



September 19, 2025

VideaHealth, Inc.  
% Adam Foresman  
Director of Quality & Regulatory Affairs  
179 South Street  
Floor 5  
Boston, MA 02111

Re: K251002

Trade/Device Name: Videa Dental AI  
Regulation Number: 21 CFR 892.2070  
Regulation Name: Medical Image Analyzer  
Regulatory Class: Class II  
Product Code: MYN  
Dated: March 13, 2025  
Received: August 18, 2025

Dear Adam Foresman:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



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

## Indications for Use

510(k) Number (if known)

K251002

Device Name

Videa Dental AI

Indications for Use (Describe)

Videa Dental AI is a computer-assisted detection (CADe) device that analyzes intraoral radiographs to identify and localize the following features. Videa Dental AI is indicated for the review of bitewing, periapical, and panoramic radiographs acquired from patients aged 3 years or older.

Suspected Dental Findings:

- Caries
- Attrition
- Broken/Chipped Tooth
- Restorative Imperfection
- Pulp Stones
- Dens Invaginatus
- Periapical Radiolucency
- Widened Periodontal Ligament
- Furcation
- Calculus

Historical Treatments:

- Crown
- Filling
- Bridge
- Post and Core
- Root Canal
- Endosteal Implant
- Implant Abutment
- Bonded Orthodontic Retainer
- Braces

Normal Anatomy:

- Maxillary Sinus
- Maxillary Tuberosity
- Mental Foramen
- Mandibular Canal
- Inferior Border of the Mandible
- Mandibular Tori
- Mandibular Condyle
- Developing Tooth
- Erupting Teeth
- Non-matured Erupted Teeth
- Exfoliating Teeth
- Impacted Teeth
- Crowding Teeth

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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)

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In accordance with 21 CFR 807.87(h) and 21 CFR 807.92 the 510(k) Summary for the Videa Dental AI device is provided below.

**1. SUBMITTER**

|                                     |                                                                                                                    |
|-------------------------------------|--------------------------------------------------------------------------------------------------------------------|
| Applicant:                          | VideaHealth, Inc.<br>179 South Street, Floor 5<br>Boston, MA, 02111<br>+1 617-340-9940<br>florian@videa.ai         |
| Contact & Submission Correspondent: | Adam Foresman<br>Director of Quality & Regulatory Affairs<br>VideaHealth, Inc.<br>+1 617-340-9940<br>adam@videa.ai |
| Date Prepared:                      | September 17, 2025                                                                                                 |

**2. DEVICE**

|                                   |                        |
|-----------------------------------|------------------------|
| Device Trade Name:                | Videa Dental AI        |
| Device Common Name:               | Dental AI System       |
| Classification Name:              | Medical image analyzer |
| Classification Regulation Number: | 21 CFR 892.2070        |
| Device Class:                     | 2                      |
| Product Code:                     | MYN                    |

**3. PREDICATE DEVICE**

|                   |                                           |
|-------------------|-------------------------------------------|
| Predicate Device: | K232384 VideaHealth's Videa Dental Assist |
|-------------------|-------------------------------------------|

#### 4. **DEVICE DESCRIPTION**

Videa Dental AI (VDA) software is a cloud-based AI-powered medical device for the automatic detection of the features listed in the Indications For Use statement in dental radiographs. The device itself is available as a service via an API (Application Programming Interface) behind a firewalled network. Provided proper authentication and an eligible bitewing, periapical or panoramic image, the device returns a set of bounding boxes and/or segmentation outlines depending on the indication representing the suspect dental finding, historical treatment or normal anatomy detected.

VDA is accessed by the dental practitioner through their dental image viewer. From within the dental viewer the user can upload a radiograph to VDA and then review the results. The device outputs a binary indication to identify the presence or absence of findings for each indication. If findings are present the device outputs the number of findings by finding type and the coordinates of the bounding boxes/segmentation outlines for each finding. If no findings are present the device outputs a clear indication that there are no findings identified for each indication. The device output will show all findings from one radiograph regardless of the number of teeth present.

The intended users of Videa Dental AI are trained dental professionals such as dentists and dental hygienists. For the suspect dental findings indications specifically, VDA is intended to be used as an adjunct tool and should not replace a dentist's review of the image. Only dentists that are performing diagnostic activities shall use the suspect dental finding indications.

