December 15, 2023

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

Re: K232384
Trade/Device Name: Videa Dental Assist
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: July 31, 2023
Received: August 8, 2023

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.

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 Radiologic 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)*
K232384

Device Name
Videa Dental Assist

Indications for Use *(Describe)*
Videa Dental Assist is a computer-assisted detection (CADe) device that analyzes intraoral radiographs to identify and localize the following features. Videa Dental Assist 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 Teeth
- Erupting Teeth
- Non-matured Erupted Teeth
- Exfoliating Teeth
- Impacted Teeth
- Crowding Teeth

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

1. SUBMITTER

Applicant:	VideaHealth, Inc. 179 South Street, Floor 5 Boston, MA, 02111 +1 617-340-9940 florian@videa.ai
Contact & Submission Correspondent:	Adam Foresman Director of Quality & Regulatory Affairs VideaHealth, Inc. +1 617-340-9940 adam@videa.ai
Date Prepared:	July 31, 2023

2. DEVICE

Device Trade Name:	Videa Dental Assist
Device Common Name:	Dental AI System
Classification Name:	Medical Image Analyzer
Classification Regulation Number:	21 CFR 892.2070
Device Class:	2
Product Code:	MYN

PREDICATE DEVICE

Device Trade Name:	Videa Caries Assist
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:	K213795 VideaHealth's Videa Caries Assist (VCA)

4. Device Description

Videa Dental Assist (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 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 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 Assist 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 Assist 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

Videa Dental Assist Indication	Patient Age in Scope	Radiographic View in Scope
Caries	3 years and older	Bitewing and Periapical
Attrition	3 years and older	Bitewing and Periapical
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 Periodontal Ligament	3 years and older	Bitewing and Periapical
Historical Treatments: All Indications	3 years and older	All on Bitewing, Periapical and Panoramic
Normal Anatomy: All Indications	12 years and older	1. Impacted Tooth 2. Mental Foramen 3. Maxillary Tuberosity On Bitewing, Periapical & Panoramic

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

5. INTENDED USE/INDICATIONS FOR USE

Videa Dental Assist is a computer-assisted detection (CADe) device that analyzes intraoral radiographs to identify and localize the following features. Videa Dental Assist 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 Assist is an expansion of the design input scope of Videa Caries Assist. Videa Dental Assist and Videa Caries 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. Both devices are intended to assist dental professionals by identifying caries regions of interest. Videa Dental Assist's Indication For Use includes additional description on the output of the device which is not a safety or efficacy concern.

Videa Dental Assist contains historical treatment and normal anatomy indications whereas Videa Caries Assist does not. 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 Assist indications do not assess quality or the need for treatment of these features. Therefore for these Videa Dental Assist indications, dental professionals are included in the intended user scope whereas Videa Caries Assist is limited to dentists as the intended user.

The difference in patient ages does not constitute a safety or efficacy concern. Videa Dental Assist 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 Assist testing has shown to be safe and effective for patients between 3 and 21 years of age with primary, mixed or permanent dentition in the image.

The difference in radiographic views does not constitute a safety or efficacy concern. Videa Dental Assist artificial intelligence algorithms were trained with bitewing, periapical and panoramic radiographs. Videa Dental Assist testing has shown to be safe and effective for bitewing, periapical and panoramic radiographs. Additionally 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 Caries Assist, K213795).

Table 2: Device Comparison Table

	Proposed Device	**Predicate Device**
510(k) Number	TBD	K213795
Applicant	VideaHealth, Inc.	VideaHealth, Inc.
Device Name	Videa Dental Assist	Videa Caries Assist
Classification Regulation	892.2070	892.2070
Product Code	MYN	MYN
Image Modality	X-Ray	X-Ray
Radiograph View Type	Bitewing Images, Periapical Images, and Panoramic Images. Radiograph view type scope is Videa Dental Assist indication specific.	Bitewing Images
Suspect Dental Findings Indications	Caries: Active and Secondary Caries at all penetration depths Additional Suspect Dental Findings listed in the Videa Dental Assist's Indications For Use statement.	Caries: Active and Secondary Caries at all penetration depths.
Historical Treatment and Normal Anatomy Indications	Included	Not Included

	Proposed Device	**Predicate Device**
Tooth Surface	For the caries indication only: Proximal, Buccal/Lingual, Occlusal, Root, Cervical. None of the additional VDA 'Suspect Dental Finding' indications are specific to a tooth surface.	Caries: Proximal, Buccal/Lingual, Occlusal, Root, Cervical.
Clinical Output	Message indicating if and how many findings were detected for each enabled Videa Dental Assist's indication for use. All Videa Dental Assist's indications use a set of togglable bounding boxes around suspected areas of interest.	Message indicating if and how many carious lesions were detected. Set of togglable bounding boxes around suspected lesions.
Patient Population	Patients ≥ 3 years of age. Patient age range is Videa Dental Assist indication specific.	Adults ≥ 22 years of age
Intended User	Dental professionals	US licensed dentists
Development Technology	Supervised Deep Learning	Supervised Deep Learning
Image Source	X-Ray Sensor	X-Ray Sensor
Image Viewing	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, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a moderate level of concern.

