March 11, 2025

Better Diagnostics AI Corp
% Rajeev Nohria
CEO
29 Alcott Way
AVON, CT 06001

Re: K241725
Trade/Device Name: Better Diagnostics Caries Assist (BDCA) Version 1.0
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: February 10, 2025
Received: February 10, 2025

Dear Rajeev Nohria:

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.

Submission Number *(if known)*

K241725

Device Name

Better Diagnostics Caries Assist (BDCA) Version 1.0

Indications for Use *(Describe)*

Better Diagnostics Caries Assist is a radiological, automated, concurrent read, CADe software intended to identify and localize carious lesions on bitewings and periapical radiographs acquired from patients aged 18 years or older. Better Diagnostics Caries assist is indicated for use by board licensed dentists. 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 or actual in vivo clinical assessment.

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)

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Better Diagnostics AI Corp.
29 Alcott Way Avon CT, 06001
USA

510(k) Summary

1. General Information

510(k) Owner	Better Diagnostics AI Corp.
Address	29 Alcott Way Avon CT, 06001 USA
Correspondence person	Raj Zaveri Quality and Regulatory Consultant
Contact information	**Email:** rajzaveri10@gmail.com **Phone:** +91 8369438297
Date prepared	March 23, 2024

2. Proposed device

Proprietary Name of Device: Better Diagnostics Caries Assist (BDCA) Version 1.0

Common or Usual Name: Medical image analyzer

Classification Panel: Radiology

Regulation Number: 21 CFR § 892.2070

Regulation Name: Medical image analyzer

Regulation Class: Class II

Product Code: MYN

3. Predicate Device

Proprietary Name of Device: Overjet Caries Assist Software (Version 1.0)

Premarket Notification: K222746

Common or Usual Name: Medical image analyzer

Classification Panel: Radiology

Regulation Number: 21 CFR § 892.2070

Regulation Name: Medical image analyzer

Regulation Class: Class II

Product Code: MYN

4. Device Description

Better Diagnostics Caries Assist (BDCA) Version 1.0 is a computer-aided detection (CADe) software designed for the automated detection of carious lesions in Bitewings and periapical dental radiographs. This software offers supplementary information to assist clinicians in their diagnosis of potentially carious tooth surfaces. It is important to note that BDCA v1.0 is not meant to replace a comprehensive clinical evaluation by a clinician, which should consider other pertinent information from the image, the patient's medical history and clinical examination. This software is intended for use in identifying carious lesions in permanent teeth of patients who are 18 years or older.

BDCA v1.0 does not make treatment recommendations or provide a diagnosis. Dentists should review images annotated by BDCA v1.0 concurrently with original, unannotated images before making the final diagnosis on a case. BDCA v1.0 is an adjunct tool and does not replace the role of the dentist. The CAD generated output should not be used as the primary interpretation by the dentists. BDCA v1.0 is not designed to detect conditions other than the following: Caries.

BDCA v1.0 comprises four main components:

- **Presentation Layer:** This component includes “AI Results Screen" a web-based interface (user interface) that allows users to view AI marked annotations. This is a custom code provided by Better Diagnostics AI Corp to Dental PMS customers. User Interface uses Angular.js and node.js technology to show images on the “AI Results Screen". System can process PNG, BMP and JPG format images. All images are converted into JPEG format for processing. Computer Vision Models

returns AI annotations and co-ordinates to the business layer. Business layer sends coordinates to the presentation layer and bounding boxes are drawn on the image using custom code written in Angular.js and node.js. Dentists can view, accept or reject the annotations based on his evaluation. Better Diagnostics AI provides UI code to customers e.g. dental practice management software and imaging firms for utilization of BCDA v1.0 software.