VDA should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. The system is to be used by trained dental professionals including, but not limited to, dentists and dental hygienists.

Depending on the specific VDA indication for use, the intended patients of Videa Dental AI are patients 3 years of age and older above with primary, mixed and/or permanent dentition undergoing routine dental visits or suspected of one of the suspected dental findings listed in the VDA indications for use statement above. VDA may be used on eligible bitewing, periapical or panoramic radiographs depending on the indication.

See Table 1 below for the specific patient age group and image modality that each VDA indication for use is designed and tested to meet. VDA uses the images metadata to only show the indications for the patient age and image modalities in scope as shown in Table 1. VDA will not show any findings output for an indication for use that is outside of the patient age and radiographic view scope.

**Table 1: VDA Indications Scope by Patient Age and Image Modality Type**

| <b>Videa Dental Assist Indication</b> | <b>Patient Age in Scope</b> | <b>Radiographic View in Scope</b> |
|---------------------------------------|-----------------------------|-----------------------------------|
| Caries                                | 3 years and older           | Bitewing and Periapical           |
| Attrition                             | 3 years and older           | Bitewing and Periapical           |

| <b>Videa Dental Assist Indication</b>  | <b>Patient Age in Scope</b>                         | <b>Radiographic View in Scope</b>                                                                                                                                                                                                                                                 |
|----------------------------------------|-----------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Broken/Chipped                         | 3 years and older                                   | Bitewing and Periapical                                                                                                                                                                                                                                                           |
| Restorative Imperfection               | 3 years and older                                   | Bitewing and Periapical                                                                                                                                                                                                                                                           |
| Pulp Stone                             | 12+ years of age and older with permanent dentition | Bitewing and Periapical                                                                                                                                                                                                                                                           |
| Dens Invaginatus                       | 3 years & older                                     | Bitewing and Periapical                                                                                                                                                                                                                                                           |
| Periapical Radiolucency                | 22 years of age and older with permanent dentition  | Periapical only                                                                                                                                                                                                                                                                   |
| Furcation                              | 22 years of age and older with permanent dentition  | Bitewing and Periapical                                                                                                                                                                                                                                                           |
| Calculus                               | 3 years and older                                   | Bitewing and Periapical                                                                                                                                                                                                                                                           |
| Widened PDL                            | 3 years and older                                   | Bitewing and Periapical                                                                                                                                                                                                                                                           |
| Historical Treatments: All Indications | 3 years and older                                   | <p>All on Bitewing, Periapical &amp; Panoramic except:</p> <ol style="list-style-type: none"> <li>1. 'Screw' VDA historical treatment identification is only on Panoramic images.</li> <li>2. 'Plate' VDA historical treatment indication is only on Panoramic images.</li> </ol> |
| Normal Anatomy: All Indications        | 12 years and older                                  | <ol style="list-style-type: none"> <li>1. Impacted Tooth</li> <li>2. Mental Foramen</li> <li>3. Maxillary Tuberosity</li> </ol> <p>On Bitewing, Periapical &amp; Panoramic</p>                                                                                                    |

| Videa Dental Assist Indication | Patient Age in Scope | Radiographic View in Scope                                                                                                                                                 |
|--------------------------------|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                | 3 years and older    | <p>All other indications are on Bitewing, Periapical &amp; Panoramic except:</p> <p>1. 'Mandibular Condyle' VDA normal anatomy indication is only on Panoramic images.</p> |

## 5. INTENDED USE/INDICATIONS FOR USE

Videa Dental AI is a computer-assisted detection (CADE) device that analyzes intraoral radiographs to identify and localize the following features. Videa Dental AI is indicated for the review of bitewing, periapical, and panoramic radiographs acquired from patients aged 3 years or older.

