



May 5, 2025

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

Re: K243893
Trade/Device Name: Second Opinion® Pediatric
Regulation Number: 21 CFR 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: April 3, 2025
Received: April 3, 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,

A handwritten signature in black ink that reads "Lu Jiang" is positioned over a large, light blue, semi-transparent watermark of the letters "FDA".

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)

K243893

Device Name

Second Opinion® Pediatric

Indications for Use (Describe)

Second Opinion® Pediatric is a computer aided detection ("CAdE") software to aid in the detection of caries in bitewing and periapical radiographs.

The intended patient population of the device is patients aged 4 years and older that have primary or permanent teeth (primary or mixed dentition) and are indicated for dental radiographs.

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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K243893 510(K) SUMMARY

1. Submitter's Identification

Pearl Inc.
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USA
(239) 450-8829
compliance@hellopearl.com

Contact Person: Ashley Brown

Position: Director of Quality & Regulatory Affairs

Date Summary Prepared: May 2, 2025

2. Trade Name of the Device

Second Opinion® Pediatric

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 primary proposed **predicate** device for clearance of Second Opinion® Pediatric is the original Second Opinion device, by Pearl Inc., cleared on March 04, 2022 (K210365) and classified as a Class II 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 the patient age group of 4 years of age and older.

6. Device Description

Second Opinion Pediatric is a radiological, automated, computer- assisted detection (CAdE) software intended to aid in the detection and segmentation of caries on bitewing and periapical radiographs. 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 Pediatric consists of three parts:

- Application Programming 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® Pediatric 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 caries are displayed as polygonal overlays atop the original radiograph which indicate to the practitioner which teeth contain detected caries 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® Pediatric is a computer aided detection ("CADe") software to aid in the detection of caries in bitewing and periapical radiographs.

The intended patient population of the device is patients aged 4 years and older that have primary or permanent teeth (primary or mixed dentition) and are indicated for dental radiographs.

8. Summary of Substantial Equivalence:

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

- 1) *Intended use*: Both devices are intended to be used to aid dental clinicians in their review of caries lesions in bitewing and periapical radiographs of permanent teeth. The difference between the subject and predicate is the expanded age group to include 4+ in the subject.
- 2) *Technology characteristics*: Both devices employ computer vision and machine learning to output detections, use cloud-based environments to conduct processing, and display caries lesions within a user interface with a graphical overlay over radiographs.
- 3) *Safety*: As both the candidate and predicate devices are software systems, neither pose a direct safety hazard to the patient. The primary hazards for both devices, subject and predicate, are potential false positives and false negatives which could result in a temporary non-serious injury. 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 performance.

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

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



Full IFU	Second Opinion® Pediatric is a computer aided detection ("CAdE") software to aid in the detection of caries in bitewing and periapical radiographs. The intended patient population of the device is patients aged 4 years and older that have primary or permanent teeth (primary or mixed dentition) and are indicated for dental radiographs.	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
Technology	Automated, CAdE software that utilizes machine learning	Automated, CAdE software that utilizes machine learning
Device Description	Detection & display of caries lesions in intraoral 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 device is the automatic detection and display of caries lesions using machine learning.

The candidate and predicate devices are technologically equivalent as follows:

- Both are software devices designed to run on Windows operating systems.
- Both devices are designed to process digital intraoral bitewing and periapical radiographs.
- Both devices use neural network-based computer vision algorithms for caries lesions display.
- Both devices display caries within the user interface with a graphical overlay on the radiograph.
- Both devices produce near-instantaneous detection results.
- Both devices are considered to be of "moderate" level of software concern.
- Both devices passed all verification and validation testing requirements.



The candidate and predicate devices technologically differ as follows: The candidate device includes only caries detection whereas the predicate includes the detection of several types of dental restorations as well. These differences in features available do not raise any concerns about the safety or efficacy of the device as compared to the predicate.

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 substantially equivalent to the predicate device. When the probable benefits and probable risks of Second Opinion® Pediatric 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® Pediatric meets the design verification and validation requirements. It is thus concluded that Second Opinion® Pediatric can be considered safe and effective, in comparison to the predicate, such that the device will aid users in the indicated user population in their radiographic review of caries lesions.