- **Application Programming Interface (API):** APIs are a set of definitions and protocols for building and integrating application software. It's sometimes referred to as a contract between an information provider and an information user. BDCA v1.0 APIs connect the Dental PMS with the business layer. API receives images input from Dental PMS and passes it to the business layer. It also receives annotations and co-ordinates from the business layer and passes it to the presentation layer hosted by Dental PMS.
- **Business Layer:** Receives image from the API Gateway and passes it to computer vision models. It also receives the bounding boxes coordinates from the model and retrieves images from the cloud storage. It sends all information to the "AI Results screen" to display rectangle bounding boxes.
- **Computer Vision Models (CV Models):** These models are hosted on a cloud computing platform and are responsible for image processing. They provide a binary indication to determine the presence or absence of carious findings. If carious findings are detected, the software will output the coordinates of the bounding boxes for each finding. If no carious lesions are found, the output will not contain any bounding boxes and will have a message stating "No Suspected: Caries Detected"

  AI models have three parts:

  - **Pre-Processing Module:** Standardization of image to specific height and width to maintain consistency for AI model. Finds out the type of image including IOPA, Bitewings or other types. BDCA v1.0 can only process Bitewings and IOPA images for patients over age 18. All other types of images will be rejected.
  - **Core Module:** This module provides carious lesion annotations and co-ordinates to draw bounding boxes.
  - **Post-Processing Module:** includes cleanup process to remove outliers/incorrect annotations from the images.

5. Intended Use/Indications for Use

Better Diagnostics Caries Assist is a radiological, automated, concurrent read, CADe software intended to identify and localize carious lesions on bitewings and periapical radiographs acquired from patients aged 18 years or older. Better Diagnostics Caries assist is indicated for use by board licensed dentists. 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 or actual in vivo clinical assessment.

6. Intended Patient Population

The intended patient population of the device is patients that have permanent dentition, and who are at least 18 years of age.

7. Substantial Equivalence

	Proposed Device	Primary Predicate Device	Substantially equivalent
510(k) Number	K241725	K222746	-
Applicant	Better Diagnostics AI Corp.	Overjet, Inc.	-
Device Name	Better Diagnostics Caries Assist	Overjet Caries Assist	-
Classification Regulation	21 CFR 892.2070	21 CFR 892.2070	Yes
Product Code	MYN	MYN	Yes
Indications for use	Better Diagnostics Caries Assist is a radiological, automated, concurrent read, CADe software intended to identify and localize carious lesions on bitewings and periapical radiographs acquired from patients aged 18 years or older. Better Diagnostics	Overjet Caries Assist (OCA) is a radiological, automated, concurrent read, CADe software intended to aid in the detection and segmentation of caries on bitewing and periapical 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	Yes[1]

	Proposed Device	**Primary Predicate Device**	**Substantially equivalent**
	Caries assist is indicated for use by board licensed dentists. 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, or actual in vivo clinical assessment.	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, or actual in vivo clinical assessment.	
Image Modality	Radiograph	Radiograph	Yes
Study Type	Bitewing and periapical Images	Bitewing and periapical Images	Yes
Reader workflow	Concurrent	Concurrent	Yes
Clinical Output	Message indicating if a carious lesion was detected. A bounding box is created to indicate	Caries detection and segmentation on radiograph resulting in outline or fill of suspected caries.	Yes[2]

	Proposed Device	**Primary Predicate Device**	**Substantially equivalent**
	suspected carious lesions.		
Patient Population	18 years or older with permanent teeth	Patients requiring dental services, all sexes, 12 years of age or older with permanent teeth	Yes[3]
Platform	Web - Edge, Chrome, Firefox	Web - Edge, Chrome, Firefox	Yes
OS	Any	Any	Yes
User Interface	Mouse, Keyboard, Trackpad	Mouse, Keyboard, Trackpad	Yes
Intended User	Dentists	Dentist	Yes
Image Source	Images are imported from dental PMS/Imaging software from multiple sensor manufacturers	Images imported from the radiographic device, or from the practice management system from multiple sensor manufacturers	Yes

	Proposed Device	**Primary Predicate Device**	**Substantially equivalent**
Image Format	Accepts image formats JPG, PNG, and BMP	JPG, PNG, EOP, TIFF, DICOM	Yes[4]
Processing Architecture	1, APIs - Dental PMS/Imaging software send x-ray image to BDCA 2. Computer vision models process the x-ray image and send results presentation layer 3. Presentation layers is plots rectangle shape annotations on the x-ray image and it is displayed to dentist using "AI Results screen"	Three layers: 1 - The Network layer works with the practice PACS or EMR to transmit the image and meta-data to Overjet. 2 - The decision layer processes the image to ensure it is the correct data type, and then annotates it via the algorithm 3 - The presentation layer displays the annotated image in a non-diagnostic viewer. The dentist can filter, display, hide, create and edit the annotations presented.	Yes*

