May 23, 2025

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

Re: K243989
Trade/Device Name: Second Opinion® 3D
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: October 30, 2024
Received: April 25, 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 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)*
K242989

Device Name

Second Opinion® 3D

Indications for Use *(Describe)*
Second Opinion® 3D is a radiological automated image processing software device intended to identify and mark clinically relevant anatomy in dental CBCT radiographs; specifically Dentition, Maxilla, Mandible, Inferior Alveolar Canal and Mental Foramen (IAN), Maxillary Sinus, Nasal space, and airway. 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 health professionals to review CBCT radiographs of patients 12 years of age or older as 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.

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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: Ashley Brown | Position: Director of Regulatory Affairs |

Date Summary Prepared: May 21, 2025

## 2. Trade Name of the Device

Second Opinion® 3D

## 3. Common or Usual Name

Radiological Automated Image Processing System

## 4. Classification Name, Regulatory Classification & Product Code

*Classification Name:* *Medical Image Management and Processing System*
*Regulatory Classification:* 21CFR 892.2050, Class II
*Product Code:* QIH (Radiological Automated Image Processing System)

## 5. Predicate Information

Predicate device: proposed predicate device for clearance of Second Opinion® 3D is Relu Creator by Relu BV, cleared in (K233925, June 13, 2024), a semi-automated software device classified as a Class II device pursuant to 21 CFR §892.2050 Medical image management and processing system under product code QIH.

The Relu Creator is a software that is part of the digital workflow of dental specialists in preoperative planning. The main purpose is the 3D modeling of the patient anatomy, which is technically called image segmentation and multimodel registration. Based on the model, simulations for preoperative and pretreatment planning can be carried out for dental applications. The 3D modeling (segmentation + registration) is performed on medical images like CBCT, IOS and FS. The preoperative/pretreatment software can be applied in various dental disciplines such as orthodontics, implantology, and maxillofacial surgery.

The Relu Creator device has the same technology (automatic segmentation algorithm) and intended use as automated image processing to aid dental professionals in the visualization of CBCT radiographs. Please see 'Predicates and Substantial Equivalence' document identified in this submission

The cleared device is a software device, indicated for use by dental health professionals as an aid in reviewing CBCT radiographs. The device utilizes computer vision technology, developed using machine learning techniques, to identify clinically relevant anatomy on CBCT radiographs.

The subject device is substantially equivalent to the predicate as the overall intended use and nature of the software remains the same.

## 6. Device Description

Second Opinion® 3D is a radiological automated image processing software device intended to identify clinically relevant anatomy in CBCT radiographs. 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 identify clinically relevant anatomy on CBCT radiographs of permanent teeth in patients 12 years of age or older as a concurrent and second reader.

Second Opinion® 3D 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 uploaded by user
2. Images are sent for processing via the API
3. The API routes images to the ML modules
4. The ML modules produce detection output
5. 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® 3D uses machine learning to identify areas of interest such as Individual teeth, including implants and bridge pontics; Maxillary Complex; Mandible; Inferior Alveolar Canal and Mental Foramen (defined as IAN); Maxillary Sinus; Nasal Space; Airway. 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. Masks are displayed as overlays atop the original CBCT radiograph which indicate to the practitioner a clinically relevant anatomy. The clinician can toggle over the image to highlight a particular anatomy. Please see the 'Device Description' document identified in this submission.

## 7. Indications for Use

Second Opinion® 3D is a radiological automated image processing software device intended to identify and mark clinically relevant anatomy in dental CBCT radiographs; specifically Dentition, Maxilla, Mandible, Inferior Alveolar Canal and Mental Foramen (IAN), Maxillary Sinus, Nasal space, and airway. 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 health professionals to review CBCT radiographs of patients 12 years of age or older as a concurrent and second reader.

## 8. Summary of Substantial Equivalence:

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

1) *Intended use:* All devices are intended to be used to aid dental clinicians in their clinically relevant anatomy on CBCT 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 3D rendering of segmentation 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 inaccurate or misplaced anatomical segmentations, 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) *Performance Bench Testing*: All devices have undergone bench studies which demonstrate statistically significant performance accuracy in segmenting defined anatomies within CBCT radiographs.

*Table 1: Comparison of Second Opinion® 3D with the predicate devices.*

| | Subject Device<br>Second Opinion® 3D | Primary Predicate<br>Relu Creator<br>K233925 |
|---|---|---|
| **Manufacturer** | Pearl Inc. | Relu BV |
| **Classification** | 892.2050 | 892.2050 |
| **Product Code** | QIH | QIH |
| **Image Modality** | Radiograph | Radiograph |
| **Intended Use** | Dental automated image processing software device to aid in reviewing CBCT radiograph by HCP | Dental automated image processing software device to aid in reviewing CBCT, IOS and FS medical images by HCP |
| **Full IFU** | Second Opinion® 3D is a radiological automated image processing software device intended to identify and mark clinically relevant anatomy in dental CBCT radiographs; specifically Dentition, Maxilla, Mandible, Inferior Alveolar Canal and Mental Foramen (IAN), Maxillary Sinus, Nasal space, and airway. It should not be used in lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis.<br><br>It is designed to aid health professionals to review CBCT radiographs of patients 12 years of age or older as a concurrent and second reader. | Relu Creator is a software program for the management, transfer, and analysis of dental and craniomaxillofacial image information, and can be used to provide design input for dental solutions. It displays and enhances digital images from various sources to support the diagnostic process and treatment planning. It stores and provides these images within the system or across computer systems at different locations. |
| **Intended body part** | 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 |
| **Device Description** | 3D modelling of patient anatomy | 3D modelling of patient anatomy |

## 9. Technological Comparison to Predicate Devices

The fundamental technological principle for both the candidate and predicate device is the automatic identification and display of dental-related anatomies using machine learning.