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® Pediatric 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

The effectiveness of Second Opinion® Pediatric was evaluated in a standalone performance assessment to validate the inclusion of caries lesion detection in pediatric patients 4-11 years of age.

The effectiveness of Second Opinion® Pediatric was evaluated in a standalone performance assessment to validate the CAD. The standalone retrospective study of 1182 radiographic images containing 1085 caries lesions on 549 abnormal images assessed the sensitivity of caries detection of Second Opinion® Pediatric compared to the Ground Truth.



The key results from this study are:

- The study met the primary endpoint, where Second Opinion® Pediatric sensitivity was > 75% for bitewing and periapical images.
- The secondary endpoints supported the conclusion of the primary endpoint.

In the 1182 images included in the standalone clinical study, there were 942 LL identified by Second Opinion® Pediatric, with a mean of 1.8 LL per image. The mean (range) Second Opinion® Pediatric rating of LLs was 0.96 (0.31, 1.00). There were 1445 NL identified by Second Opinion® Pediatric, with a mean of 2.1 NL per image. The mean (range) Second Opinion rating of NLs was 0.74 (0.31, 1.00). On normal images (no true caries identified on the image), there were 538 (1.8 per image) NL identified by Second Opinion® Pediatric for caries overall.

The z-score analysis of the lesion level sensitivity for caries detection showed the estimated lesion level sensitivity (95% CI) was 0.87 (0.84, 0.90). The test that the sensitivity was greater than 70% was statistically significant (p-value: <0.0001). The FPPI (95% CI) was 1.22 (1.14, 1.30), wAFROC FOM (95% CI) was 0.86 (0.84, 0.88), HR-ROC FOM was 0.94 (0.93, 0.96) and the LS mean Dice Score (95% CI) was 0.76 (0.75, 0.77). All additional accuracy measures support the primary endpoint and demonstrate the high accuracy of Second Opinion® Pediatric, including the LS mean Dice score lower bound of the CI > 0.70.

The lesion level sensitivity, FPPI, HR-ROC FOM, wAFROC FOM and Dice score (segmentation accuracy) and their associated 95% CI.

The results of the standalone clinical testing of Second Opinion® Pediatric demonstrate that the caries detection performance of Second Opinion® Pediatric is comparable to that of primary predicate Second Opinion®.

14. Comparison to Predicate Clinical Outcomes

Predicate: Original Second Opinion

Standalone testing demonstrated that Second Opinion performed comparably to unaided readers in detecting pathologic and restoration features, based on Jaccard Index of ≥ 0.4 for lesion localization.

- Jaccard Index of 0.4 corresponds to an overlap area between the device's outputs and truth of 57% in theory. Using Jaccard Index of 0.4 leads to the device's standalone performance wAFROC-FOM 95% CI (0.73, 0.79), (0.71, 0.78), (0.78, 0.85) and (0.75, 0.84) for Caries, margin discrepancy (MD), Calculus, and periapical radiolucency (PR) with consensus truthing method, respectively.



- Jaccard Index of 0.5 corresponds to an overlap area between the device's outputs and truth of 67% in theory. Using Jaccard Index of 0.5 leads to the device's standalone performance wAFROC-FOM 95% CI (0.61, 0.68), (0.62, 0.68), (0.75, 0.81) and (0.69, 0.78) for Caries, MD, Calculus, and PR with consensus truthing method, respectively.

The standalone sensitivity and false positive rate were also assessed:

- Sensitivity defined as the number of dental pathologies (of a given type) detected as a percentage of the same type of GT pathologies on a given slide. ○ Range 76.39% – 89.77%
- False positive rate, defined as the number of false positive findings of a given type identified on a given slide and expressed in terms of FPPI (false positive per image).
 - Range 0.46 – 4.85

15. Conclusions

Conclusion: Based on the information presented above, Second Opinion® Pediatric and its predicate device, Second Opinion®, are deemed to have similar intended uses as devices which aid in the detection of caries that can appear in dental radiographic imagery. Second Opinion® Pediatrics' clinical trial results demonstrated that the device effectively performs as well as the predicate device.