July 15, 2026

Better Diagnostics AI Corp.
% Raj Zaveri
Founder & CEO
LucidMind Consulting
B202, Park Ave., Mg Rd.
Kandivli W.
Mumbai, Maharashtra 400067
INDIA

Re: K260851
Trade/Device Name: Better Diagnostics Dental Assist (BDDA) Version 1.0
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: March 16, 2026
Received: March 16, 2026

Dear Raj Zaveri:

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

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

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)*
K260851

Device Name
Better Diagnostics Dental Assist (BDDA) Version 1.0

Indications for Use *(Describe)*
Better Diagnostics Dental Assist (BDDA) Version 1.0 is a computer aided detection ("CADe") software intended to aid dental professionals in the measurements of mesial and distal bone levels associated with each tooth from bitewing and periapical radiographs. The device is also intended to identify and mark regions in relation to suspected dental findings which include marginal discrepancy, calculus, periapical radiolucency (Only IOPA), crowns, filling and root canals. 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. The intended patient population of the device is patients who are 18 years or older and do not have any remaining primary teeth.

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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510(k) Summary

K260851

1. General Information

510(k) Owner	Better Diagnostics AI Corp.
Manufacturer Address	29 Alcott Way Avon CT, 06001 USA
Correspondence person	Raj Zaveri, Founder & CEO LucidMind Consulting
Correspondent address	B202, Park Ave., Mg Rd. Kandivli W., Mumbai, Maharashtra 400067 IND
Contact information	**Email:** rajzaveri10@gmail.com **Phone:** +91 8369438297
Date prepared	March, 2026

2. Proposed device

Proprietary Name of Device: Better Diagnostics Dental Assist (BDDA) (Version 1.0)

Regulation Name: Medical Image Analyzer

Classification Panel: Radiology

Regulation Number: 21 CFR § 892.2070

Regulation Class: Class II

Product Code: MYN

3. **Predicate Device**

Proprietary Name of Device: Second Opinion

Premarket Notification: K210365

Regulation Name: Medical Image Analyzer

Classification Panel: Radiology

Regulation Number: 21 CFR § 892.2070

Regulation Class: Class II

Product Code: MYN

4. **Predicate Device**

Proprietary Name of Device: Overjet Dental Assist

Premarket Notification: K210187

Regulation Name: Medical image management and processing system.

Classification Panel: Radiology

Regulation Number: 21 CFR § 892.2050

Regulation Class: Class II

Product Code: LLZ

5. **Device Description**

Better Diagnostics Dental Assist (BDDA) Version 1.0 is a computer-aided detection (CADe) software designed for the automated measurements of mesial and distal bone levels associated with each tooth from bitewing and periapical radiographs. This software measures and displays the distance between the CEJ (Cemento-Enamel Junction) and the tip of the alveolar bone (in mm). The device is also intended for the automated detection of suspected dental findings which include marginal discrepancy, calculus, periapical radiolucency, crowns, filling, and root canal in bitewings and periapical dental radiographs. This software offers supplementary information to assist dentists in their diagnosis of these findings. It is important to note that BDDA

v1.0 is not meant to replace a comprehensive clinical evaluation by a dentist, which should consider other pertinent information from the image, the patient's medical history and clinical examination. This software is intended for use in patients who are 18 years or older.

BDDA v1.0 does not make treatment recommendations or provide a diagnosis. Dentists should review images annotated by BDDA v1.0 concurrently with original, unannotated images before making the final diagnosis on a case. BDDA 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. BDDA v1.0 is not designed to detect conditions and findings other than the ones mentioned above.

BDDA 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 (Practice Management Software) customers and imaging firms for utilization of BDDA v1.0 software. User Interface uses Angular.js and node.js technology to show images on the “AI Results Screen". The system can process PNG, BMP, JPG format images. All images are converted into JPEG format for processing. Computer Vision Models return AI annotations and co-ordinates to the business layer. The business layer sends coordinates to the UI layer; bounding boxes and/or polygons are drawn on the image using custom code written in Angular.js and node.js. Dentists can view, accept or reject the annotations (bounding boxes and polygons) based on their evaluation.

  Further, based on the coordinates shared by the business layer, lines are drawn (in mm) on the image that denotes the distance between the CEJ (Cemento-Enamel Junction) and the tip of the alveolar bone. This is also based on custom code written in Angular.js and node.js.

- 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. BDDA v1.0 APIs connect the Dental PMS with the business layer. API takes 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 back to the presentation layer hosted by Dental PMS.

- Business Layer: Receives request from the API Gateway and passes it to the computer vision models. It also receives the bounding boxes and

polygon coordinates and retrieves images from the cloud storage. It sends annotations and co-ordinates to the "AI Results screen".

