



January 16, 2025

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

Re: K242522
Trade/Device Name: Second Opinion CC
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: August 1, 2024
Received: December 18, 2024

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,

A large, light blue 'FDA' watermark is visible in the background. Overlaid on it is a handwritten signature in black ink that reads '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

Indications for Use

510(k) Number (if known)

K242522

Device Name

Second Opinion CC

Indications for Use (Describe)

Second Opinion® CC is a computer aided detection ("CAdE") software to aid dentists in the detection of caries by drawing bounding polygons to highlight the suspected region of interest.

It is designed to aid dental health professionals to review bitewing and periapical radiographs of permanent teeth in patients 19 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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510(K) SUMMARY

1. Submitter's Identification

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

Contact Person: William Birdsall

Position: Chief Compliance Officer

Date Summary Prepared: July 23, 2024

2. Trade Name of the Device

Second Opinion CC

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

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 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 potential caries lesions 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 CC has the same intended use for detection of caries in bitewing and periapical radiographs. The only

difference is that Second Opinion CC uses polygons instead of boxes to mark the detection.

The proposed secondary predicate device is Overjet Dental Caries Assist by Overjet Inc., cleared on March 27, 2023 (K222746) under product code MYN. The Overjet Dental Caries Assist has the same technology (AI software) and intended use as CAdE to aid in dental review of radiographs and detection of caries using polygonal contours.

6. Device Description

Second Opinion CC (Caries Contouring) is a radiological, automated, computer-assisted detection (CAdE) software intended to aid in the detection of caries on bitewing and periapical radiographs using polygonal contours. The device is not intended as a replacement for a complete dentist's review or their clinical judgment which considers other relevant information from the image, patient history, or actual in vivo clinical assessment.

Second Opinion CC consists of three parts:

- Application Programming 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 CC uses machine learning to detect 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 polygonal 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. In addition, the clinician has the ability to edit the detections as they see fit to align with their diagnosis.

7. Indications for Use

Second Opinion CC is a computer aided detection ("CAdE") software to aid dentists in the detection of caries by drawing bounding polygons to highlight the suspected region of interest.

It is designed to aid dental health professionals to review bitewing and periapical radiographs of permanent teeth in patients 19 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.
- 2) *Technology characteristics*: Both 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 device 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*: Both devices have undergone clinical studies which demonstrate statistically significant improvement in aided reader performance.

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

	Subject Device Second Opinion CC	Primary Predicate Second Opinion K210365	Secondary Predicate Overjet K222746
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 CC is a computer aided detection ("CAdE") software to aid dentists in the detection of caries by drawing bounding polygons to highlight the suspected region of interest. It is designed to aid dental health professionals to review bitewing and periapical radiographs of permanent teeth in patients 19 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	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
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	Subject Device Second Opinion CC	Primary Predicate Second Opinion K210365	Secondary Predicate Overjet K222746
		radiographs of permanent teeth in patients 12 years of age or older as a second reader.	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 of caries using polygons.	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 using polygons.

9. Technological Comparison to Predicate Devices

The fundamental technological principle for both the candidate and predicate devices is the automatic detection of caries 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 bitewing radiographs.

- All devices use neural network-based computer vision algorithms for caries 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 localizes caries detections as bounding boxes whereas Overjet Caries Assist and Second Opinion CC localize caries detections with polygons.

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

Pearl demonstrated the benefits of the device through a non-inferiority standalone clinical study. The results of the study showed statistically significant non-inferiority in caries detection accuracy in the subject device using polygon contouring to delineate potential caries when compared to the bounding boxes of Second Opinion. This study was conducted using ground truth caries lesions represented as polygons. When the probable benefits and probable risks of Second Opinion CC 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 CC 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 CC can be considered safe and effective such that the device will aid users in the indicated user population in their radiographic detection of caries.

11. Cybersecurity

Pearl developed Security controls and processes in accordance with *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions: Guidance for Industry and Food and Drug Administration Staff* dated September 2023 and *Postmarket Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff* dated December 2016. These processes are used in both the development of Second Opinion CC 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 Standalone Tests Performed

Pearl has conducted performance testing according to FDA's "Guidance for Industry and Food and Drug Administration Staff Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions Document" issued on 03 Jul 2012. Clinical evaluation of Second Opinion CC was performed to validate the efficacy of the system in detecting potential caries lesions using polygons instead of bounding boxes on intraoral radiographs. Second Opinion CC was clinically tested as a standalone device in comparison to the predicate device, Second Opinion, using a non-inferiority study.

