June 12, 2025

Pearl Inc.
% William Birdsall
Chief Compliance Officer
2515 Benedict Canyon Dr.
BEVERLY HILLS, CA 90210

Re: K243234
Trade/Device Name: Second Opinion® CS
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: May 8, 2025
Received: May 8, 2025

Dear William Birdsall:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243234

Device Name

Second Opinion® CS

Indications for Use *(Describe)*

Second Opinion® CS is a computer aided detection ("CADe") software to aid in the detection and segmentation of caries in periapical radiographs.

It is designed to aid dental health professionals to review periapical radiographs of permanent teeth in patients 12 years of age or older as a 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.

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K243234

510(K) SUMMARY

1. Submitter's Identification

Pearl Inc.
2515 Benedict Canyon Dr.
Beverly Hills, CA, 90210
USA
(239) 450-8829

Contact Person: Ashley Brown, Director of Quality and Regulatory Affairs

Officer Date Summary Prepared: May 22, 2025

2. Trade Name of the Device

Second Opinion® CS

3. Common or Usual Name

Analyzer, Medical Image

4. Classification Name, Regulatory Classification & Product Code

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

5. Predicate Information

Predicate device: The proposed primary predicate device is the first clearance of the Second Opinion device, by Pearl Inc., cleared on March 04, 2022 (K210365) 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 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 potential caries with bounding boxes.

The subject device is substantially equivalent to the first clearance as the overall intended use and nature of the software remains the same. Caries detection was originally cleared (K210365) based on standalone and MRMC studies. Second Opinion CS has the same intended use for detection of caries in periapical radiographs. The only difference is that Second Opinion CS now provides a detailed analysis of the lesion’s overlap with dentin and enamel, presented as a percentage.

The proposed secondary predicate device is Overjet Dental Caries Assist by Overjet Inc., cleared in K222746 (03/22/2023). The product code for the predicate is MYN. This device has the same technology (AI software) and intended use as CADe to aid in dental review of radiographs.

6. Device Description

Second Opinion CS detects suspected carious lesions and presents them as an overlay of segmented contours. The software highlights detected caries with an overlay and provides a detailed analysis of the lesion's overlap with dentine and enamel, presented as a percentage. The output of Second Opinion CS is a visual overlay of regions of the input radiograph which have been detected as potentially containing caries. The user can hover over the caries detection to see the segmentation analysis.

Second Opinion PC consists of three parts:

- Application Programing Interface ("API")
- Machine Learning Modules ("ML Modules")
- Client User Interface ("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 CS uses machine learning to detect and segment caries. 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 carious lesions are displayed as overlays atop the original radiograph which indicate to the practitioner which teeth contain which detected carious lesions that may require clinical review. The clinician can toggle over the image to highlight a potential condition for viewing. Further, the clinician can hover over the detected caries to show a hover information box containing the segmentation of the caries in the form of percentages.

7. Indications for Use

Second Opinion® CS is a computer aided detection ("CADe") software to aid dentists in the detection and segmentation of caries in periapical radiographs.

It is designed to aid dental health professionals to review periapical radiographs of permanent teeth in patients 12 years of age or older as a second reader.

8. Summary of Substantial Equivalence:

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

1) *Intended use:* All three devices are intended to be used to aid dental clinicians in their detection of caries in radiographs of permanent teeth. Both the subject device and the secondary predicate are intended for segmentation of detected carious lesions.
2) *Technology characteristics:* All three devices employ computer vision and machine learning to output detections, use cloud-based environments to conduct processing, and demarcate detected caries within a user interface with a graphical overlay over radiographs.
3) *Safety*: As both the candidate and predicate devices are CADe 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*: All devices have undergone clinical studies which demonstrate statistically significant improvement in aided reader performance.

