November 14, 2025

Pearl Inc.
% Ashley Brown
Director of Regulatory Affairs
2515 Benedict Canyon Dr.
BEVERLY HILLS, CA 90210

Re: K250525
Trade/Device Name: Second Opinion® Panoramic
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: February 21, 2025
Received: October 17, 2025

Dear Ashley Brown:

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 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)*
K250525

Device Name
Second Opinion® Panoramic

Indications for Use *(Describe)*

Second Opinion® Panoramic is a radiological automated image processing software device intended to identify and mark regions, in panoramic radiographs, in relation to suspected dental findings which include: Caries, Periapical radiolucency, and Impacted third molars.
It is designed to aid dental health professionals to review panoramic radiographs of permanent teeth in patients 16 years of age or older as both a concurrent and second reader.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K250525

510(K) SUMMARY

1. Submitter's Identification

Pearl Inc.
9200 Sunset Blvd
Suite 430
West Hollywood, CA 90069
USA
(239) 450-8829

Contact Person: Ashley Brown; Director of Regulatory Affairs

Date Summary Prepared: Nov. 14th, 2025

2. Trade Name of the Device

Second Opinion® Panoramic

3. Common or Usual Name

Medical Image Analyzer

4. Classification Name, Regulatory Classification & Product Code

Classification Name: Medical Image Analyzer
Regulatory Classification: 21CFR 892.2070, Class II
Product Code: MYN (Analyzer, Medical Image)

5. Predicate Information

Primary Predicate Device: The primary proposed **predicate** device for clearance of Second Opinion® PR is Denti.AI Detect by Denti.AI Technology, Inc., cleared in (K230144, October 6, 2023), an automated software device classified as a Class II device pursuant to 21 CFR §892.2070, under product code MYN (Analyzer, Medical Image).

Denti.AI Detect is a Computer-Assisted Detection (CADe) software device intended to be used by dental professionals, including dentists and dental specialists, while reading extraoral and intraoral 2D dental radiographs. The device aims to assist in detecting and highlighting uncategorized regions of interest (ROIs) within the teeth area, which include caries and periapical radiolucency, as a second reader.

The Denti.AI Detect device has the same technology (AI software) and intended use as automated image processing to aid dental professionals in the detection of caries and

periapical radiolucencies in panoramic radiographs.

Secondary Predicate Device: The proposed secondary predicate is the Second Opinion® device, by Pearl Inc., cleared on March 04, 2022 (K210365) and classified as a Class II Medical Image Analyzer pursuant to 21 CFR §892.2070, under product code MYN (Analyzer, Medical Image).

The cleared device is a computer aided detection (CADe) software device, indicated for use by dental health professionals as an aid in their assessment of bitewing and periapical radiographs of permanent teeth in patients 12 years of age or older, as second reader. The device utilizes computer vision technology, developed using machine learning techniques, to identify and mark anatomy & pathology in bitewing and periapical radiographs.

The subject device is substantially equivalent to the predicate as the overall intended use and nature of the software remains the same. The difference with the subject device is the addition of detections in panoramic radiographs.

6. Device Description

Second Opinion® PR is a radiological automated image processing software device intended to identify and mark regions, in panoramic radiographs, in relation to suspected dental findings which include: caries, periapical radiolucency, and impacted third molars. It should not be used in lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis.

It is designed to aid dental health professionals to review panoramic radiographs of permanent teeth in patients 16 years of age or older as a concurrent and second reader.

Second Opinion® PR consists of three parts:

- Application Programing Interface (“API”)
- Machine Learning Modules (“ML Modules”)
- Client User Interface (UI) (“Client”)

The processing sequence for an image is as follows:

1. Images are sent for processing via the API
2. The API routes images to the ML modules
3. The ML modules produce detection output
4. The UI renders the detection output

The API serves as a conduit for passing imagery and metadata between the user interface and the machine learning modules. The API sends imagery to the machine learning modules for processing and subsequently receives metadata generated by the machine

learning modules which is passed to the interface for rendering.