- Computer Vision Models (CV Models): These models are hosted on a cloud computing platform and are responsible for image processing. For calculus, the model provides a binary indication to determine the presence or absence of calculus. If calculus and marginal discrepancy is detected, the software will output the coordinates of the bounding boxes. For Periapical Radiolucency and restorations, the models will output the coordinates of the polygon. For Bone level, the model measures and displays the distance between the CEJ (Cemento-Enamel Junction) and RBL (Remaining alveolar Bone Levels) (in mm).

AI models have three parts:

- **Pre-processing module:** Standardization of image to specific height and width to maintain consistency for AI models. Pre-processing also includes classifications AI model to determine the type of image i.e IOPA, Bitewings.
- **Core Module:** Object detection, Segmentation and Key point detection AI models provide findings, annotations and co-ordinates to draw bounding boxes, polygons and lines (in mm).
- **Post processing:** includes cleanup process to remove outliers/incorrect annotations from the images.

6. Intended Use/Indications for Use

Better Diagnostics Dental Assist (BDDA) Version 1.0 is a computer aided detection ("CADe") software intended to aid dental professionals in the measurements of mesial and distal bone levels associated with each tooth from bitewing and periapical radiographs. The device is also intended to identify and mark regions in relation to suspected dental findings which include marginal discrepancy, calculus, periapical radiolucency (Only IOPA), crowns, filling and root canals. 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. The intended patient population of the device is patients who are 18 years or older and do not have any remaining primary teeth.

7. Substantial Equivalence

	Proposed Device	Predicate Device	Predicate Device
510(k) Number	K260851	K210365	K210187
Applicant	Better Diagnostics AI Corp	Pearl, Inc.	Overjet, Inc.
Device Name	Better Diagnostics Dental Assist	Second Opinion	Overjet Dental Assist
Classification Regulation	21 CFR 892.2070	21 CFR 892.2070	21 CFR 892.2050
Product Code	MYN	MYN	LLZ
Indications for use	Better Diagnostics Dental Assist (BDDA) Version 1.0 is a computer aided detection ("CADe") software intended to aid dental professionals in the measurements of mesial and distal bone levels associated with each tooth from bitewing and periapical radiographs. The device is also intended to identify and mark regions	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	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

	Proposed Device	Predicate Device	Predicate Device
	in relation to suspected dental findings which include marginal discrepancy, calculus, periapical radiolucency (Only IOPA), crowns, filling and root canals. 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. The intended patient population of the device is patients who are 18 years or older and do not have any remaining primary teeth.	health professionals to review bitewing and periapical radiographs of permanent teeth in patients 12 years of age or older as a second reader.	system is to be used by trained professionals including, but not limited to, dentists and dental hygienists. The intended patient population of the device is patients living in the US, who are 22 years or older and that do not have any remaining primary teeth. Overjet has not evaluated the performance of the device on primary dentition.
Image Modality	Radiograph	Radiograph	Radiograph
Study Type	Bitewing and periapical Images	Bitewing and periapical Images	Bitewing and periapical Images
Clinical Output	Bounding boxes for calculus and	Bounding boxes /Fixed	Line

	Proposed Device	Predicate Device	Predicate Device
	marginal discrepancies Polygon for Periapical Radiolucency and restorations Lines (in mm) for distance between CEJ and RBL		
Patient Population	Patients requiring dental services, all sexes, 18 years of age or older with permanent teeth	Patients requiring dental services, all sexes, 12 years of age or older with permanent teeth	Patients requiring dental services, all sexes, 22 years of age or older with permanent teeth
Hardware requirements	WINDOWS 11 or higher	WINDOWS 7 or higher	Any
Intended User	Dental clinicians	Dental clinicians	Dental clinicians
Image Format	Accepts image formats JPG, and PNG, BMP	Accepts image formats from RVG, DICOM, JPEG, TIFF, and PNG and converts to JPEG.	Accepts image formats from JPG, PNG, JFIF, EOP, ETP, JIF
Processing Architecture	1. APIs - Dental PMS/Imaging software send x-ray image to BDDA 2. Computer vision models process the x-ray image and	Utilizes computer vision neural network algorithms, developed from open-source models using supervised machine learning techniques.	-

	Proposed Device	Predicate Device	Predicate Device
	send results presentation layer 3. Presentation layers is plots rectangle, polygon and lines shape annotations on the x-ray image and it is displayed to dentist using "AI Results screen"		
Type of device	CADe	CADe	CADe

Better Diagnostics Dental Assist (BDDA) Software (Version 1.0) and Second Opinion are both class II devices with the same product classification code - MYN. Both devices are computer aided detection ("CADe") software intended to identify and mark regions in relation to similar suspected dental findings on bitewing and periapical radiographs.