The candidate and predicate devices are technologically equivalent as follows:

- Both devices are designed to process CBCT radiographs.

- Both devices use neural network-based computer vision algorithms for 3D modelling of patient anatomy.
- Both devices display a mask overlay on the CBCT radiograph.
- Both devices produce near-instantaneous identification results.
- Both devices require a Basic Documentation Level.
- Both devices passed all verification and validation testing requirements.

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

Pearl demonstrated the benefits of the device through a standalone bench performance 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® 3D 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® 3D meets the design verification and validation requirements. It is thus concluded that Second Opinion® 3D can be considered safe and effective such that the device will aid users in the indicated user population in their CBCT radiographic review.

## 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® 3D 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. Second Opinion® verification testing of software, unit testing, software integration testing, and software system testing were conducted. Verification and validation activities for Second Opinion® were conducted to provide evidence that the design meets user needs, intended use and application specification. The testing results support that all the software specifications have met the acceptance criteria and the claims of substantial equivalence.

## 13. Discussion of Bench Performance Tests

Bench testing was performed Second Opinion® 3D to clinically validate the different anatomical structures in CBCT radiographs of permanent teeth. The software modification is intended to assist dentists with their manual comparison by identifying and marking clinically relevant anatomy in CBCT radiographs. The effectiveness of Second Opinion® 3D was gauged via bench performance testing to determine the segmentation accuracy of

Second Opinion® 3D in identifying different anatomical structures in CBCT radiographs of permanent teeth of patients 12 years of age or older.

The bench performance testing included 100 images of the following anatomies: dentition, maxilla, mandible, IAN space, sinus, nasal space, airway. These anonymized images represent patients across the United States with permanent teeth and are representative of the intended patient population. These images were also used to carry out sub-group analysis that demonstrated generalizability of the device across the intended patient population. The success criteria for this study has been defined as a clinically meaningful measure of accuracy. In the table below, the results of the anomalies with corresponding statistical analysis can be observed:

| AnatomyID | Anatomy Name | Mean (95% CI) | Median [Min., Max.] | Std.dev. | one-sample t-test (p_value) |
|---|---|---|---|---|---|
| 1 | Dentition | 0.86 (0.83, 0.89) | 0.88 [0.55, 0.93] | 0.08 | <0.000001 |
| 2 | Maxillary Complex | 0.91 (0.91, 0.92) | 0.92 [0.72, 0.94] | 0.03 | <0.000001 |
| 3 | Mandible | 0.97 (0.97, 0.97) | 0.97 [0.94, 0.98] | 0.01 | <0.000001 |
| 4 | IAN Canal | 0.76 (0.74, 0.78) | 0.78 [0.4, 0.88] | 0.09 | <0.000001 |
| 5 | Maxillary Sinus | 0.97 (0.97, 0.98) | 0.98 [0.73, 0.99] | 0.03 | <0.000001 |
| 6 | Nasal Space | 0.9 (0.89, 0.91) | 0.91 [0.72, 0.96] | 0.04 | <0.000001 |
| 7 | Airway | 0.95 (0.94, 0.96) | 0.96 [0.58, 0.98] | 0.04 | <0.000001 |

Dentition, Maxilla, Mandible, IAN space, Sinus, Nasal space, and airway passed their individually associated threshold.[1] The Second Opinion® 3D device, has therefore been determined to accurately segment the identified anatomies based on the analysis of results with p-values below 0.05, showing statistically significant accuracy at a 95% confidence interval.

(1) Albano, D., Galiano, V., Basile, M. et al. Artificial intelligence for radiographic imaging detection of caries lesions: a systematic review. BMC Oral Health 24, 274 (2024).

## 14. Comparison to Predicate Clinical Outcomes

Primary predicate: Relu Creator

Performance bench testing of the Relu Creator software was performed utilizing a dataset of 40 CBCT scans acquired with different scanning parameters. The Relu Creator software demonstrated in a study on the segmentation of dental implants in CBCT images reported a Dice Similarity Coefficient score of 0.92±0.02, demonstrating the effectiveness of their model in accurately segmenting dental implants.These examples illustrate that

models utilizing Relu Creator can achieve high segmentation accuracy, as evidenced by substantial Dice Coefficient scores.

## 15. Conclusions

Based on the information presented above, Second Opinion® 3D and its primary predicate device, Relu Creator, are deemed to have similar intended uses as devices which aid in identifying clinically relevant anatomy in CBCT radiographs. Second Opinion® 3D's bench performance testing the results demonstrate that the device effectively performs as well as the primary predicate device.

Second Opinion® 3D 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.