Second Opinion® PR uses machine learning to detect regions of interest. Images received by the ML modules are processed yielding detections which are represented as metadata. The final output is made accessible to the API for the purpose of sending to the UI for visualization. Detected regions of interest are displayed as mask overlays atop the original radiograph which indicate to the practitioner which regions contain which detected potential conditions that may require clinical review. The clinician can toggle over the image to highlight a potential condition for viewing.

7. Indications for Use

Second Opinion® Panoramic is a radiological automated image processing software device intended to identify and mark regions, in panoramic radiographs, in relation to suspected dental findings which include: Caries, Periapical radiolucency, and Impacted third molars.

It is designed to aid dental health professionals to review panoramic radiographs of permanent teeth in patients 16 years of age or older as both a concurrent and second reader.

8. Summary of Substantial Equivalence:

The primary and secondary predicate devices and subject device are similar devices in the following ways:

1) *Intended use:* All three devices are intended to be used to aid dental clinicians in their detection of anatomical and pathological findings in radiographs of permanent teeth.
2) *Technology characteristics:* All devices employ computer vision and machine learning to output detections, use cloud-based environments to conduct processing, and demarcate detections within a user interface with a graphical overlay over radiographs.
3) *Safety*: As both the candidate and predicate device are automated image processing software systems, neither pose a direct safety hazard to the patient. The primary hazards for all devices, subject and predicates, are potential false positives and false negatives. In the case of each device, users are not meant to rely solely on detection output for clinical decision-making.
4) *Clinical Performance*: Both devices have undergone clinical studies which demonstrate statistically significant improvement in aided reader performance.

Table 1: Comparison of Second Opinion® PR with the predicate devices.

	Subject Device Second Opinion® Panoramic	Primary Predicate Denti.AI Detect K230144	Secondary Predicate Second Opinion® K210365
Manufacturer	Pearl Inc.	Denti.AI Technology, Inc.	Pearl Inc.
Classification	892.2070	892.2070	892.2070
Product Code	MYN	MYN	MYN
Image Modality	Radiograph	Radiograph	Radiograph
Intended Use	Dental CADe to aid with the detection of regions of interest in panoramic radiograph review by HCP	Dental CADe to aid with the detection of regions of interest in dental radiograph review by HCP	Dental CADe to aid in dental radiograph review by HCP
Full IFU	Second Opinion® Panoramic is a radiological automated image processing software device intended to identify and mark regions, in panoramic radiographs, in relation to suspected dental findings which include: Caries, Periapical radiolucency, and Impacted third molars. It is designed to aid dental health professionals to review panoramic radiographs of permanent teeth in patients 16 years of age or older as both a concurrent and second reader.	Denti.AI Detect is a Computer-Assisted Detection (CADe) software device intended to be used by dental professionals, comprising dentists and dental specialists, while reading extraoral and intraoral 2D dental radiographs. The device aims to assist in detecting and highlighting uncategorized regions of interest (ROIs)within the teeth area, which include caries and periapical radiolucency, as a second reader. The device is also intended to aid in the measurements of mesial and distal bone levels associated with each tooth. The device is aimed to be used with images from the patients of 22 years age and older without remaining primary dentition. The device is not intended to replace a complete clinician's review or clinical judgment that considers other relevant information from the image or patient history.	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 of age or older as a second reader.
Intended body part	Dental	Dental	Dental
Technology	Automated, CADe software that utilizes machine learning	Automated, CADe software that utilizes machine learning	Automated, CADe software that utilizes machine learning
Device Description	Detection and display of anatomy and pathologies in extraoral radiographs	Detection and display of anatomy and pathologies in intraoral and extraoral radiographs	Detection and display of anatomy and pathologies in intraoral radiographs

9. Technological Comparison to Predicate Devices

The fundamental technological principle for both the candidate and predicate devices is the automatic detection of anatomical and pathological findings using machine learning.

The candidate and predicate devices are technologically equivalent as follows:

- All are software devices designed to run on Windows operating systems.
- All devices are designed to process digital radiographs.
- All devices use neural network-based computer vision algorithms for anatomical and pathological detection.
- All devices demarcate detections within the user interface with a graphical overlay on the radiograph.
- All devices produce near-instantaneous detection results.
- All devices are considered to be of basic documentation level.
- All devices passed all verification and validation testing requirements.