BDCA v1.0 and Overjet Caries Assist are both class II devices with the same product classification code - MYN. Both devices are radiological, automated, concurrent read, CADe software that are used to detect caries on bitewing and periapical radiographs. BDCA v1.0 has minor differences compared to the predicate device in terms of the following:

- Yes[1] - BDCA v1.0 detects caries by drawing coloured bounding boxes on bitewing and periapical radiographs whereas Overjet caries assist uses segmentation to outline the carious regions on bitewing and periapical radiographs. These are two different approaches prevalent for automated caries detection. Choosing either approach has no impact whatsoever on the outcome. This is supported by the results of the Multi-Reader, Multi-Case (MRMC) study, where BDCA v1.0 demonstrated robust performance in detecting caries lesions with sensitivity improvements as discussed in section 8.a.ii given below. Additionally, the standalone study showed that BDCA significantly improved cavity detection capability without compromising specificity, with consistent performance across various clinical settings and variables.

- Yes[2] - BDCA v1.0 localizes caries via bounding boxes **on bitewing and periapical radiographs** whereas Overjet caries assist uses segmentation to outline or fill the carious regions **on bitewing and periapical radiographs. Both lead to the same clinical outcome i.e detection of caries.**

- Yes[3] - BDCA v1.0 is intended to mark carious regions on radiographs acquired from patients aged 18 years or above, whereas Overjet carries assist marks carious regions on radiographs acquired from patients aged 12 years or above. This additional functionality on the Overjet's part has no impact whatsoever on the outcome of BDCA v1.0. Further, the software verification and validation performed as per IEC 62304 validates the performance of BDCA v1.0.

- Yes[4] - BDCA v1.0 supports BMP, JPG, and PNG and Overjet supports JPG, PNG, EOP, TIFF, DICOM. The additional formats supported by Overjet has no impact whatsoever on the outcome of BDCA v1.0. Further, the software verification and validation performed as per IEC 62304 validates this claim as well as the performance of BDCA v1.0.

8. Performance Testing

Safety and performance of BDCA v1.0 has been evaluated and verified in accordance with software specifications and the following applicable

performance standards through software verification and validation, identification and mitigation of device-related hazards via cybersecurity and risk management, labeling validation, human factors testing, standalone and clinical performance testing :

- IEC 62304 Edition 1.1 2015-06 Medical device software – Software life cycle processes
- IEC 62366-1:2015: Medical devices-Part 1: Application of usability engineering to medical devices.
- ISO 14971 Third Edition 2019-12 Medical Devices - Application of risk management to medical devices.
- ISO 15223-1:2021: Medical devices Symbols to be used with information to be supplied by the manufacturer.

Additionally, the software validation activities were performed in accordance with the FDA Guidance documents, "Content of Premarket Submissions for Device Software Functions" and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".

Performance data from standalone and clinical performance assessments are summarized below.

a. Standalone and clinical performance assessments

Better Diagnostic has conducted performance testing according to FDA's "Guidance for Industry and Food and Drug Administration Staff Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions Document" and the "Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data in Premarket Notification [510(k)] Submissions" Guidance, as part of the development process of the caries model. Performance testing included standalone testing and a clinical reader evaluation. All testing demonstrated that BDCA met prespecified requirements.

i. Standalone Testing

In the standalone study, BW and IOPA images were analyzed separately. A patient had at most one BW and one IOPA image included in the analysis dataset. For BW images, out of 614 images, 310 indicated the presence of cavities. Among the 15,687 surfaces examined within these images, 585 were positively identified with cavities, while 15,102 were

negative. Similarly, for IOPA images, of the 684 images analyzed, 367 showed indications of cavities. Out of 9,253 surfaces reviewed, 618 showed positive results for cavities, and 8,635 were negative. The Standalone analysis demonstrated the use of Intersection over Union (IOU) 0.5.

Ground truth was determined through the consensus of two out of three experienced, licensed dentists, each with over 10 years of professional experience. These dentists examined and labeled dental surfaces, agreeing on the final labels for analysis when at least two dentists identified a surface as carious. The comprehensive analyses targeted both primary and secondary endpoints, focusing on the sensitivity and specificity at both the surface and image levels.

