewing and periapical radiographs of permanent teeth in patients 12 years	Overjet Dental Assist is a radiological semi-automated image processing software device intended to aid dental professionals in the measurements of mesial and distal bone levels associated with each tooth from bitewing and periapical radiographs. It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. The system is to be used by trained professionals including, but not limited to, dentists and dental hygienists. Intended Patient Population:	Smile Dx® has similar indications for use to predicate K212519 for detecting caries, reference device K210365 for detecting PARLs, and reference device K210187 for measurement of bone levels. Thus, the subject device combines the indications for use of the three identified predicate and reference devices. All three devices share the same intended use to identify suspected areas of interest in intra-oral radiographs.

Characteristic	Smile Dx®	Predicate Device: Overjet Caries Assist (K212519)	Reference Device: Second Opinion (K210365)	Reference Device: Overjet Dental Assist (K210187)	Comparison
	each tooth. The device is not intended as a replacement for a complete dentist's review or their clinical judgment that takes into account other relevant information from the image, patient history, and actual in vivo clinical assessment. Smile Dx® supports both digital and phosphor sensors.	information from the image, patient history, and actual in vivo clinical assessment.	of age or older as a second reader.	The intended patient population of the device is patients living in the United States, who are 22 years old or older, and that do not have any remaining primary teeth. Overjet has not evaluated the performance of the device on primary dentition.	
Detections and/or measurements	• Normal anatomy • Caries • Periapical radiolucencies • Bone level measurements (mesial and distal) • Restorations	Caries	Caries, Margin discrepancy, Calculus, Periapical radiolucencies, Restorations	Bone level measurements (mesial and distal)	Smile Dx® detects caries similar to predicate Overjet Caries Assist K212519. Smile Dx® also detects PARLs and restorations, similar to reference device Second Opinion K210365. Second Opinion also detects other features such as margin discrepancy and calculus, however, these are not supported by subject device. The absence of these features in Smile Dx® does not create a new intended use. Smile Dx® also measures mesial and distal bone levels, same as reference device Overjet

Characteristic	Smile Dx®	Predicate Device: Overjet Caries Assist (K212519)	Reference Device: Second Opinion (K210365)	Reference Device: Overjet Dental Assist (K210187)	Comparison
					Dental Assist K210187.
Intended User	Dentists	Dentists	Dentists	Dental professionals including, but not limited to, dentists and dental hygienists.	Smile Dx® is intended for use by licensed dentists, same as all of the identified predicate and reference devices. The reference device Overjet Dental Assist is also intended for use by other dental professionals, such as dental hygienists. However, use of Smile Dx® has been limited to use by licensed dentists only.
Patient Population	Patients requiring dental services, all sexes, at least 22 years of age, and with permanent dentition.	Patients requiring dental services, all sexes, at least 18 years of age, and with permanent dentition.	Patients requiring dental services, all sexes, at least 12 years of age, and with permanent dentition.	Patients requiring dental services, all sexes, at least 22 years of age, and with permanent dentition.	The intended patient population for Smile Dx® is limited to patients with permanent dentition who are at least 22 years of age. This is identical to the reference device Second Opinion. This intended patient population age has been supported by use of representative patient data in testing.
Rx or OTC	Rx-only	Rx-only	Rx-only	Rx-only	Same
Technical Characteristics					
Platform	Web - Edge, Chrome, FireFox, Safari	Web - Edge, Chrome, Firefox	Local computer application (Cloud-based installation)	Web - Edge, Chrome, Firefox	The subject device is a web-based application, similar to Overjet Caries Assist and Overjet

Characteristic	Smile Dx®	Predicate Device: Overjet Caries Assist (K212519)	Reference Device: Second Opinion (K210365)	Reference Device: Overjet Dental Assist (K210187)	Comparison
					Dental Assist. It is compatible with similar browsers and is also compatible with Safari, which is a commonly used browser.
OS	Any	Any	Windows 7 or higher	Any	The subject device is compatible with any operating system, same as predicate Overjet Caries Assist and reference device Overjet Dental Assist.
User Interface	Mouse, Keyboard, Trackpad	Mouse, Keyboard, Trackpad	Mouse, Keyboard	Mouse, Keyboard, Trackpad	Same
Image Modality	Radiograph	Radiograph	Radiograph	Radiograph	Same
Radiograph Type	Bitewing and periapical	Bitewing and periapical	Bitewing and periapical	Bitewing and periapical	Same
Image Input Sources	Images imported from local computer, from a range of manufacturers	Images imported from the radiographic device, or from the practice management system, from Carestream or Schick sensors	Radiography devices from a range of manufacturers	Images imported from the radiographic device, or from the practice management system	Images are manually imported from the dentist user's local computer into Smile Dx®. The subject device does not connect to practice management systems like Overjet Caries Assist and Overjet Dental Assist. However, this difference does not raise any new questions of safety and effectiveness. Additionally, Smile Dx® is compatible with images from a range of radiography device