### Suspected Dental Findings:

- Caries
- Attrition
- Broken/Chipped Tooth
- Restorative Imperfections
- Pulp Stones
- Dens Invaginatus
- Periapical Radiolucency
- Widened Periodontal Ligament
- Furcation
- Calculus

### Historical Treatments:

- Crown
- Filling
- Bridge
- Post and Core
- Root Canal
- Endosteal Implant
- Implant Abutment
- Bonded Orthodontic Retainer
- Braces

### Normal Anatomy:

- Maxillary Sinus

- Maxillary Tuberosity
- Mental Foramen
- Mandibular Canal
- Inferior Border of the Mandible
- Mandibular Tori
- Mandibular Condyle
- Developing Tooth
- Erupting Teeth
- Non-matured Erupted Teeth
- Exfoliating Teeth
- Impacted Teeth
- Crowding Teeth

## 6. SUBSTANTIAL EQUIVALENCE

### Comparison of Indications

Videa Dental AI has the same indications for use statement and intended use as Videa Dental Assist. The only differences are the inclusion of a second output style (segmentation in addition to bounding boxes) and a second operating point (high sensitivity and high specificity) as user toggle settings. Videa Dental AI and Videa Dental Assist both analyze dental radiographs and highlight regions of interest in an image viewer. For the VDA suspect dental finding indications, both devices are only intended as an aid to the trained professional and are not intended to replace the diagnosis by the physician.

Videa Dental AI contains historical treatment and normal anatomy indications. These indications are not intended to be diagnostic aides. They are used for general understanding of features present in a radiograph and to assist the dental practice in patient operations management. These Videa Dental AI indications do not assess quality or the need for treatment of these features.

Videa Dental AI's artificial intelligence algorithms were trained with that patient population and VideaHealth followed the pediatric medical device guidance document among other standards and guidance documents listed in Section 7 below in the design process. Videa Dental AI testing has shown to be safe and effective for patients between the ages of 3 and 21 years of age with primary, mixed or permanent dentition in the image.

Videa Dental AI artificial intelligence algorithms were trained with bitewing, periapical and panoramic radiographs. Videa Dental AI testing has shown to be safe and effective for bitewing, periapical and panoramic radiographs. Panoramic radiographs are only intended to be used on historical treatment and normal anatomy indications which are not diagnostic aides.

### Technological Comparisons

Table 2 compares the key technological feature of the subject devices to the predicate device (Videa Dental Assist., K232384).

**Table 2: Device Comparison Table**

|                                                            | <b>Proposed Device</b>                                                                                                                                                                             | <b>Proposed Device</b>                                                                                                                                                                             |
|------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>510(k) Number</b>                                       | K251002                                                                                                                                                                                            | K232384                                                                                                                                                                                            |
| <b>Applicant</b>                                           | VideaHealth, Inc.                                                                                                                                                                                  | VideaHealth, Inc.                                                                                                                                                                                  |
| <b>Device Name</b>                                         | Videa Dental AI                                                                                                                                                                                    | Videa Dental Assist                                                                                                                                                                                |
| <b>Classification Regulation</b>                           | 892.2070                                                                                                                                                                                           | 892.2070                                                                                                                                                                                           |
| <b>Product Code</b>                                        | MYN                                                                                                                                                                                                | MYN                                                                                                                                                                                                |
| <b>Image Modality</b>                                      | X-Ray                                                                                                                                                                                              | X-Ray                                                                                                                                                                                              |
| <b>Radiograph View Type</b>                                | <p>Bitewing Images, Periapical Images, and Panoramic Images.</p> <p>Radiograph view type scope is Videa Dental Assist indication specific.</p>                                                     | <p>Bitewing Images, Periapical Images, and Panoramic Images.</p> <p>Radiograph view type scope is Videa Dental Assist indication specific.</p>                                                     |
| <b>Suspect Dental Findings Indications</b>                 | <p>Caries: Active and Secondary Caries at all penetration depths</p> <p>Additional Suspect Dental Findings listed in the Videa Dental Assist's Indications For Use statement.</p>                  | <p>Caries: Active and Secondary Caries at all penetration depths</p> <p>Additional Suspect Dental Findings listed in the Videa Dental Assist's Indications For Use statement.</p>                  |
| <b>Historical Treatment and Normal Anatomy Indications</b> | Included                                                                                                                                                                                           | Included                                                                                                                                                                                           |
| <b>Tooth Surface</b>                                       | <p>For the caries indication only: Proximal, Buccal/Lingual, Occlusal, Root, Cervical.</p> <p>None of the additional VDA 'Suspect Dental Finding' indications are specific to a tooth surface.</p> | <p>For the caries indication only: Proximal, Buccal/Lingual, Occlusal, Root, Cervical.</p> <p>None of the additional VDA 'Suspect Dental Finding' indications are specific to a tooth surface.</p> |