The primary analysis in the standalone study was conducted at the surface level, comparing the performance metrics—BW Surface Level Sensitivity, BW Surface Level Specificity, IOPA Surface Level Sensitivity, and IOPA Surface Level Specificity—against predefined performance goals. As a maximum of one BW and one IOPA image was considered for each patient, avoiding inter-image correlation. However, multiple cavities (surfaces) within an image might lead to potential positive correlations, hence unadjusted 95% CIs are reported at the surface level, with adjusted CIs provided using the bootstrapping method. The analysis at the image level was conducted under two definitions, namely Conservative Definition and Optimistic Definition (per the FDA). Under Conservative Definition: A TP is defined as an image being classified as TP if all lesions marked by the GT within the image are also accurately marked by the AI device. Under Optimistic Definition: A TP is defined as an image being classified as TP if at least one lesion within the image is labeled as "present" (indicating a cavity) by both the device prediction and the GT.

The BDCA demonstrated robust performance in detection of caries lesions.

Primary Analysis:

BW Surface Level: The BDCA achieved a sensitivity of 89.2% with an adjusted 95% CI of [86.15%, 92.13%], and a specificity of 99.5% with a CI of [99.32%, 99.57%]. These figures significantly surpass the predefined performance goals of 0.74 and 0.95 respectively, illustrating the device's high accuracy in identifying caries at the surface level.

- **IOPA Surface Level**: The device reached a sensitivity of 88.2% with a CI of [85.27%, 90.78%] and a specificity of 99.1%

with a CI of [98.88%, 99.31%], exceeding the goals of 0.76 and 0.95 respectively. This indicates a robust precision in detecting surface caries within IOPA images, supported by statistically significant outcomes.

Secondary Analysis:

- **BW Image Level**: Sensitivity under conservative conditions was reported at 81.0%, with a CI of [76.15%, 85.18%], and under optimistic conditions, it improved to 91.9%, with a CI of [88.33%, 94.71%]. Specificity remained consistent at 98.4% across definitions with a CI of [96.20%, 99.44%]. These results validate the BDCA's capacity to maintain high diagnostic accuracy across varied operational settings, emphasizing the reliability of its detection capabilities at the image level.
- **IOPA Image Level**: Sensitivity was remarkably high at 83.1% with a CI of [78.87%, 86.80%] under conservative conditions, and under optimistic conditions, it improved to 91.8%, with a CI of [88.54%, 94.42%], substantially exceeding the target goal of 0.75. Specificity was also impressive at 98.4% with a CI of [96.20%, 99.44%]. These metrics significantly surpass the performance thresholds, confirming the device's superior performance in accurately delineating caries within IOPA images.

Subgroup Analyses

Subgroup analyses were also performed for patient demographics, sensor manufacturer,at the both image and surface levels (including cavity type) for both BW and IOPA images. These analyses demonstrated that the BDCA toolmaintains consistent diagnostic performance across various demographic and technical subgroups, respectively.

ii. Clinical Evaluation-Reader Improvement

The MRMC study evaluates the BDCA v1.0 Software in a multi-reader, fully crossed format to assess its effectiveness on 328 digital radiographs, including 108 BW and 220 IOPA. 72 out of 108 of BW images and 91 out of 220 of IOPA images demonstrated cavities. At the surface level, cavities were positively identified in 221 out of 2716 surfaces in BW images, and 160 out of 2967 surfaces in IOPA images. Twenty-nine United States (US) licensed dentists interpreted these radiographs twice: once with and once without BDCA Software assistance. The ground truth was established through consensus of two among three licensed US dentists.

Dentists were randomly assigned to two groups: Group 1 started with BDCA v1.0 assistance, and Group 2 started without. To mitigate recollection bias, a 30-day washout period was included in the study. Post washout period, group 2 assessed radiographs with BDCA's assistance and group 1 without. The study measures diagnostic performance of the model using Alternative Free Response Operating Characteristic (AFROC), sensitivity and specificity at the image and surface levels for comparing the performance between readers aided by BDCA v1.0 and reader unaided by BDCA v1.0.