Characteristic	Smile Dx®	Predicate Device: Overjet Caries Assist (K212519)	Reference Device: Second Opinion (K210365)	Reference Device: Overjet Dental Assist (K210187)	Comparison
					manufacturers, similar to Second Opinion. This has been supported by using data from a range of manufacturers during testing.
Image Format	jpg, png, tif, tig, dex, gif, bitmap/bmp, and raw	jpg, png, eop, jif, dicom	jpeg, png, rvg, dcm, tiff, and dic	jpg, png, jfif, eop, etp, jif	Smile Dx® supports image formats that are commonly used in dental radiographs. The difference in supported image formats between the subject and predicate devices is considered to be minor and does not interfere with the ability of Smile Dx® to achieve its intended use.
Processing Architecture	Three layers: - The Network layer contains a login module and a data ingestion module. Radiographs are manually uploaded from local computer to the server. - The Detection and Measurement layer processes the image and classifies it as either bitewing or periapical, and then annotates it via the algorithm - The visualization layer displays the annotated image via Smile Dx®'s	Three layers: - The Network layer works with the practice PACS or EMR to transmit the image and meta-data to Overjet. - The decision layer processes the image to ensure it is the correct data type, and then annotates it via the algorithm - The presentation layer displays the annotated image in a non diagnostic viewer. The dentist can filter,	The Second Opinion Client continuously monitors a local or networked resource for dental radiographs. When new images are found, it sends them to cloud-based Computer Vision Models (CV Models) for analysis. These models generate metadata describing the nature and location of detected features in the radiographs. The metadata is returned to the Second Opinion® Client, which	Unknown	Smile Dx® has a similar processing architecture to the predicate Overjet Caries Assist (K212519) and reference device Second Opinion (K210365). All devices obtain radiographs, annotate them, and present annotations to via a user interface. One of the main differences in processing architecture is that the predicate device can establish connections with external sources to upload images, whereas the subject

Characteristic	Smile Dx®	Predicate Device: Overjet Caries Assist (K212519)	Reference Device: Second Opinion (K210365)	Reference Device: Overjet Dental Assist (K210187)	Comparison
	user interface. The dentist can adjust image settings, display and hide the presented annotations.	display, hide, create and edit the annotations presented.	displays it within its user interface. Detected features are highlighted with color-coded boundary boxes overlaid on the original radiograph.		device exclusively uploads images from the local computer. Similarly, users of Smile Dx® are required to manually upload images to the software, whereas the reference device Second Opinion automatically uploads images. Nevertheless, these technological differences do not raise new questions of safety and effectiveness. The absence of these features in the subject device does not impede its ability to fulfill its intended use.
Algorithm	Utilizes computer vision machine learning algorithm(s).	Utilizes computer vision machine learning algorithm(s).	Utilizes computer vision neural network algorithms, developed from open-source models using supervised machine learning techniques.	Utilizes computer vision techniques.	Same. Smile Dx® utilizes computer vision techniques, specifically, machine learning algorithms to detect suspected findings, same as the identified predicate and reference devices.
Output	Suspected findings (i.e., caries, PARLs) and measurements (bone levels) are overlaid on the original radiograph	Caries detection and segmentation on radiograph resulting in outline of suspected caries	Detected features (e.g., caries, PARLs) are highlighted with color-coded boundary boxes overlaid on the original radiograph	Bone-level annotations on radiograph	The output of Smile Dx® is similar to the outputs of all of the identified predicate and reference devices, as they all overlay the findings on the original radiograph.
Marker Type/Size	Contour segmentations for caries and periapical	Presents suspected carious lesions as segmented	Color-coded bounding boxes / Fixed	Color-coded lines for bone levels	The subject device has similar marker types to its predicate and reference