Further, Better Diagnostics Dental Assist (BDDA) Software (Version 1.0) and Overjet Dental Assist are both class II devices and are CADe software intended to aid dental professionals in the measurements of mesial and distal bone levels associated with each tooth from bitewing and periapical radiographs.

Better Diagnostics Dental Assist (BDDA) Software (Version 1.0) has minor differences compared to the predicate devices in terms of the following:

- BDDA v1.0 is intended to identify and mark regions in relation to suspected dental findings which include marginal discrepancy, calculus, periapical radiolucency, crowns, filling, and root canal whereas Second opinion also includes caries in addition to the aforementioned findings. This is an additional feature offered by the predicate device and has no impact whatsoever on the outcome of BDDA v1.0.

- BDDA v1.0 output includes bounding boxes for calculus and marginal discrepancies, polygon for Periapical Radiolucency and restorations; and lines in mm for distance between the CEJ (Cemento-Enamel Junction) and the tip of the alveolar bone whereas Second Opinion and Overjet Dental Assist output includes bounding boxes and lines respectively. The additional functionality of

the BDDA v1.0 has no impact whatsoever on the outcome of BDDA v1.0. Further, the software verification and validation performed as per IEC 62304 validates the performance of BDDA v1.0.

- BDDA v1.0 is intended for patients aged 18 years or above, whereas Second Opinion identifies and marks similar suspected dental findings on radiographs acquired from patients aged 12 years or above and Overjet Dental Assist is intended for patients aged 22 years and above. This additional functionality (12 to 18 years) on the Second Opinion's part has no impact whatsoever on the outcome of BDDA v1.0. The results of the standalone and MRMC study discussed in the subsequent section along with the software verification and validation performed as per IEC 62304 validate the performance of BDDA v1.0.

- BDDA v1.0 supports BMP, JPG, and PNG, Second opinion supports RVG, DICOM, JPEG, TIFF, and PNG and converts to JPEG whereas Overjet Dental Assist supports JPG, PNG, JFIF, EOP, ETP, JIF. The additional formats supported by Second opinion and Overjet Dental Assist have no impact whatsoever on the outcome of BDDA v1.0. The software verification and validation performed as per IEC 62304 validates this claim.

8. Performance testing

a. Summary of Non-Clinical Performance data

Safety and performance of BDDA 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, "Guidance for the Content of Premarket

Submissions for Software Contained in Medical Devices" and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".

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

b. Summary of Clinical Performance data

i. Standalone Testing

A comprehensive standalone performance assessment was conducted to evaluate the diagnostic accuracy of the BDDA Software (version 1.0) across five intended dental indications: **Existing Restoration, Margin Discrepancy, Calculus, Periapical Radiolucency, and Bone Level**. All evaluations were performed independently of dentist interaction and were assessed against expert-established ground truth defined by consensus agreement from at least two of three licensed dentists with more than ten years of clinical experience.

Primary Performance

For **Existing Restoration, Margin Discrepancy, Calculus, and Periapical Radiolucency**, primary performance was evaluated at the dental surface level using sensitivity and specificity as predefined endpoints. Analyses were conducted separately for BW and IOPA radiographs, with Periapical Radiolucency assessed exclusively on IOPA images in accordance with clinical diagnostic relevance. Across all four radiographic anomalies and applicable imaging modalities, the BDDA Software consistently met all predefined performance goals. All lower bounds of the adjusted 95% confidence intervals for both sensitivity and specificity exceeded the respective acceptance thresholds (0.75 for sensitivity and 0.95 for specificity).

The evaluation was supported by a large and representative dataset. For Existing Restoration, a total of 7,174 dental surfaces from 895 BW images and 4,573 dental surfaces from 897 IOPA images were analyzed. For Margin Discrepancy, analysis included 9,773 dental surfaces from 700 BW images and 4,716 dental surfaces from 699 IOPA images. For Calculus, 8,218 dental surfaces from 715 BW images and 4,558 dental surfaces from 737 IOPA images were evaluated. For Periapical Radiolucency, which was assessed on IOPA images only, a total of 2,935 dental surfaces from 821 IOPA images were included.

