February 6, 2023

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

Re: K223296
Trade/Device Name: Videa Perio Assist
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: January 5, 2023
Received: January 6, 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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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
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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)*
K223296

Device Name
Videa Perio Assist

Indications for Use *(Describe)*
Videa Perio Assist is a radiological semi-automated image processing software device intended to aid dental professionals in the measurements and visualization of mesial and distal bone levels associated with each tooth from bitewing and periapical radiographs. Measurements are made available as linear distances or relative percentages.

It 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 professionals including, but not limited to, dentists and dental hygienists.

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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In accordance with 21 CFR 807.87(h) and 21 CFR 807.92 the 510(k) Summary for the Videa Perio 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:	October 14, 2022

2. DEVICE

Device Trade Name:	Videa Perio Assist
Device Common Name:	Interproximal bone level measurement
Classification Name	Medical image management and processing system
Classification Regulation Number	21 CFR 892.2050
Device Class:	2
Product Code:	QIH

3. PREDICATE DEVICE

Predicate Device:	K210187 Overjet Dental Assist (Overjet, Inc.)

4. Device Description

Videa Perio Assist (VPA) software is a cloud-based AI-powered medical device for the automatic measurement of tooth interproximal alveolar bone level in dental radiographs. The device itself is available as an API (Application Programming Interface) behind a firewalled network. The device returns 1) a series of points with connecting lines measuring the mesial and distal alveolar bone levels associated with each tooth 2) this distance expressed in millimeters and/or as a percentage of the root length.

Videa Perio Assist is accessed by the trained professional through their image viewer. From within the image viewer the user can upload a radiograph to Videa Perio Assist and then review the results. The device outputs a line to identify these points which calculate the interproximal bone level.

The device output will show all applicable measurements from one radiograph regardless of the number of teeth present. If no teeth are present the device outputs a clear indication that there are no identifiable teeth to calculate the interproximal bone level.

The intended users of Videa Perio Assist are trained professionals such as dentists and dental hygienists.

The intended patients of Videa Perio Assist are patients 12 years and above with permanent dentition undergoing routine dental visits or suspected of having interproximal bone level concerns. Videa Perio Assist may only be used with patients with permanent dentition present in the radiograph.

5. Intended Use/Indications for Use

Videa Perio Assist is a radiological semi-automated image processing software device intended to aid dental professionals in the measurements and visualization of mesial and distal bone levels associated with each tooth from bitewing and periapical radiographs. Measurements are made available as linear distances or relative percentages.

It 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 professionals including, but not limited to, dentists and dental hygienists.

6. Substantial Equivalence

Comparison of Indications

Overjet Dental Assist and Videa Perio Assist both analyze dental radiographs and measure interproximal bone level. 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 and measuring interproximal bone levels on dental radiographs. Videa Perio Assist's Indication For Use includes additional description on the output of the device which is not a safety or efficacy concern.

The difference in patient ages does not constitute a safety or efficacy concern as both devices limit use to permanent dentition patients, Videa Perio Assist artificial intelligence algorithm was trained with that patient population and the Videa Perio Assist testing has shown to be safe and effective for patients between the ages of 12 and 22 years of age with permanent dentition present in the radiograph. Likewise the image format differences are not a safety or efficacy concern as Videa Perio Assist has performed all required training and testing with the image formats listed in Table 1.

Technological Comparisons

Table 1 compares the key technological feature of the subject devices to the predicate device (Overjet Inc., K210187).

Table 1: Device Comparison Table

	Proposed Device	**Predicate Device**
510(k) Number	TBD	K210187
Applicant	VideaHealth, Inc.	Overjet, Inc.
Device Name	Videa Perio Assist	Overjet Dental Assist
Classification Regulation	892.2050	892.2050
Product Code	QIH	LLZ
Image Modality	X-Ray	X-Ray
Study Type	Bitewing and periapical Images	Bitewing and periapical Images
Patient Population	Patients ≥12 years of age with permanent dentition present in the radiograph	Adults ≥ 22 years of age
OS	Any	Any
Intended User	Dentists and dental hygienists	Dentists and dental hygienists
Image Input Source	Images imported from the radiographic device, or from the practice management system	Images imported from the radiographic device, or from the practice management system

	Proposed Device	Predicate Device
Image Format	DICOM, rvg, png, tiff, jpg, jpeg, dex	jpg, png, jfif, eop, etp, jif
Includes Image Measurement tools	Linear distance	Linear distance

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.

Bench Testing

Non-clinical bench testing was performed on 996 radiographs and 16,131 landmarks. Bitewing and periapical radiographs were ground truth labeled across two phases. The Videa Perio Assist measurement results where scored versus ground-truthed landmarks. Bench testing demonstrated that the Videa Perio Assist meets performance requirements.

The acceptance criteria was as follows:

- A recall greater than 82%
- A precision greater than 82%

VPA met pre-specified acceptance criteria on bitewing radiographs with a recall of 94.4% and precision of 84.3%.

VPA met pre-specified acceptance criteria on periapical radiographs with a recall of 91.9%. In the CEJ-ABL subgroup study, participants were more likely to estimate an obscured interproximal bone level point on overlapping teeth and the precision was 79.1%.

Bench testing has sensor manufacturer and patient age subgroup analysis for generalizability in a similar method as described in the clinical study generalizability section below. The sensor manufacturer and patient age did not have any outliers in the bench study.