The candidate and predicate devices are technologically different as follows:

- Second Opinion localizes detections in bitewing and periapical radiographs only whereas Denti.AI Detect and Second Opinion® PR localize detections in panoramic radiographs as well. In addition, Second Opinion® PR includes the detection of impactions whereas the predicates do not.

10. Assessment of Benefit-Risk, Safety and Effectiveness, and Substantial Equivalence to Predicate Device

Pearl demonstrated the benefits of the device through a standalone clinical study and fully-crossed MRMC study. The results of the study showed the system is both safe and effective for its intended use. When the probable benefits and probable risks of Second Opinion® PR are weighed against one another, the weight of benefits significantly exceeds that of risks. This judgment can be made based on review of the submitted materials showing that Second Opinion® PR meets the design verification and validation requirements. It is thus concluded that Second Opinion® PR can be considered safe and effective such that the device will aid users in the indicated user population in their radiographic review of caries, periapical radiolucencies, and impacted third molars.

11. Cybersecurity

Pearl developed Security controls and processes in accordance with *FDA Guidance - Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions dated September 2023*. These processes are used in both the development of Second Opinion® PR and in post-market surveillance to ensure the product upholds the highest standards of privacy and security.

12. Discussion of Non-Clinical Tests Performed

The device is a software-only device, so most testable characteristics common to other device types, including Biocompatibility/Materials, Shelf Life/Sterility, Electromagnetic Compatibility and Electrical Safety, Magnetic Resonance (MR) Compatibility, are not applicable to this device.

13. Discussion of Clinical Tests Performed

Clinical evaluation of Second Opinion® PR was performed to validate the efficacy of the system in detecting caries, periapical radiolucencies, and impacted third molars in panoramic radiographs. Second Opinion® PR was clinically tested as a standalone device in comparison to the predicate device, Second Opinion, using both a standalone clinical study and a fully-crossed MRMC study. The test dataset includes a diverse range of conditions aligned with the device's intended use, including primary and secondary caries, as well as cysts, bone loss and caries present within or around an impaction.

The Weighted Alternative Free-Response Receiver Operating Characteristic (wAFROC) paradigm was used as the metric of efficacy for the study. The ground truth (GT) was established using the consensus approach based on agreement among at least three out of four expert readers. The enriched regionally balanced image set of 795 images were independently reviewed by four board-certified dentists each with a minimum of five years practice experience as ground truth readers to establish the location of any caries, periapical radiolucencies, and impactions for each radiograph in the set using polygons for PRs and caries, and bounding boxes for impactions. These ground truth readers were not aware of any outputs from the enrichment process. Each GT reader independently marked areas on any radiograph wherein they identified a caries, periapical radiolucency lesion, or impaction. Readers marked detected features using CVAT, an open-source annotation software tool, allowing them to circumscribe each detected caries, periapical radiolucency lesion, or impaction within a polygon or bounding box respectively.

The GT dataset for the clinical evaluation of the Second Opinion® PR system is characterized by a diverse distribution of radiographs across various geographical regions, genders, ages, imaging devices, and image types. Geographically, with respect to the United States, the included dataset of geographic distribution is seen in Table 2 below.

Table 2 Geographic distribution

Region/Geo	Impacted Teeth N=420	Periapical Radiolucency N=496	Caries N=511
Northwest	95	102	96
Northeast	99	101	117

South	73	93	95
West	60	88	89
Midwest	93	112	114

In terms of gender distribution, the table below describes the gender distribution of the ground truth data by dental feature.

Table 3 Gender distribution

Gender	Impacted Teeth N=420	Periapical Radiolucency N=496	Caries N=511
Female	186	231	234
Male	191	226	225
Unknown	43	39	52

In addition, in terms of age, the table below describes the age distribution of the ground truth data by dental feature.

Table 4 Age distribution

Age Group	Impacted Teeth N=420	Periapical Radiolucency N=496	Caries N=511
>16 - 34 years	178	157	208
35 - 64 years	156	208	203
>= 65 years	86	131	100

The table below summarizes the image characteristics of the ground truth datasets by dental feature.