- For **Existing Restoration**, the software achieved exceptionally high sensitivity, specificity, PPV, and NPV on both BW and IOPA images. On BW images, sensitivity was 0.989 (95% CI: 0.984–0.994), specificity was 0.990 (95% CI: 0.987–0.993), PPV was 0.979 (95% CI: 0.972–0.985), and NPV was 0.995 (95% CI: 0.992–0.997). On IOPA images, sensitivity reached 0.988 (95% CI: 0.979–0.994), specificity was 0.989 (95% CI: 0.985–0.993), PPV

was 0.970 (95% CI: 0.958–0.980), and NPV was 0.996 (95% CI: 0.992–0.998). In all cases, the lower bounds of the confidence intervals for sensitivity and specificity were well above the predefined acceptance criteria of 0.75 and 0.95, respectively.

- For **Margin Discrepancy**, BDDA demonstrated high sensitivity, near-perfect specificity, PPV, and NPV on both BW and IOPA images. On BW images, sensitivity was 0.917 (95% CI: 0.891–0.940), specificity was 0.997 (95% CI: 0.996–0.998), PPV was 0.957 (95% CI: 0.936–0.974), and NPV was 0.994 (95% CI: 0.992–0.996). On IOPA images, sensitivity was 0.908 (95% CI: 0.877–0.935), specificity was 0.998 (95% CI: 0.996–0.999), PPV was 0.981 (95% CI: 0.962–0.996), and NPV was 0.989 (95% CI: 0.985–0.992). All confidence interval lower bounds for sensitivity and specificity exceeded predefined thresholds.

- For **Calculus**, robust performance was observed across both imaging modalities. On BW images, sensitivity was 0.916 (95% CI: 0.893–0.936), specificity was 0.980 (95% CI: 0.976–0.983), PPV was 0.835 (95% CI: 0.810–0.860), and NPV was 0.991 (95% CI: 0.988–0.993). On IOPA images, sensitivity was 0.884 (95% CI: 0.857–0.908), specificity was 0.974 (95% CI: 0.969–0.979), PPV was 0.855 (95% CI: 0.826–0.882), and NPV was 0.980 (95% CI: 0.974–0.985). All confidence interval lower bounds exceeded predefined sensitivity and specificity acceptance criteria, with consistently high specificity across modalities.

- For **Periapical Radiolucency**, which was evaluated exclusively on IOPA images, BDDA met all required performance goals. Sensitivity was 0.809 (95% CI: 0.769–0.847), specificity was 0.973 (95% CI: 0.965–0.981), PPV was 0.847 (95% CI: 0.808–0.882), and NPV was 0.966 (95% CI: 0.957–0.974). The lower bounds of the confidence intervals for sensitivity and specificity exceeded the predefined acceptance thresholds.

For the **Bone Level** indication, primary performance metrics included sensitivity for detection of pathologic bone-level reduction, specificity for identification of normal bone levels, and quantitative agreement assessed by MAE. Performance was evaluated against predefined acceptance criteria of sensitivity ≥ 0.82, specificity ≥ 0.81, and MAE ≤ 1.5 mm.

- Performance for the Bone Level indication was evaluated using both diagnostic classification and quantitative measurement accuracy. Across a total of 1,318 images (681 BW and 637 IOPA) and 12,031 interproximal line measurements, BDDA demonstrated high diagnostic accuracy for identifying abnormal bone levels, with sensitivity and specificity exceeding predefined acceptance thresholds across both imaging modalities. The lower bounds of

the 95% confidence intervals surpassed the required criteria for all evaluated subgroups.

- Quantitative accuracy was assessed using mean absolute error (MAE) relative to expert-established reference measurements. For BW images, the overall MAE was 0.203 mm (95% CI: 0.197–0.208), and for IOPA images, the overall MAE was 0.235 mm (95% CI: 0.226–0.243), both well below the predefined acceptance threshold of 1.5 mm. These results indicate precise and reliable measurement of interproximal alveolar bone levels.

Table 1: Standalone Study - Overall Performance Summary - Primary Endpoints (Sensitivity and Specificity)

Radiographic Anomaly	Primary Endpoints	Act. Surface Perf.	Act. Surface Perf. (Adj. CI)	PDT	Meet PDT
(1) Restoration	BW Sensitivity	0.989	[0.984, 0.994]	0.75	Yes
	BW Specificity	0.990	[0.987, 0.993]	0.95	Yes
	IOPA Sensitivity	0.988	[0.979, 0.994]	0.75	Yes
	IOPA Specificity	0.989	[0.985, 0.993]	0.95	Yes
(2) Margin Discrepancy	BW Sensitivity	0.917	[0.891, 0.940]	0.75	Yes
	BW Specificity	0.997	[0.996, 0.998]	0.95	Yes
	IOPA Sensitivity	0.908	[0.877, 0.935]	0.75	Yes
	IOPA Specificity	0.998	[0.996, 0.999]	0.95	Yes
(3) Calculus	BW Sensitivity	0.916	[0.893, 0.936]	0.75	Yes