Among others, the following standards and guidance documents were used during the Videa Dental Assist 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 Premarket Assessment of Pediatric Medical Devices Guidance Document (*March 24, 2014)

Bench Testing

A Standalone Performance Assessment was conducted to measure and report the performance of Videa Dental Assist 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 patients in the dataset were 18% female and 17% male, 16% other and 48% unknown. There were N=17 sensor manufacturers in the study and 8 sensor manufacturers had enough samples to perform generalizability statistical analysis on. Those image sensors were: AirTechniques, Carestream, Dexis, Gendex, Kavo, Schick, PaloDex Group, and Sirona. Tables 3 and 4 describe the distribution of the study for the two significant design input expansions between Videa Dental Assist and the predicate Videa Caries Assist; patient age and radiographic view.

Table 3: Demographic breakdown by age

Subject Age (Years)	Percentage
3 - 11	13%
12 - 21	15%
22 - 40	19%
41 - 60	19%
61 and older	16%
Unknown	18%

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

Table 4: Image breakdown by radiographic view

Radiographic View	Percentage
Bitewing	45%
Periapical	43%
Panoramic	12%

Tables 5, 6 and 7 contain the sensitivity and specificity for all Videa Dental Assist indications from the bench study. All of these sensitivity and specificity results met their acceptance criteria.

All of VDA indications' standalone performance was assessed against the following potential patient, device input and image confounders: age, gender, image dentition type, radiograph view type, image quality, imaging sensor manufacturer, bit-depth, image size, and image clinic acquisition location among others.

Additionally VDA indication-specific standalone performance was assessed against the following potential subject and image confounders:

- Caries type, severity, location and specific tooth dentition type
- Periapical radiolucency type
- Crown material type
- Filling material type
- Onlay or inlay material type
- Bridge material type
- Root canal material type

The bench study results were:

- All VDA historical treatment and normal anatomy indications that were included in the indications for use statement above met their sensitivity and specificity acceptance criteria. All specificity values for all historical treatment and normal anatomy indications were above their acceptance criteria regardless of their prevalence rates.
- All VDA suspect dental findings indications met their sensitivity and specificity acceptance criteria with the exception of caries specificity. Caries specificity was the only to not pass the target however performed well enough to still pass the clinical study

Additional statistical analysis were performed for each VDA indication including the VDA's false positive fraction rate, non-lesion fraction, and positive predictive value.

Generalizability was observed for all confounders and warnings and limitations were listed in the Instructions For Use where necessary. The generalizability analysis results and related information including a list of types (such as material types) are in the Videa Dental Assist Instructions For Use for users.

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: AFROC FOM_{aided} - AFROC $FOM_{unaided} \leq 0$

H_1: AFROC FOM_{aided} - AFROC $FOM_{unaided} > 0$

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

All suspect dental finding VDA indications were in scope of the clinical test. 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=26 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 Assist and the predicate Videa Caries Assist; patient age and radiographic view.

Table 5: Demographic breakdown by age

Subject Age (Years)	Percentage
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

Radiographic View	Percentage
Bitewing	56%
Periapical	44%
Panoramic	N/A. Not in scope.

Table 7 contains the AFROC FOM results for all Videa Dental Assist indications in the clinical study. All of these results met their acceptance criteria.

Table 7: Clinical Performance Metrics of VDA by radiographic view type and line type.

Videa Dental Assist Indication	Average Percentage Improvement With VDA (VDA Aided vs. Unaided Mean AFROC FOM)
Attrition	0.171 (28.5% improvement; p-value 3.3e-16)
Broken or Chipped	0.105 (15.3% improvement; p-value 1.5e-11)

Videa Dental Assist Indication	Average Percentage Improvement With VDA (VDA Aided vs. Unaided Mean AFROC FOM)
Calculus	0.163 (23.0% improvement; p-value e-12)
Caries	0.024 (4.3% improvement; p-value 0.0085)
Dens Invaginatus	0.236 (36.8% improvement; p-value 1.9e-9)
Furcation	0.199 (29.7% improvement; p-value 0.00057)
Periapical Radiolucency	0.092 (11.5% improvement; p-value 0.0072)
Pulp Stone	0.211 (35.4% improvement; p-value 2.2e-16)
Restorative Imperfection	0.164 (27.9% improvement p-value of <1e-16)
Widened Periodontal Ligament	0.141 (28.4% improvement; p-value of 9.6e-13)
Historical Treatments: All Indications	Not applicable. Not a clinical diagnostic aide.
Normal Anatomy: All Indications	Not applicable. Not a clinical diagnostic aide.

All of VDA indications' clinical performance was assessed against the following potential patient, device input and image confounders among others: age, sex, clinician experience level in years of practice, image dentition type, radiograph view type, image quality, imaging sensor manufacturer, bit-depth, image size, and image clinic acquisition location.