Animal Testing

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

Clinical Testing

Clinical testing was performed on 189 radiographs and analyzed over 2,350 lines. US licensed dentists labeled data across two phases, and two US licensed periodontists adjudicated those labels to establish a reference standard for the study. These final results were analyzed against the Videa Perio Assist predictions.

Table 2: Demographic breakdown by age

Subject Age	Percentage
12 - 21	31%
22 - 40	35%
41 - 60	21%
61 - 75	9%
75 +	4%

Table 3: Demographic breakdown by gender

Subject Gender	Percentage
Male	47%
Female	53%

Table 4: Intraoral sensor breakdown by manufacturer

Sensor Manufacturer	Percentage
Dentsply Sirona	13%
KaVo Kerr	48%
Carestream Dental	39%

There were seven intraoral sensor models across these three manufacturers.

Ethnicity data was not available for the radiographs.

The acceptance criteria was as follows:

- A sensitivity greater than 82%
- A specificity greater than 81%
- A mean absolute error less than 1.5mm

VPA met pre-specified acceptance criteria on bitewing radiographs with a sensitivity of 92.8%, specificity of 89.4% and mean absolute error below the thresholds.

VPA met pre-specified acceptance criteria on periapical radiographs with a sensitivity of 88.3%, specificity of 87.0% and mean absolute error below the thresholds. All subgroups except for periapical CEJ-ABL, where study participants were more likely to estimate an obscured interproximal bone level point on overlapping teeth, met the pre-specified acceptance criteria.

Table 5: Clinical Performance Metrics of VPA by radiographic view type and line type.

Radiographic View Type	Line Type	Sensitivity (%)	Specificity (%)	Mean Absolute Error (mm)
Bitewing	*CEJ->ABL*	Met acceptance criteria	Met acceptance criteria	Met acceptance criteria
Periapical	*All*	Met acceptance criteria	Met acceptance criteria	Met acceptance criteria
	CEJ->ABL	Met acceptance criteria	Did not meet acceptance criteria	Met acceptance criteria
	CEJ->RT	Met acceptance criteria	Met acceptance criteria	Met acceptance criteria
	ABL->RT	Met acceptance criteria	Met acceptance criteria	Met acceptance criteria

No adverse events were observed during the clinical study.

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

Generalizability

The intraoral sensor manufacturer and patient age influence on bench testing and clinical testing results was assessed for Videa Perio Assist's generalizability.

The results for the clinical testing analysis are in Table 6 and Table 7. For both tables, the generalizability acceptance criteria was met if the metric's mean met the respective target acceptance criteria threshold (for example if 'patient's 12 to 21 years of age' subgroup's analysis was greater than or containing 82% for sensitivity).

Table 6: Clinical Performance Metrics of VPA by intraoral sensor manufacturer across all models.

Radiographic View Type	Dentsply Sirona	KaVo Kerr	Carestream Dental
Bitewing Measurements	Met acceptance criteria for sensitivity and mean absolute error. Specificity did not meet acceptance criteria.	Met acceptance criteria for all 3 metrics	Met acceptance criteria for all 3 metrics
Periapical Measurements	Met acceptance criteria for all 3 metrics	Met acceptance criteria for all 3 metrics	Met acceptance criteria for all 3 metrics

In both the bench and clinical studies, statistical analysis by sensors demonstrated a high level of generalizability. No sensor manufacturers or models were clear outliers. From Table 6, the VPA device missed the acceptance criteria for specificity in the Sirona sensors on bitewing radiographs vs. the acceptance criteria. This is not a safety or effectiveness concern as this does not impact the millimeter accuracy when a prediction is made.

Table 7: Clinical Performance Metrics of VPA by patient age.

Radiographic View Type	Patients 12 to 21 Years of Age	Patients 22 to 40 Years of Age	Patients 41 to 60 Years of Age	Patients 61 Years of Age and Older
Bitewing Measurements	Met acceptance criteria for all 3 metrics	Met acceptance criteria for all 3 metrics	Met acceptance criteria for all 3 metrics	Met acceptance criteria for sensitivity and mean absolute error. Specificity did not meet acceptance criteria.
Periapical Measurements	Met acceptance criteria for all 3 metrics	Met acceptance criteria for all 3 metrics	Met acceptance criteria for all 3 metrics	Met acceptance criteria for all 3 metrics

In both the bench and clinical studies, statistical analysis by patient age demonstrated a high level of generalizability. No patient age group was a clear outlier. From Table 7, the VPA device missed the acceptance criteria for specificity in the ‘Patients 61 Years and older’ on bitewing radiographs vs. the acceptance criteria. This is not a safety or effectiveness concern as this does not impact the millimeter accuracy when a prediction is made.

Conclusion

There are technological differences, as discussed above these differences in technological characteristics do not raise different questions of safety and efficacy. Although the exact definition of a pass or fail for sensitivity and specificity calculations may differ between OverJet Dental Assist and VideaHealth, the results of the bench testing and clinical testing demonstrate that the performance of Videa Perio Assist is comparable to that of Overjet Dental Assist. Both Overjet Dental Assist and Videa Perio Assist met their acceptance criteria and both did not pass a specific subgroup on periapical images where tooth overlap was common. Therefore, Videa Perio Assist can be found substantially equivalent to Overjet Dental Assist.