Radiographic Anomaly	Primary Endpoints	Act. Surface Perf.	Act. Surface Perf. (Adj. CI)	PDT	Meet PDT
	BW Specificity	0.980	[0.976, 0.983]	0.95	Yes
	IOPA Sensitivity	0.884	[0.857, 0.908]	0.75	Yes
	IOPA Specificity	0.974	[0.969, 0.979]	0.95	Yes
(4) Periapical Radiolucency	IOPA Sensitivity	0.809	[0.769, 0.847]	0.75	Yes
	IOPA Specificity	0.973	[0.965, 0.981]	0.95	Yes
(5) Bone Level	BW Sensitivity	0.866	[0.858, 0.875]	0.82	Yes
	BW Specificity	0.913	[0.900, 0.925]	0.81	Yes
	BW MAE	0.203	[0.197, 0.208]	1.5 mm	Yes
	IOPA Sensitivity	0.889	[0.876, 0.900]	0.82	Yes
	IOPA Specificity	0.915	[0.897, 0.931]	0.81	Yes
	IOPA MAE	0.235	[0.226, 0.243]	1.5 mm	Yes

Act. Surface Perf. = Actual Surface Performance; Act. Surface Perf. (Adj. CI) = Actual Surface Performance (Adjusted 95% Confidence Interval); PDT = Predefined Threshold; Se = Sensitivity; Sp = Specificity

Table 2: Standalone Study - Overall Performance Summary - Primary Endpoints (PPV and NPV)

Radiographic Anomaly	Primary Endpoints	Act. Surface Perf.	Act. Surface Perf. (Adj. CI)
(1) Restoration	BW Surface Level PPV	0.979	[0.972, 0.985]
	BW Surface Level NPV	0.995	[0.992, 0.997]
	IOPA Surface Level PPV	0.970	[0.958, 0.980]
	IOPA Surface Level NPV	0.996	[0.992, 0.998]
(2) Margin Discrepancy	BW Surface Level PPV	0.957	[0.936, 0.974]
	BW Surface Level NPV	0.994	[0.992, 0.996]
	IOPA Surface Level PPV	0.981	[0.962, 0.996]
	IOPA Surface Level NPV	0.989	[0.985, 0.992]
(3) Calculus	BW Surface Level PPV	0.835	[0.810, 0.860]
	BW Surface Level NPV	0.991	[0.988, 0.993]
	IOPA Surface Level PPV	0.855	[0.826, 0.882]
	IOPA Surface Level NPV	0.980	[0.974, 0.985]
(4) Periapical Radiolucency	IOPA Surface Level PPV	0.847	[0.808, 0.882]
	IOPA Surface Level NPV	0.966	[0.957, 0.974]

Radiographic Anomaly	Primary Endpoints	Act. Surface Perf.	Act. Surface Perf. (Adj. CI)
(5) Bone Level	BW PPV	0.966	[0.961, 0.970]
	BW NPV	0.708	[0.690, 0.725]
	IOPA PPV	0.964	[0.956, 0.971]
	IOPA NPV	0.763	[0.739, 0.785]

Act. Surface Perf. = Actual Surface Performance; Act. Surface Perf. (Adj. CI) = Actual Surface Performance (Adjusted 95% Confidence Interval); PPV = Positive Predictive Value; NPV = Negative Predictive Value

Secondary Performance

In addition to the primary surface-level evaluation, a secondary assessment was conducted to evaluate the diagnostic performance of the BDDA Software (version 1.0) at the image level for four radiographic anomalies: **Existing Restoration, Margin Discrepancy, Calculus, and Periapical Radiolucency**. Image-level analysis was performed to determine whether the software could reliably identify radiographs containing relevant radiographic anomalies, complementing the surface-level assessment.

Image-level sensitivity and specificity were evaluated separately for bitewing (BW) and intraoral periapical (IOPA) radiographs, consistent with clinical practice. Performance was assessed under both Conservative and Optimistic classification definitions, representing strict and permissive criteria for true positive classification, respectively.

Across all four evaluated radiographic anomalies, the BDDA Software met or exceeded all predefined image-level performance criteria. For all imaging modalities and evaluative definitions, the lower bounds of the adjusted 95% confidence intervals for both sensitivity and specificity exceeded the predefined acceptance threshold of 0.75. Overall, the secondary image-level results were consistent with the strong performance observed in the primary surface-level analysis. The BDDA Software demonstrated reliable and stable diagnostic performance across radiographic anomalies, imaging modalities, and evaluative frameworks.