|                               | Proposed Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Proposed Device                                                                                                                                                                                                                                     |
|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Clinical Output</b>        | <p>Message indicating if and how many findings were detected for each enabled Videa Dental AI's indication for use.</p> <p>All Videa Dental AI's indications use a set of toggleable bounding boxes around suspected areas of interest.</p> <p>The user has the option to toggle to segmentation view (also called isocontour view) instead of bounding boxes for caries and calculus.</p> <p>The user has the option to toggle between operating points (high sensitivity vs. high specificity) for a caries and periapical radiolucency.</p> <p>The user has the option to toggle normal tooth anatomy segmentations including enamel, pulp, crown dentin and root dentin on and off.</p> | <p>Message indicating if and how many findings were detected for each enabled Videa Dental Assist's indication for use.</p> <p>All Videa Dental Assist's indications use a set of toggleable bounding boxes around suspected areas of interest.</p> |
| <b>Patient Population</b>     | <p>Patients <math>\geq 3</math> years of age.</p> <p>Patient age range is Videa Dental Assist indication specific.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <p>Patients <math>\geq 3</math> years of age.</p> <p>Patient age range is Videa Dental Assist indication specific.</p>                                                                                                                              |
| <b>Intended User</b>          | Dental professionals                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Dental professionals                                                                                                                                                                                                                                |
| <b>Development Technology</b> | Supervised Deep Learning                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Supervised Deep Learning                                                                                                                                                                                                                            |
| <b>Image Source</b>           | X-Ray Sensor                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | X-Ray Sensor                                                                                                                                                                                                                                        |
| <b>Image Viewing</b>          | Image Viewer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Image Viewer                                                                                                                                                                                                                                        |

## 7. PERFORMANCE DATA

### **Biocompatibility, Sterilization, and Reprocessing**

Not applicable. The subject device is a software-only device. There are no direct or indirect patient-contacting components of the subject device. There are no sterile or reprocessed components.

### **Electrical Safety and Electromagnetic Compatibility (EMC)**

Not applicable. The subject device is a software-only device. It contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

### **Software Verification and Validation Testing**

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions."

Among others, the following standards and guidance documents were used during the Videa Dental AI design, development, and testing.

- ISO 14971:2019 Application of Risk Management to Medical Devices.
- AAMI CR34971:2022 Guidance on the Application of ISO 14971 to Artificial Intelligence and Machine Learning
- IEC 62304 Edition 1.1 2015-06 Consolidated Version: Medical Device Software - Software Life Cycle Processes
- Good Machine Learning Practice for Medical Device Development: Guiding Principles October 2021.
- *FDA Content of Premarket Submissions for Device Software Functions* (June 14, 2023)

### **Bench Testing**

A Standalone Performance Assessment was conducted to measure and report the performance of Videa Dental AI by itself, in the absence of any interaction with a dental professional in identifying the regions of interest for that specific indication. All suspect dental finding, historical treatment and normal anatomy VDA indications were in scope. The dataset was 1,445 radiographs collected from more than 35 US sites that were ground-truthed by three US board-certified dentists. The same data distribution was used for the new design of Videa Dental AI vs. the predicate Videa Dental Assist.

Because there was no lesion-detection AI training for Videa Dental AI, the predicate Videa Dental Assist generalizability analysis for lesion detection still applies. Generalizability was not reperformed for this analysis.

The bench study results were:

- VDA caries had a DICE of 0.720 and calculus had a DICE of 0.716 respectively.
- The normal tooth anatomy segmentations the following DICE statistics.
  - Enamel is 0.907
  - Pulp is 0.825
  - Crown Dentin is 0.878
  - Root Dentin is 0.874

## Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence.