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

	Subject Device Second Opinion PC	Primary Predicate Second Opinion K210365	Secondary Predicate Overjet K231678
Manufacturer	Pearl Inc.	Pearl Inc.	Overjet, Inc.
Classification	892.2070	892.2070	892.2070
Product Code	MYN	MYN	MYN
Image Modality	Radiograph	Radiograph	Radiograph
Intended Use	Dental CADe to aid in dental radiograph review by HCP	Dental CADe to aid in dental radiograph review by HCP	Dental CADe to aid in dental radiograph review by HCP

Full IFU	Second Opinion® CS is a computer aided detection ("CADe") software to aid in the detection and segmentation of caries in periapical radiographs. It is designed to aid dental health professionals to review periapical radiographs of permanent teeth in patients 12 years of age or older as a second reader.	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.	Overjet Caries Assist (OCA) is a radiological, automated, concurrent-read, computer-assisted detection (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 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.
Intended body part	Dental	Dental	Dental
Technology	Utilizes computer vision neural network algorithms, developed from open-source models using supervised machine learning techniques	Utilizes computer vision neural network algorithms, developed from open-source models using supervised machine learning techniques	Automated, concurrent-read, CADe software that utilizes machine learning
Device Description	Detection and segmentation of caries.	Detection of radiological dental findings: 5 restorations (crowns, bridges, implants, root canals, fillings), 4 pathologies (caries, margin discrepancy, calculus, periapical radiolucency) using bounding boxes.	Detection and segmentation of caries.

9. Technological Comparison to Predicate Devices

The fundamental technological principle for both the candidate and predicate devices is the automatic detection of periapical radiolucencies 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 intraoral radiographs.
- All devices use neural network-based computer vision algorithms for periapical radiolucencies 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 “moderate” level of software concern.
- All devices passed all verification and validation testing requirements.

The candidate and predicate devices are technologically different as follows:

- Second Opinion does not include segmentation, whereas Overjet Caries Assist and Second Opinion CS include caries segmentation.

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. 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 CS are weighed against one another, the weight of benefits significantly exceeds that of risks. This judgement can be made based on review of the submitted materials showing that Second Opinion CS meets the design verification and validation and labeling Special Controls required for clearance of Class II medical image analyzers. It is thus concluded that Second Opinion CS can be considered safe and effective such that the device will aid users in the indicated user population in their radiographic detection and segmentation of caries lesions.

11. 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.

12. Discussion of Clinical Tests Performed

The effectiveness of Second Opinion CS was evaluated in a standalone performance assessment to validate the inclusion of a new caries lesion anatomical segmentation. The standalone retrospective study of 1250 periapical radiograph images containing 404 overall caries lesions on 286 abnormal images assessed the sensitivity of caries detection of Second Opinion CS compared to the Ground Truth.

The GT dataset for the clinical evaluation of the Second Opinion CS system is characterized by a diverse distribution of radiographs across various geographical regions, genders, ages, and imaging devices. Geographically, with respect to the United States, the dataset includes radiographs from the Northwest (11.0%), from the Northeast (18.8%), from the South (29.2%), from the West (15.6%), and from the Midwest (25.5%).

In terms of gender distribution, the dataset comprises radiographs from females

(50.1%), males (44.6%), and unknown gender (5.3%). Age-wise, radiographs are from individuals aged 12-18 (12.3%), aged 18-75 (81.7%), and aged 75+ (6.0%).

The imaging devices used include radiographs from Carestream-Trophy KodakRVG6100 (25.7%), 79 from Carestream-Trophy RVG5200 (3.2%), 674 from Carestream-Trophy RVG6200 (27.0%), 480 from DEXIS Platinum (19.2%), 471 from DEXIS Titanium (18.8%), 21 from Kodak-Trophy KodakRVG6100 (0.8%), and 133 from unknown devices (5.3%).

Below is a table describing the composition of the dataset with respect to presence of caries.

Standalone Testing

The effectiveness of Second Opinion CS was evaluated in a standalone performance assessment to validate the inclusion of a new caries lesion anatomical segmentation. The standalone retrospective study of 1250 radiograph images containing 404 overall caries lesions on 286 abnormal images assessed the sensitivity of caries detection of Second Opinion CS compared to the Ground Truth.