Table 6 Summary of Image characteristics

	Impacted Teeth N=420	Periapical Radiolucency N=496	Caries N=511
Overall status, n (%)			
Normal	225 (53.6)	294 (59.3)	292 (57.1)
Abnormal	195 (46.4)	202 (40.7)	219 (42.9)
Number of dental features on abnormal images			
Total, n	459	309	654
Mean (SD)	2.35 (1.1)	1.53 (1.1)	2.99 (3.3)
Median (range)	2 (1, 4)	1 (1, 11)	2 (1, 25)

Dental feature size on abnormal images (percent of image pixels)			
Mean (SD)	0.83 (0.22)	0.09 (0.1)	0.06 (0.07)
Median (range)	0.8 (0.23, 1.59)	0.05 (0.0, 0.83)	0.03 (0.0, 0.42)

In addition, SOPR was assessed using a meaningful number of cases for each of the major U.S. panoramic manufacturers, including but not limited to Carestream, Gendex, Ray, Planmeca, Sirona, and Vatech.

Standalone Testing

The results of this standalone clinical performance study demonstrate that Second Opinion® Panoramic is both safe and effective for its intended use in aiding dental professionals in the detection and localization of impacted third molars, periapical radiolucencies, and caries on panoramic radiographs.

Across all analytic levels—lesion, surface, and image—the device achieved high accuracy, sensitivity, and localization consistency. Both lesion and image level wAFROC metrics show diagnostic performance comparable to or exceeding that of published benchmarks for AI-assisted radiographic analysis. The segmentation and localization metrics (Dice ≥ 0.68, Jaccard ≥ 0.62) confirm that the device accurately delineates lesion boundaries, an important factor for clinical usability and diagnostic confidence.

The standalone evaluation of Second Opinion® Panoramic demonstrated high efficacy in detecting and localizing dental pathologies across all three target lesion types — impacted third molars, periapical radiolucency, and caries — when compared with consensus ground truth established by expert dental radiologists.

The study met the primary efficacy endpoint, with the weighted alternative free-response receiver operating characteristic (wAFROC) figure of merit (FOM) exceeding the pre-specified performance thresholds for all evaluated dental features. Specifically, the device achieved wAFROC values of 0.9788, 0.8113, and 0.7211 for impacted third molars, periapical radiolucency, and caries, respectively, surpassing the minimum benchmarks derived from published clinical literature (0.78, 0.71, and 0.70).

These results were statistically significant ($p < 0.0001$) and indicate that the device consistently discriminates true-positive lesion regions while maintaining low false-positive rates. The high wAFROC values (0.99, 0.91, and 0.90 across features) reinforce the model’s diagnostic reliability at the image level.

The secondary efficacy measures, including lesion-level sensitivity, false positives per image (FPPI), and Dice/Jaccard indices, support the robustness of the primary findings. Second Opinion®

Panoramic achieved lesion-level sensitivities of 99%, 82%, and 77% across the three features, indicating strong detection ability even for small or low-contrast lesions.

Subgroup analyses by age, gender, geography, and imaging device showed consistent trends, confirming that model performance generalizes well across demographics and image acquisition conditions. No significant outliers or bias were observed, suggesting adequate representation and algorithmic robustness across populations.

In total, these findings confirm that Second Opinion® Panoramic provides clinically meaningful detection performance that meets or exceeds the expectations for dental CADe systems in panoramic radiography.

Importantly, subgroup evaluations across age, gender, imaging device type, and confounding factors demonstrated stability in performance, suggesting broad generalizability and low bias potential. The test dataset includes a diverse range of conditions aligned with the device's intended use, including primary and secondary caries, as well as cysts, bone loss and caries present within or around an impaction.No subgroup exhibited statistically significant degradation in efficacy.

In terms of safety, the retrospective, non-patient-contact nature of the study and the absence of device-related adverse events reaffirm the device's favorable risk profile. Any residual risks
(false-positive/false-negative) are mitigated through proper user training and clear labeling emphasizing that the software serves as an assistive, not autonomous, diagnostic tool.