Table 3: Standalone Study - Overall Performance Summary - Secondary Endpoints (Sensitivity and Specificity)

Radiographic Anomaly	Secondary Endpoints	Act. Surface Perf.	Act. Surface Perf. (CI)	PDT	Meet PDT
(1) Restoration	BW Image Level Se (Conservative)	0.961	[0.948, 0.975]	0.75	Yes
	BW Image Level Se (Optimistic)	0.988	[0.976, 0.995]	0.75	Yes
	BW Image Level Sp	1.000	[0.988, 1.000]	0.75	Yes
	IOPA Image Level Se (Conservative)	0.973	[0.955, 0.985]	0.75	Yes
	IOPA Image Level Se (Optimistic)	0.984	[0.969, 0.992]	0.75	Yes
	IOPA Image Level Sp	1.000	[0.990, 1.000]	0.75	Yes
(2) Margin Discrepancy	BW Image Level Se (Conservative)	0.848	[0.806, 0.884]	0.75	Yes
	BW Image Level Se (Optimistic)	0.966	[0.942, 0.982]	0.75	Yes
	BW Image Level Sp	0.994	[0.979, 0.999]	0.75	Yes
	IOPA Image Level Se (Conservative)	0.872	[0.833, 0.906]	0.75	Yes
	IOPA Image Level Se (Optimistic)	0.954	[0.926, 0.973]	0.75	Yes
	IOPA Image Level Sp	0.997	[0.984, 0.999]	0.75	Yes
(3) Calculus	BW Image Level Se (Conservative)	0.829	[0.783, 0.869]	0.75	Yes
	BW Image Level Se (Optimistic)	0.949	[0.919, 0.971]	0.75	Yes
	BW Image Level Sp	0.870	[0.833, 0.901]	0.75	Yes

Radiographic Anomaly	Secondary Endpoints	Act. Surface Perf.	Act. Surface Perf. (CI)	PDT	Meet PDT
	IOPA Image Level Se (Conservative)	0.806	[0.759, 0.848]	0.75	Yes
	IOPA Image Level Se (Optimistic)	0.948	[0.917, 0.969]	0.75	Yes
	IOPA Image Level Sp	0.879	[0.843, 0.907]	0.75	Yes
(4) Periapical Radiolucency	IOPA Image Level Se (Conservative)	0.815	[0.771, 0.853]	0.75	Yes
	IOPA Image Level Se (Optimistic)	0.858	[0.818, 0.891]	0.75	Yes
	IOPA Image Level Sp	0.929	[0.901, 0.951]	0.75	Yes

Act. Surface Perf. = Actual Surface Performance; Act. Surface Perf. (CI) = Actual Surface Performance (95% Confidence Interval); PDT = Predefined Threshold; Se = Sensitivity; Sp = Specificity

Table 4: Standalone Study - Overall Performance Summary - Secondary Endpoints (PPV and NPV)

Radiographic Anomaly	Definition Type	Secondary Endpoints	Act. Surface Perf.	Act. Surface Perf. (CI)
(1) Restoration	Conservative	BW Image Level PPV	1.000	[0.994, 1.000]
		BW Image Level NPV	0.929	[0.895, 0.954]
		IOPA Image Level PPV	1.000	[0.993, 1.000]
		IOPA Image Level NPV	0.959	[0.933, 0.977]

Radiographic Anomaly	Definition Type	Secondary Endpoints	Act. Surface Perf.	Act. Surface Perf. (CI)
	Optimistic	BW Image Level PPV	1.000	[0.994, 1.000]
		BW Image Level NPV	0.977	[0.953, 0.991]
		IOPA Image Level PPV	1.000	[0.993, 1.000]
		IOPA Image Level NPV	0.975	[0.953, 0.989]
(2) Margin Discrepancy	Conservative	BW Image Level PPV	0.993	[0.976, 0.999]
		BW Image Level NPV	0.864	[0.826, 0.896]
		IOPA Image Level PPV	0.997	[0.982, 0.999]
		IOPA Image Level NPV	0.889	[0.854, 0.918]
	Optimistic	BW Image Level PPV	0.994	[0.979, 0.999]
		BW Image Level NPV	0.966	[0.942, 0.982]
		IOPA Image Level PPV	0.997	[0.983, 0.999]
		IOPA Image Level NPV	0.957	[0.931, 0.975]
(3) Calculus	Conservative	BW Image Level PPV	0.834	[0.789, 0.874]
		BW Image Level NPV	0.865	[0.828, 0.897]
		IOPA Image Level PPV	0.840	[0.794, 0.879]
		IOPA Image Level NPV	0.852	[0.814, 0.884]