The key results from this study are:

- The study met the primary endpoint, where Second Opinion CS sensitivity was > 70%.
- The results remained statistically significant after controlling for multiple comparisons (p-value < 0.001).

The z-score analysis of the lesion level sensitivity for overall caries detection by image type showed the estimated lesion level sensitivity (95% CI) was 0.88. The tests that the sensitivity was greater than 70% was statistically significant (Hommel adjusted p-value: <0.0001).

The caries subgroup sensitivity (95% CI) was 0.95 (0.92, 0.97) enamel and 0.86 (0.81, 0.90) dentin. The caries subgroup FPPI (95% CI) was 0.76 (0.70, 0.83) enamel and 0.48 (0.43, 0.52) dentin.

MRMC Testing

The efficacy of Second Opinion® CS was evaluated through a fully crossed multi-reader multi-case (MRMC) study to validate its caries detection and anatomical segmentation (enamel, dentin) capabilities in periapical radiographs. The study included 330 radiographs with 508 caries lesions across 179 abnormal images. Twenty-one U.S.-certified dentists compared aided (using Second Opinion® CS) and unaided performance, with ground truth determined by four experienced dentists achieving consensus (Jaccard index ≥0.4). A standalone analysis compared standalone CAD performance to unaided readers demonstrated equivalence to the predicate, Overjet Caries Assist (K222746).

The primary endpoint, the difference in weighted alternative free-response receiver operating characteristic (wAFROC) figure of merit (FOM) between aided and unaided readers, was analyzed using the Hommel procedure to control family-wise error at 5%, with Holm-adjusted 95% confidence intervals (CI). Aided readers showed a significant improvement in caries detection for periapical images (wAFROC-FOM difference: 0.05, 95% CI: 0.01–0.09, adjusted p=0.0345).

Secondary endpoints revealed a significant increase in lesion-level sensitivity (0.20, 95% CI: 0.16–0.24). False positives per image (FPPI) increased slightly (0.16, 95% CI: -0.03–0.36). Surface-level specificity decreased marginally (-0.02, 95% CI: -0.04–0.00). Localization and segmentation accuracy, measured by the Jaccard index, was consistent across readers, confirming reliable identification of caries and anatomical structures. The standalone performance of Second Opinion® CS matched or exceeded unaided readers, supporting equivalence to the predicate.

For overall caries, Standalone CAD outperformed unaided readers, achieving higher wAFROC-FOM and sensitivity, though with higher FPPI, reflecting a sensitivity-driven design manageable by clinician oversight, similar to the predicate. These results highlight the CAD's superior ability to detect and segment caries independently, reinforcing its equivalence to the predicate and its value as an adjunct tool.

For enamel and dentin, the wAFROC-FOM difference was 0.04 (95% CI: 0.01, 0.08) for enamel and 0.05 (95% CI: 0.02, 0.08) for dentin. Lesion level sensitivity increased significantly (0.20, 95% CI: 0.16-0.25) for enamel (0.19, 95% CI: 0.15-0.23) for dentin. FPPI rose slightly (0.21, 95% CI: 0.04, 0.37) for enamel and 0.08 (95% CI: -0.08, 0.23) for dentin. Standalone CAD vs. unaided readers demonstrated comparable or superior wAFROC-FOM and sensitivity, confirming robust detection and segmentation performance. The slight increase in FPPI is mitigated by clinical review in accordance with the intended use.

Exploratory subgroup analyses by age, gender, geographic area, and imaging device showed no notable differences, though the study was not powered for these comparisons. The results demonstrate that Second Opinion® CS enhances caries detection, particularly for periapical images, and reliably segments anatomical structures, affirming its efficacy as a diagnostic aid.

13. Conclusions

Based on the information presented above, Second Opinion CS and its predicate devices are deemed to have similar intended uses as devices which aid in the detection and segmentation of caries that can appear in dental radiographic imagery. Second Opinion CS's clinical trial results demonstrate that the device is safe and effective.
As Second Opinion CS 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.