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. Each GT expert independently marked areas on any radiograph wherein they marked using the smallest possible polygonal contour to encompass the entire region identified. 500 images were reviewed by all four GT readers and used for the standalone comparison study.

The GT dataset for the clinical evaluation of the Second Opinion CC 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 dataset includes 76 radiographs from the Northwest (15.2%), 89 from the Southwest (17.8%), 123 from the South (24.6%), 113 from the East (22.6%), 98 from the Midwest (19.6%), and 1 with an unknown origin (0.2%).

In terms of gender distribution, the dataset comprises 95 radiographs from females (19.0%), 125 from males (25.0%), 38 from other genders (7.6%), and 242 with unknown gender (48.4%). Age-wise, 9 radiographs are from individuals aged 12-18 (1.8%), 233 from those aged 18-75 (46.6%), 13 from those aged 75+ (2.6%), and 245 with unknown age (49.0%).

The imaging devices used include 65 radiographs from Carestream-Trophy KodakRVG6100 (13.0%), 2 from Carestream-Trophy RVG5200 (0.4%), 96 from Carestream-Trophy RVG6200 (19.2%), 1 from DEXIS (0.2%), 59 from DEXIS Platinum (11.8%), 10 from KaVo Dental Technologies DEXIS Titanium (2.0%), 108 from Kodak-Trophy KodakRVG6100 (21.6%), 68 from XDR EV71JU213 (13.6%), and 91 from unknown devices (18.2%).

The image types are nearly evenly split with 249 periapical radiographs (49.8%) and 251 bitewing radiographs (50.2%). Below is a table describing the composition of the dataset with respect to presence of caries.

Table 2 - Summary of image characteristics.

Total N=500	
Overall status, n (%)	
Healthy	288 (57.6)
Containing Caries	212 (42.4)
Number of lesions on abnormal images	
Total, n	356
Mean (SD)	1.7 (1.23)
Median (range)	1.0 (1, 9)
Lesion size on abnormal images (percent of image pixels)	
Mean (SD)	1.5 (1.95)
Median (range)	0.6 (0,11)

The clinical study design consisted of one non-inferiority trial: comparing the ability of Second Opinion CC (polygonal localization) and Second Opinion (bounding box localization) to identify caries lesions. The 500 unique unannotated images were analyzed by both Second Opinion and Second Opinion CC. The results for each image were grouped into one of two categories:

- Non-Lesion Localization (NL): A predicted region which does not overlap with a ground truth region at or above a specified Jaccard index
- Lesion Localization (LL): A predicted region which does overlap with a ground truth region at or above a specified Jaccard index

The Jaccard Index used for the study was 0.4. The primary performance comparison of Second Opinion CC Second Opinion was conducted using wAFROC-FOM. A secondary analysis was carried out using HR-ROC-AUC.

There were a total number of lesion localizations (mean per image) of 204 (1.5) and 322 (1.6) by Second Opinion and Second Opinion CC respectively resulting from the non-inferiority study. The Obuchowski-Rockette analysis of jackknife and ANOVA estimate of the FOM difference between Second Opinion devices showed the estimated difference (95% CI) was 0.26 (0.22, 0.31). The lower bound of the 95% CI exceeded -0.05 showing Second Opinion CC was non-inferior to Second Opinion at the 5% level of significance. The wAFROC-FOM, 95% CI for Second Opinion CC was 0.81 (0.77, 0.85) and HR-ROC-AUC, 95% CI was 0.88 (0.85, 0.91). The null hypothesis was rejected.

The HR-ROC analysis further supports that Second Opinion CC's caries detection is non-inferior to that of Second Opinion. Second Opinion CC demonstrated a lesion level sensitivity (95% CI) of 90% (87%, 94%) and average false positives per image (95% CI) of 1.34 (1.20, 1.48).

The segmentation accuracy was assessed to demonstrate clinically-acceptable accuracy using the Dice coefficient. The least squares (LS) mean (95% CI) for the Dice coefficient for true positives (n=322) was 0.73 (0.71, 0.75). The LS mean and 95% CI are from a linear mixed model with subject as random effect since more than one true positive may be on each image. The lower bound of the 95% CI exceeds the pre-defined clinically justified acceptance criteria of > 0.70.

14. Conclusions

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

As Second Opinion CC 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.