Radiographic Anomaly	Definition Type	Secondary Endpoints	Act. Surface Perf.	Act. Surface Perf. (CI)
	Optimistic	BW Image Level PPV	0.852	[0.811, 0.888]
		BW Image Level NPV	0.956	[0.929, 0.975]
		IOPA Image Level PPV	0.860	[0.820, 0.895]
		IOPA Image Level NPV	0.955	[0.929, 0.974]
(4) Periapical Radiolucency	Conservative	IOPA Image Level PPV	0.904	[0.868, 0.934]
		IOPA Image Level NPV	0.858	[0.824, 0.888]
	Optimistic	IOPA Image Level PPV	0.909	[0.874, 0.937]
		IOPA Image Level NPV	0.887	[0.855, 0.914]

Act. Surface Perf. = Actual Surface Performance; Act. Surface Perf. (CI) = Actual Surface Performance (95% Confidence Interval); PPV = Positive Predictive Value; NPV = Negative Predictive Value

Generalizability Performance

To evaluate the generalizability of the BDDA Software's performance across diverse patient demographics and imaging conditions, subgroup analyses were conducted based on age, sex, sensor type, and restoration type (for Existing Restoration only). Each subgroup was analyzed independently using the same performance metrics applied in the primary and secondary analyses.

Across all eligible subgroups, the BDDA Software demonstrated generally consistent diagnostic performance, with sensitivity and specificity estimates in most subgroups remaining aligned with the overall study results. While minor variations were observed in a few smaller subgroups, none showed patterns indicating a meaningful

loss of diagnostic accuracy or systematic performance degradation, almost all subgroups demonstrated a clinically meaningful improvement in performance .

The standalone performance assessment demonstrated that the BDDA Software (version 1.0) consistently meets all predefined clinical performance objectives across its five intended indications. High sensitivity and specificity were observed for all diagnostic indications, supported by narrow confidence intervals and consistent performance across imaging modalities and evaluative definitions. For the Bone Level indication, the combination of strong diagnostic accuracy and precise quantitative measurement further supports clinical reliability.

ii. Clinical Evaluation-Reader Improvement

In addition to standalone performance evaluations, a multi-reader multi-case (MRMC) reader study was conducted to assess the clinical impact of BDDA Software (version 1.0) assistance on dentist diagnostic performance for three radiographic anomalies: Margin Discrepancy, Calculus, and Periapical Radiolucency (IOPA images only). The primary objective of the study was to evaluate whether BDDA assistance improves diagnostic accuracy compared with unaided interpretation.

The MRMC study employed a fully crossed, random-reader, random-case design. A total of 15 U.S.-licensed dentists independently interpreted the same set of radiographs under both unaided and BDDA-assisted conditions. Diagnostic accuracy was measured using the area under the AFROC AUC, and analyses were performed separately for BW and IOPA radiographs, consistent with clinical use. The MRMC datasets included 1,397 images for Margin Discrepancy (699 BW and 698 IOPA) with 13,795 tooth surfaces evaluated (9,193 BW and 4,602 IOPA); 1,451 images for Calculus (714 BW and 737 IOPA) with 12,803 tooth surfaces evaluated (8,225 BW and 4,578 IOPA); and 821 IOPA images for Periapical Radiolucency with 2,920 IOPA tooth surfaces evaluated.

Primary Performance

Across all evaluated radiographic anomalies and image types, BDDA assistance resulted in a statistically significant improvement in AFROC AUC compared with unaided interpretation. For every endpoint, the mean AUC difference (Aided – Unaided) was positive, the corresponding 95% confidence interval excluded zero, and the hypothesis test demonstrated statistical significance.

- For Margin Discrepancy, BDDA assistance improved AUC from 0.808 to 0.905 on BW radiographs (difference: 0.097, 95% CI: [0.087, 0.120]) and from 0.831 to 0.917 on IOPA radiographs (difference: 0.086, 95% CI: [0.083, 0.112]).

- For Calculus, aided performance increased from 0.809 to 0.913 on BW radiographs (difference: 0.104, 95% CI: [0.078, 0.137]) and from 0.793 to 0.910 on IOPA radiographs (difference: 0.117, 95% CI: [0.098, 0.147]).
- For Periapical Radiolucency (IOPA only), BDDA assistance improved AUC from 0.847 to 0.939 (difference: 0.092, 95% CI: [0.075, 0.110]).

Overall, the findings establish that BDDA Software (version 1.0) provides a meaningful diagnostic benefit across all MRMC-evaluated radiographic anomalies and imaging modalities, thereby meeting the predefined primary performance objectives of the study.