Unassisted vs. Assisted AFROC Score

The MRMC AFROC analysis across various subgroups for BW and IOPA images convincingly demonstrates that AI assistance significantly enhances diagnostic accuracy in radiographic interpretations. The results from the aided groups, displaying AUCs of 0.848 for BW and 0.845 for IOPA images, significantly surpass those of the unaided groups, which recorded AUCs of 0.806 and 0.807, respectively. The statistically significant differences in AUCs, marked by p-values less than 0.001, affirm that the use of BDCA v1.0 improves the precision with which readers identify targets in the images.

Subgroup analyses were also performed for dentist experience, patient demographics, sensor, and cavity type. Subgroup analyses of the BDCA v1.0 tool revealed significant improvements in detection accuracy across various demographic and technical variables.

Unassisted vs. Assisted Sensitivity at the Image Level

MRMC sensitivity performance analysis at the image level clearly demonstrates the advantages of AI assistance in radiographic interpretations under both the Optimistic and Conservative definitions. The findings indicate that BDCA v1.0 significantly enhances the ability of readers to detect lesions more effectively when compared to unaided conditions. Under the Optimistic Definition, which considers any lesion detection as successful, aided conditions showed a marked improvement in sensitivity, with the majority of readers experiencing increased detection rates. Specifically, for BW images, the sensitivity improved from 0.857 to 0.890, and for IOPA images from 0.761 to 0.809 under aided conditions. The Conservative Definition establishes that BDCA v1.0 assistance aids in the comprehensive detection and accurate marking of all identified lesions, contributing to an overall increase in diagnostic precision.

For BW images, the aided sensitivity is quantified at 0.509, an increase from the unaided sensitivity of 0.444. Similarly, for IOPA images, aided sensitivity rises to 0.619 from 0.564 in unaided conditions. The fact that these improvements are consistent across most readers under such rigorous evaluation criteria underscores the effectiveness of BDCA v1.0 assistance in enhancing diagnostic accuracy.

Unassisted vs. Assisted Specificity at the Image Level

MRMC specificity analysis for both BW and IOPA images at the image level indicates a general trend of improvement in specificity when BDCA v1.0 is employed. For BW images, the overall specificity increased slightly from 0.634 in unaided conditions to 0.682 in aided conditions. This improvement underscores the potential of BDCA v1.0 to enhance the accuracy of negative lesion identifications in radiographic images. On the other hand, the specificity analysis for IOPA images shows a more pronounced improvement under aided conditions, with specificity increasing from 0.813 to 0.844. This difference is statistically significant, suggesting that BDCA v1.0 is more reliably beneficial in enhancing the specificity of IOPA image interpretations.

Unassisted vs. Assisted Sensitivity at the Surface Level

MRMC sensitivity performance analysis at the surface level provides clear evidence that AI assistance substantially enhances diagnostic sensitivity. This improvement is consistent across almost all readers and demonstrates a notable enhancement in the ability to detect lesions at the surface level when compared to unaided conditions. For BW Images, the overall sensitivity under aided conditions is significantly higher (0.763) compared to unaided conditions (0.707), with a statistically significant mean increase of 0.056. This improvement indicates a robust benefit provided by BDCA in enhancing lesion detection capabilities. For IOPA Images, aided conditions show a higher overall sensitivity (0.746) than unaided conditions (0.691), with a significant mean increase of 0.055. This indicates that AI assistance consistently enhances the detection of lesions, providing clear benefits in clinical diagnostics.

Unassisted vs. Assisted Specificity at the Surface Level

MRMC specificity analysis at the surface level for both BW and IOPA images reveals that AI assistance leads to statistically significant improvements in specificity. For BW Images, the overall specificity under aided conditions shows an increase to 0.980 from 0.974 in unaided

conditions. This slight but significant improvement reflects the capability of AI to enhance the precision of radiographic diagnostics by minimizing false positives. Similarly for IOPA Images, the overall specificity under aided conditions is slightly improved at 0.983 compared to 0.979 in unaided conditions.

9. Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing, the Better Diagnostics Caries Assist (BDCA) Version 1.0 raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device Overjet Caries Assist Software (Version 1.0) (K222746) in terms of safety, effectiveness, and performance.