In conclusion, the results provide substantial evidence of safety and effectiveness, supporting the use of Second Opinion® Panoramic as an adjunctive diagnostic aid in routine clinical practice. The device demonstrates a strong benefit-to-risk ratio and aligns with regulatory expectations for CADe systems intended for dental panoramic radiography.

MRMC Testing

The fully crossed MRMC study successfully demonstrated that use of SOPR significantly improves reader performance for detection of dental findings in panoramic radiographs. The primary endpoint was met, with statistically significant increases in wAFROC area under the curve (at both a lesion level and image level) for all three evaluated dental features—impacted third molars, periapical radiolucencies, and caries—when readers were aided by SOPR.

Key findings include:

- **Periapical radiolucency** detection showed the most pronounced improvement, with a lesion level wAFROC difference of 0.0705 (95% CI: 0.04–0.10; $p < 0.00001$), image level wAFROC difference of 0.0715 (95% CI: 0.07, 0.07; $p < 0.00001$) and an increase in lesion-level sensitivity of 0.2045 (95% CI: 0.17–0.24; $p< 0.00001$).

- **Caries** detection improved with a lesion level wAFROC difference of 0.0306 (95% CI: 0.00–0.06; p = 0.0195), image level wAFROC difference of 0.0176 (95% CI: 0.02, 0.02; p < 0.00001) and a lesion-level sensitivity gain of 0.1169 (95% CI: 0.08–0.15).
- **Impacted teeth** detection demonstrated a lesion level wAFROC difference of 0.0093 (95% CI: 0.00–0.02; p = 0.0326), image level wAFROC difference of 0.0715 (95% CI: 0.07, 0.07; p < 0.00001) and a lesion-level sensitivity gain of 0.0192 (95% CI: 0.01–0.03).

At the **lesion level**, SOPR improved reader sensitivity, wAFROC, and localization accuracy, particularly for periapical radiolucencies, confirming enhanced lesion detection precision.

At the **surface level**, high specificity was maintained (≥0.97) across features, demonstrating minimal over-marking on normal regions.

At the **image level**, improvements in wAFROC metrics, coupled with stable FPPI values, indicate that the device improves reader diagnostic performance without clinically meaningful increases in false positives.

Across all endpoints, the improvements in detection accuracy were achieved without statistically significant increases in false positives per image (FPPI) or reductions in specificity. Localization accuracy, as measured by the Dice coefficient and Jaccard Index, also improved consistently across all features, confirming that SOPR enhances the precision with which readers identify the true location of dental findings.

Exploratory subgroup analyses by age, gender, geography, and imaging device demonstrated no clinically meaningful variability in device performance, suggesting consistent effectiveness across patient populations and imaging platforms.

In conclusion, the MRMC study supports that the Second Opinion Panoramic Radiographs (SOPR) system performs safely and effectively within its intended use. The results demonstrate statistically significant and clinically meaningful improvement in diagnostic performance compared to unaided reading, without increasing user or patient risk.

These findings, together with the device's technological equivalence and established predicate safety profile, provide strong evidence that no new questions of safety or effectiveness are raised by the use of SOPR on panoramic radiographs.

14. Comparison to Predicate Clinical Outcomes

Based on the above considerations, Pearl has concluded that Second Opinion® PR is substantially equivalent to the primary predicate device Denti.AI Detect (K230144) and secondary predicate Second Opinion® (K120365), as it has similar software,

technological, operating characteristics and intended use. Standalone performance testing has demonstrated Second Opinion® PR is as safe and effective as the legally marketed predicate devices and does not raise different questions of safety and effectiveness than the predicate devices.

15. Conclusions

Based on the information presented above, Second Opinion® PR and its predicate devices, are deemed to have similar intended uses as devices which aid in the detection of anatomical and pathological findings that can appear in dental radiographic imagery. Second Opinion® PR's clinical trial results demonstrate that the device effectively performs as well as the primary predicate device.

Second Opinion® PR raises no new or different questions of safety or effectiveness, performs in accordance with its specifications, meets user needs, meets the intended use and therefore was found substantially equivalent to the predicate devices.