Table 5: MRMC Study - Overall Performance Summary - Primary Endpoints AFROC AUC

Radiographic Anomaly	Primary Endpoints	Act. Aided Perf.	Act. Unaided Perf.	Diff. [Aided-Unaided]	Diff. (95% CI)	Sig.
(1) Margin Discrepancy	BW AFROC	0.905	0.808	0.097	[0.087, 0.120]	Yes
	IOPA AFROC	0.917	0.831	0.086	[0.083, 0.112]	Yes
(2) Calculus	BW AFROC	0.913	0.809	0.104	[0.078, 0.137]	Yes
	IOPA AFROC	0.910	0.793	0.117	[0.098, 0.147]	Yes
(3) Periapical Radiolucency	IOPA AFROC	0.939	0.847	0.092	[0.075, 0.110]	Yes

Act. Aided Perf. = Actual Aided Performance; Act. Unaided Perf. = Actual Unaided Performance; Diff. = Difference; Diff. (95% CI) = Difference with 95% Confidence Interval; Sig. = Statistically Significant

Key Secondary Performance

Beyond the primary AFROC AUC analysis, a key secondary assessment was conducted to evaluate surface-level diagnostic performance by comparing reader sensitivity and specificity with and without BDDA Software (version 1.0) assistance for each imaging modality. This analysis was performed for three radiographic

anomalies: Margin Discrepancy, Calculus, and Periapical Radiolucency (IOPA images only).

Across all evaluated radiographic anomalies and applicable imaging modalities, BDDA assistance resulted in statistically significant improvements in both sensitivity and specificity at the dental surface level. For all secondary endpoints, the aided–unaided differences were positive, and the corresponding 95% confidence intervals excluded zero, indicating statistically meaningful improvements in diagnostic accuracy. These findings confirm that BDDA Software improves reader diagnostic performance not only at the image level but also at the clinically actionable dental surface level, supporting its intended use as a computer-assisted decision-support tool.

Table 6: MRMC Study - Overall Performance Summary - Key Secondary Endpoints Sensitivity and Specificity at the Surface Level

Radiographic Anomaly	Key Secondary Endpoints	Act. Aided Perf.	Act. Unaided Perf.	Diff. [Aided-Unaided]	Diff. (95% CI)
(1) Margin Discrepancy	BW Surface Se	0.914	0.788	0.126	[0.105, 0.147]
	BW Surface Sp	0.988	0.980	0.008	[0.005, 0.011]
	IOPA Surface Se	0.908	0.813	0.095	[0.074, 0.116]
	IOPA Surface Sp	0.988	0.971	0.017	[0.013, 0.021]
(2) Calculus	BW Surface Se	0.907	0.716	0.191	[0.137, 0.246]
	BW Surface Sp	0.988	0.983	0.006	[0.004, 0.008]
	IOPA Surface Se	0.908	0.709	0.199	[0.153, 0.246]
	IOPA Surface Sp	0.980	0.966	0.013	[0.009, 0.018]

Radiographic Anomaly	Key Secondary Endpoints	Act. Aided Perf.	Act. Unaided Perf.	Diff. [Aided-Unaided]	Diff. (95% CI)
(3) Periapical Radiolucency	IOPA Surface Se	0.909	0.747	0.162	[0.129, 0.196]
	IOPA Surface Sp	0.988	0.979	0.009	[0.005, 0.012]

Act. Aided Perf. = Actual Aided Performance; Act. Unaided Perf. = Actual Unaided Performance; Diff. = Difference; Diff. (95% CI) = Difference with 95% Confidence Interval; Se = Sensitivity; Sp = Specificity

Generalizability Performance

Generalizability of BDDA Software (version 1.0) performance was evaluated through additional image-level assessments, exploratory ROC analyses, and predefined subgroup analyses within the MRMC study. Across these analyses, BDDA assistance demonstrated stable diagnostic performance that was consistent with the primary and key secondary MRMC findings. Improvements in image-level sensitivity and specificity, as well as ROC AUC at both the surface and image levels, supported the robustness of aided interpretation across multiple analytic perspectives.

Subgroup analyses were conducted across reader experience levels, patient age groups, sex, and a range of imaging sensor types. Across the majority of evaluated subgroups, BDDA assistance yielded diagnostic performance patterns comparable to the overall study results. These findings indicate that the diagnostic benefit of BDDA is maintained across diverse reader backgrounds, patient demographics, and imaging acquisition conditions.

9. Conclusion

Based on the information submitted in this premarket notification, and the indications for use, technological characteristics and performance testing, the Better Diagnostics Dental Assist (BDDA) Software (Version 1.0) raises no new questions of safety and effectiveness and is substantially equivalent to the predicate devices Second Opinion (K210365) and Overjet Dental Assist (K210187) in terms of safety, effectiveness, and performance.