## Clinical Testing

A fully crossed, randomized, multiple reader multiple case (MRMC) controlled study was performed to determine whether the diagnostic accuracy of readers aided by VDA is superior to reader accuracy when unaided by VDA, as determined by the AFROC Figure of Merit (AFROC FOM). The hypothesis to be tested is:

$$H_0: \text{AFROC FOM}_{\text{aided}} - \text{AFROC FOM}_{\text{unaided}} \leq 0$$

$$H_1: \text{AFROC FOM}_{\text{aided}} - \text{AFROC FOM}_{\text{unaided}} > 0$$

where  $\text{AFROC FOM}_{\text{aided}}$  is the population-mean AFROC FOM for aided reads, and similarly with  $\text{AFROC FOM}_{\text{unaided}}$  for unaided reads.

Suspect dental finding VDA indications that had segmentation view and/or a second operating point were in scope of the clinical test. The other indications are unchanged from the predicate Videa Dental Assist's clinical test results. Clinical testing was performed on 378 radiographs collected from over 25 US locations spread across the country. US licensed dentists labeled the data and a US licensed dentist adjudicated those labels to establish a reference standard for the study.

There were N=20 readers that participated in the study and reviewed all images with and without VDA AI predictions in a randomized fashion.

The patients in the dataset were 24% female and 21% male, 15% other and 39% unknown. There were N=6 sensor manufacturers that had enough samples to perform generalizability statistical analysis on. Those image sensor manufacturers were: AirTechniques, Carestream, Dexis, Gendex, Kavo, and Schick. Tables 5 and 6 describe the distribution of the study for the two significant design input expansions between Videa Dental AI and the predicate Videa Dental Assist; patient age and radiographic view.

**Table 5: Demographic breakdown by age**

| <b>Subject Age (Years)</b> | <b>Percentage</b> |
|----------------------------|-------------------|
| 3 - 11                     | 28%               |
| 12 - 21                    | 20%               |
| 22 - 40                    | 14%               |
| 41 - 60                    | 14%               |
| 61 and older               | 8%                |
| Unknown                    | 15%               |

All images, regardless of patient age, were classified as being primary dentition only, mixed dentition and permanent dentition only.

**Table 6: Image breakdown by radiographic view**

| <b>Radiographic View</b> | <b>Percentage</b>  |
|--------------------------|--------------------|
| Bitewing                 | 56%                |
| Periapical               | 44%                |
| Panoramic                | N/A. Not in scope. |

Across 8 Videa Dental AI Suspect Dental Finding indications in the clinical study, there was no statistically significant difference between bounding box and segmentation view types in detection performance. The average amount of aided improvement over unaided performance across these 8 VDA indications was 0.002%. Additionally none of the 8 VDA indications individually had a statistically significant difference between bounding box or segmentation.

The caries and periapical radiolucency VDA indications in the clinical study with a second operating point all showed that clinicians had statistically significant improvement in detection performance regardless of the operating point used. Some clinicians performed better at one setting than the other however all showed clinical benefit regardless of the operating point used. VDA caries had a standalone specificity of 0.867 for caries' and 0.989 for PRL' second operating points respectively.

No adverse events were observed during the clinical study. Clinical testing demonstrated that the Videa Dental AI meets performance requirements.

## Conclusion

There are no differences in design input scopes between Videa Dental AI and Videa Dental Assist. They also have the same indications for use statements and intended uses. The design changes for the differences between Videa Dental AI and the predicate do not raise different questions of safety and effectiveness as shown in the Videa Dental AI testing. There was no retraining between Videa Dental AI and Videa Dental Assist in the AI model lesion localization identification or other technological differences that raise different questions of safety and effectiveness.

Although there are differences in the testing methodology (namely the inclusion of segmentation view type and a second operating point for certain VDA indications), they do not raise different questions of safety and effectiveness. The calculations methodology for sensitivity, specificity, Alternative Free-response Receiver Operating Characteristic Figure of Merit (AFROC FOM) and other statistical techniques are the same between Videa Dental AI and Videa Dental Assist. Both Videa Dental AI and Videa Dental Assist had the same clinical study acceptance criteria. The results of the bench testing and clinical testing demonstrate that the performance of Videa Dental AI is comparable to that of Videa Dental Assist. Both Videa Dental AI and Videa Dental Assist met their acceptance criteria. Therefore, Videa Dental AI can be found substantially equivalent to Videa Dental Assist.