Additionally VDA indication-specific clinical performance was assessed against the following potential lesion and image confounders:

- Caries type, severity, location and tooth dentition type
- 'Periapical Radiolucency' type

Additional statistical analysis were performed for each VDA indication including the VDA stand-alone Alternative Free-response Receiver Operating Characteristic Figure of Merit (AFROC FOM), false positive fraction rate, non-lesion fraction, and positive predictive value.

Because multiple indications were being tested in parallel, VideaHealth performed a multiple endpoint statistical analysis using the FDA's *Multiple Endpoints in Clinical Trials Guidance for Industry* (October 2022). Per the guidance, this minimizes the chances of a falsely favorable conclusion for any primary endpoint due to Type 1 error, regardless of which and how many of these endpoints in the study have no effect. VideaHealth performed a Holms analysis according to the FDA guidance document and determined that this Type 1 error risk across all VDA suspect dental finding indications is acceptable. A Type 1 error of 0.05 was used for this analysis (I.E. the probability of falsely finding a favorable effect on at least one primary endpoint (VDA indication) is approximately 0.05). The VDA suspect dental findings indications were verified as being independent for this analysis.

Generalizability was observed for all confounders and warnings and limitations were listed in the Instructions For Use where necessary. The clinical testing confirmed that the patient age ranges listed above are appropriate. The generalizability analysis results and related information are in the Videa Dental Assist Instructions For Use for users.

The primary device expansions of VDA over the predicate VCA include adding periapical radiographs and the pediatric patient population. The AFROC analysis for those two device expansions are provided below. These analyses are reference only, therefore no p-values are provided. These tables were a part of the generalizability assessment, but not the primary acceptance criteria, portion of the clinical study.

AFROC Scores On Periapical Radiographs

VDA Suspect Dental Finding Indication	Average Percentage Improvement With VDA (VDA Aided vs. Unaided Mean AFROC FOM)
Attrition	0.157 (25.9% improvement)
Broken/Chipped Tooth	0.075 (10.4% improvement)
Calculus	0.207 (31.1% improvement)
Caries	0.031 (5.0% improvement)
Dens Invaginatus	0.216 (34.2% improvement)
Furcation	0.187 29.3% improvement)

VDA Suspect Dental Finding Indication	Average Percentage Improvement With VDA (VDA Aided vs. Unaided Mean AFROC FOM)
Periapical Radiolucency	N/A. See table above on the overall PRL indication level results. PRL is only applicable on periapical radiographs so there is no subgroup analysis to perform.
Pulp Stones	0.244 (39.8% improvement)
Restorative Imperfections	0.167 (28.2% improvement)
Widened PDL	0.120 (24.4% improvement)

AFROC Scores On Pediatric Patients (Ages 3 to 21 Years of Age Unless Otherwise Noted)

VDA Suspect Dental Finding Indication	Average Percentage Improvement With VDA (VDA Aided vs. Unaided Mean AFROC FOM)	Notes
Attrition	0.199 (35.3% improvement)	None
Broken/Chipped Tooth	0.125 (18.4% improvement)	None
Calculus	0.230 (37.0% improvement)	Calculus is only intended for patients 12 years of age and older.
Caries	0.028 (5.2% improvement)	None
Dens Invaginatus	0.247 (39.3% improvement)	None
Furcation	N/A	Furcation is only intended for patients 22 years of age and older.
Periapical Radiolucency	N/A	Periapical radiolucency is only intended for patients 22 years of age and older.

VDA Suspect Dental Finding Indication	Average Percentage Improvement With VDA (VDA Aided vs. Unaided Mean AFROC FOM)	Notes
Pulp Stones	0.196 (33.2% improvement)	Pulp Stones indication is only intended for patients 12 years of age and older.
Restorative Imperfections	0.231 (39.4% improvement)	None
Widened PDL	0.131 (26.1% improvement)	None

No adverse events were observed during the clinical study.

Clinical testing demonstrated that the Videa Dental Assist meets performance requirements.

Conclusion

There are differences in design input scopes between Videa Dental Assist and Videa Caries Assist namely the indications, patient population, and radiograph view types. As shown in the Videa Dental Assist testing these differences do not raise different questions of safety and efficacy. There are no significant differences between Videa Dental Assist and Videa Caries Assist in the AI model training methodology or other technological differences that raise different questions of safety and efficacy.

Although there are differences in the testing methodology (namely the use of an adjudicator in addition to ground truthers for VDA that was not used for VCA to identify smaller or more subtle findings), they do not raise different questions of safety and efficacy. 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 Assist and Videa Caries Assist. Both Videa Dental Assist and Videa Caries Assist had the same clinical study acceptance criteria. The results of the bench testing and clinical testing demonstrate that the performance of Videa Dental Assist is comparable to that of Videa Caries Assist. Both Videa Dental Assist and Videa Caries Assist met their acceptance criteria. Therefore, Videa Dental Assist can be found substantially equivalent to Videa Caries Assist.