Characteristic	Smile Dx®	Predicate Device: Overjet Caries Assist (K212519)	Reference Device: Second Opinion (K210365)	Reference Device: Overjet Dental Assist (K210187)	Comparison
	radiolucencies. Color-coded lines for bone levels	polygons outlining the prediction			devices. For suspected caries, the subject device creates a contour of the suspected caries, similar to the predicate (Overjet Caries Assist). For periapical radiolucencies, the subject device creates countours. This is different to reference device's (Second Opinion) bounding boxes. The performance and accuracy of the segmentations has been supported with appropriate performance testing. For bone levels, the subject device outputs color-coded lines depending on the level of measured boneloss, similar to reference device Overjet Dental Assist.
Image Measurement	Linear distance	N/A	N/A	Linear distance	Smile Dx® is similar to reference device Overjet Dental Assist in that it creates a linear distance for measured bone levels.
Image Viewing	Full, Thumbnail	Full, Thumbnail	Full, Thumbnail	Full, Thumbnail	Same
Image Manipulation	Image adjustment tools (e.g., brightness, contrast, opacity,	Annotations	Image adjustment tools (e.g., brightness,	Annotation (line)	Smile Dx® has similar image adjustment tools as reference devie Second Opinion

Characteristic	Smile Dx®	Predicate Device: Overjet Caries Assist (K212519)	Reference Device: Second Opinion (K210365)	Reference Device: Overjet Dental Assist (K210187)	Comparison
	rotation prior to upload)		contrast, zoom, invert, rotate)		(e.g., contrast and brightness). Smile Dx® introduces a new tool (i.e., opacity adjustment), however, this does not raise any new questions of safety and effectiveness and is a common image adjustment tool. Smile Dx® lacks some of the features found in the predicate and reference devices (e.g., zoom, invert, and manual annotation tools). However, these tools are not needed to accomplish the intended use of the device and do not raise new questions of safety and effectiveness.
Performance Testing	• Standalone performance study for pathologic feature (i.e., caries and periapical radiolucency) detection, non-pathologic feature detection (i.e., normal anatomy and restorations) and bone level measurement performance. • Multiple-Reader, Multiple-Case (MRMC) study for pathologic dental features	• Standalone study for pathologic feature detection performance. • Multiple-Reader, Multiple-Case (MRMC) study for pathologic dental features • Analysis included: • Sensitivity and specificity evaluations • Dice coefficient analysis	• Standalone study for pathological and non-pathologic feature detection performance. • Multiple-Reader, Multiple-Case (MRMC) study for pathologic dental features • Analysis included: • wAFROC-FOM analysis for primary endpoints •Determination of the changes in sensitivity and change in number	• Bench testing evaluated precision and recall against labeled keypoints within radiographs. • Retrospective clinical performance testing that compared adjudicated measurements against Overjet Dental Assist's predicted measurements. Analysis included	Smile Dx® underwent similar evaluations as predicate and reference devices, following recommendations in 2022 FDA Guidance "Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions".

Characteristic	Smile Dx®	Predicate Device: Overjet Caries Assist (K212519)	Reference Device: Second Opinion (K210365)	Reference Device: Overjet Dental Assist (K210187)	Comparison
	• Analysis included: • wAFROC analysis for primary endpoint • Sensitivity and specificity evaluations		of false positive dental pathologies of a given type per image (FPPI)	sensitivity and specificity.	

9. PERFORMANCE TESTING

9.1. Software Verification and Validation

As Smile Dx® is a SaMD, software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Device Software Functions".

9.2. CADe Testing

Smile Dx® was subjected to clinical performance testing according to 2022 FDA Guidance "Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions" Testing involved both standalone performance testing and a fully-crossed multi-reader multi-case (MRMC) reader clinical evaluation. As CADe devices, predicate device Overjet Caries Assist (K212519) and Second Opinion (K210365) also underwent the recommended testing.

9.2.1. Standalone Testing

Caries and Periapical Radiolucency Detection

Smile Dx®'s caries and periapical radiolucency detection performance was evaluated using a test dataset of 867 cases collected from multiple U.S. sites. The test results were as follows:

Metric	Caries	Periapical Radiolucency
Dice	0.74 [0.72 0.76]	0.77 [0.74, 0.80]
Sensitivity	overall: 88.3% [83.5%, 92.6%]	86.1% [80.2%, 91.9%]

Bone Level Detection and Bone Loss Measurement

Smile Dx®'s bone level detection and bone loss measurement performance was evaluated using a test dataset of 352 cases collected from multiple U.S. sites. The test results were as follows:

Radiograph Type	Bone Level Detection - Sensitivity	Bone Level Detection - Specificity	Bone Loss Measurement (Mean Absolute Error [95% CI]
Bitewing	95.5% [94.3%, 96.7%]	94.0% [91.1%, 96.6%]	0.30 mm [0.29mm, 0.32mm]
Periapical	87.3% [85.4%, 89.2%]	92.1% [89.9%, 94.1%]	2.6% [2.4%, 2.8%]

Normal Anatomy and Restorations

Smile Dx®'s performance for normal anatomy and restoration detection was evaluated using a test dataset of 200 cases collected from different U.S. sites. The test results were as follows:

Non-pathologic Region	Dice	Sensitivity (Pixel-level)	Sensitivity (Contour-level)	Specificity (Contour-level)
Normal Anatomy	0.84 [0.83, 0.85]	86.1% [85.4%, 86.8%]	95.2% [94.5%, 96%]	93.5% [91.6%, 95.8%]
Restorations	0.87 [0.85, 0.90]	83.1% [80.3%, 86.4%]	90.9% [88.2%, 93.9%]	99.6% [99.3%, 99.8%]

9.2.2. MRMC Clinical Evaluation - Reader Improvement

The clinical performance assessment for Smile Dx® used a fully-crossed, multiple-reader multiple-case (MRMC) evaluation method. The test dataset consisted of 352 cases collected from multiple U.S. sites. Smile Dx® underwent clinical evaluation using methods similar to those used for the primary predicate device Overjet Caries Assist (K212519):

Both devices were evaluated in a multi-reader, multi-case (MRMC) retrospective study with at least 13 US licensed dentists (Smile Dx® had 14 readers). Ground truth was established by the consensus labels of at least three US licensed dentists (the ground truth for Smile Dx®'s study was established by four US licensed dentists). Half of the data set contained unannotated images, and the second half contained radiographs that had been processed through the CADe device. The radiographs were presented to the readers in alternating groups throughout two different sessions, which were separated by a washout period. The results were compared against the consensus ground truth, and the sensitivity, specificity, and alternative free response receiver operating characteristic (AFROC) was evaluated to characterize the performance of the readers with and without viewing the model annotations.

Primary Endpoint: wAFROC Analysis

The weighted alternative free-response receiver operating characteristic (wAFROC) figure of merit serves as the primary performance metric, giving equal importance to each case while reducing the influence of cases with multiple lesions.

The wAFROC analysis revealed statistically significant improvements, with an increase of $\Delta\theta$ for both caries detection (+0.127 [0.081, 0.172]) and PARL detection (+0.098 [0.061, 0.135]). These results demonstrate that Smile Dx® enhances reader sensitivity without compromising specificity, thereby meeting the acceptance criteria for effective detection of caries and PARLs.

	$\theta_{control}$	θ_{CAD}	$\Delta\theta$ [95% CI]	p-value
Caries	0.781	0.908	+0.127 [0.081, 0.172]	< 0.001
PARLs	0.849	0.947	+0.098 [0.061, 0.135]	< 0.001

Secondary Endpoint: Sensitivity and Specificity

Sensitivity metrics were determined at the lesion level. Specificity metrics were determined at the case level.

Sensitivity
For caries detections, reader sensitivity improved from 64.3% without device to 83.9% with device, an increase of 19.6% [12.8%, 26.4%]. For PARL detections, reader sensitivity improved from 70.7% without device to 89.8% with device, an increase of 19.1% [13.6%, 24.7%].

Specificity
For caries detections, reader specificity improved from 73.6% without device to 90.2% with device, a difference of 16.7% [13.5%, 19.9%]. For PARL detections, reader specificity improved from 92.6% without device to 97.3% with device, a difference of 4.7% [3%, 6.4%].

Sub-group Analysis

Sub-group analyses were performed for patient demographics (i.e., age, sex, race), imaging hardware, and primary vs. secondary classification (caries). No distinct differences in performance were observed among sub-groups that raise concerns about the effectiveness of Smile Dx®.

10. CONCLUSION

Smile Dx® is substantially equivalent to the identified predicate device. Specifically, the subject device has similar indications and technological characteristics when compared to the predicate device. Any differences in technological characteristics do not raise new questions of safety or effectiveness.

Additionally, the results of the performance testing (i.e., software verification and validation, standalone performance assessment and MRMC clinical evaluation) of Smile Dx® support that the subject device's performance is as effective as the predicate and reference devices.