April 21, 2022

VideaHealth, Inc
% Donna-Bea Tillman
Senior Consultant
Biologics Consulting Group
1555 King St, Suite 300
ALEXANDRIA VA 22314

Re: K213795
Trade/Device Name: Videa Caries Assist
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: March 23, 2022
Received: March 24, 2022

Dear Donna-Bea Tillman:

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K213795

Device Name
Videa Caries Assist

Indications for Use *(Describe)*
Videa Caries Assist is a computer-assisted detection (CADe) device that analyzes intraoral radiographs to identify and localize carious lesions. Videa Caries Assist is indicated for use by board licensed dentists for the concurrent review of bitewing (BW) radiographs acquired from adult patients aged 22 years or older.

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 Caries Assist device is provided below.

1. SUBMITTER

Applicant:	VideaHealth, Inc. 19 Kingston St, Floor 3 Boston, MA, 02114 +1 617-340-9940 florian.hillen@videahealth.io
Contact:	Florian Hillen CEO and Founder VideaHealth, Inc. 617-528-8643 florian.hillen@videahealth.io
Submission Correspondent:	Donna-Bea Tillman, Ph.D. Senior Consultant Biologics Consulting 1555 King St, Suite 300 Alexandria, VA 22314 410-531-6542 dtillman@biologicsconsulting.com

Date Prepared: March 23, 2022

2. DEVICE

Device Trade Name:	Videa Caries Assist
Device Common Name:	Medical Image Analyzer
Classification Name	21 CFR 892.2070 Analyzer, Medical Image
Regulatory Class:	2
Product Code:	MYN

3. PREDICATE DEVICE

Predicate Device: P980025 Logicon Caries Detection Software (Carestream Dental LLC)

4. DEVICE DESCRIPTION

Videa Caries Assist (VCA) software is a cloud-based AI-powered medical device for the automatic detection of carious lesions 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 a bitewing image, the device returns a set of bounding boxes representing the carious lesions detected.

VCA is accessed by the dental practitioner through their Dental Viewer. From within the Dental Viewer the user can upload a radiograph to VCA and then review the results. The device outputs a binary indication to identify the presence or absence of findings. If findings are present the device outputs the coordinates of the bounding boxes for each finding. If no findings are present the device outputs a clear indication that there are no carious lesions identified.

5. INTENDED USE/INDICATIONS FOR USE

Videa Caries Assist is a computer-assisted detection (CADe) device that analyzes intraoral radiographs to identify and localize carious lesions. Videa Caries Assist is indicated for use by board licensed dentists for the concurrent review of bitewing (BW) radiographs acquired from adult patients aged 22 years or older.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

Logicon Caries Detector and Videa Caries Assist both analyze dental radiographs and identify regions of interest. Logicon Caries Detector aids in diagnosis of caries that have penetrated in the dentin for each tooth, where Videa Caries Assist detects carious lesions for all types of caries lesions. However, both devices are only intended as an aid to the physician and not intended to replace the diagnosis by the physician. The differences in Indications for Use do not constitute a new intended use, as both devices are intended to assist dental professional by identifying and marking Regions of Interest (ROI) in dental radiographs.

Technological Comparisons

Table 1 compares the key technological feature of the subject devices to the predicate device (Logicon Caries Detector, P980025).

Table 1: Technological Comparison

	Proposed Device	**Predicate Device**
510(k) Number	TBD	P980025
Applicant	VideaHealth, Inc.	Carestream Dental LLC
Device Name	Videa Caries Assist	Logicon Caries Detector
Classification Regulation	892.2070	892.2070

	Proposed Device	Predicate Device
Product Code	MYN	MYN
Indications for Use	Videa Caries Assist is a computer-assisted detection (CADe) device that analyzes intraoral radiographs to identify and localize carious lesions. Videa Caries Assist is indicated for use by board licensed dentists for the concurrent review of bitewing (BW) radiographs acquired from adult patients aged 22 years or older.	Logicon Caries Detector is a software device that is an aid in the diagnosis of caries that have penetrated into the dentin on un-restored proximal surfaces of secondary dentition through the statistical analysis of digital intra-oral radiographic imagery. The device provides additional information for the clinician to use in his/her diagnosis of a tooth surface suspected of being carious. It is designed to work in conjunction with an existing CareStream Dental RVG Digital X-Ray Radiographic System with Dental Imaging Software (DIS) for Windows XP or higher.
Image Modality	X-Ray	X-Ray
Study Type	Bitewing Images	Digital intra-oral radiographic imagery
Clinical Finding	Active and Secondary Caries at all penetration depths	Caries penetrating into dentin
Tooth Surface	Proximal, Buccal/Lingual, Occlusal, Root, Cervical	Proximal
Clinical Output	Message indicating if and how many carious lesion were detected Set of togglable bounding boxes around suspected lesions	Message indicating if a carious lesion was detected. An outline of the potential lesion site is shown
Patient Population	Adults ≥ 22 years of age	Adults ≥ 22 years of age
Intended User	US licensed dentists	Dentists
Development Technology	Supervised Deep Learning	Computer Vision
Image Source	X-Ray Sensor	X-Ray Sensor
Image Viewing	Image Viewer	CareStream Dental RVG Digital X-Ray Radiographic System with Dental Imaging Software (DIS)

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 (Standalone Study)

A Standalone Performance Assessment was conducted to measure and report the performance of Videa Caries Assist by itself, in the absence of any interaction with a dentist. The dataset was 1034 adult radiographs collected from 10 US sites that were ground-truthed by three US board-certified dentists. The patients in the dataset were 53% female and 47% male, with 55% having age 22-40, 34% age 41-60, 9% age 61-75, and 2% over age 76. The number of lesions per image was: 0 lesions (39%), 1 lesions (22%), 2-3 lesions (26%), and 4+ lesions (13%). Image sensors included in the study were: DEXIS Platinum, DEXIS Titanium, Gendex GXS-700, Kodak RVG, 6100, RVG 5200, RVG 6200, and Schick 33.

The standalone overall average Alternative Free-response Receiver Operating Characteristic Figure of Merit (AFROC FOM) was found to be 0.740 (95% confidence interval: 0.721, 0.760) with a corresponding average image-based Sensitivity of 70.8% and PPV of 59.5% (Table 2).

Table 2: Standalone: AFROC FOM, Image-based Se, PPV. Lesion-based estimates in *italics*.

	Mean	**95% Confidence Interval**
Overall average FOM	0.740	(0.721, 0.760)
Overall average Se - image-based (%)	70.8	(68.0, 73.7)
Overall average PPV - image-based (%)	59.5	(56.5, 62.5)
Overall average Se (%) - lesion-based (pooled)	*73.6*	*(71.1, 76.0)*
Overall average PPV (%) - lesion-based (pooled)	*64.9*	*(62.3, 67.6)*

We observed a False Positive Fraction FPF of 0.335 and a Non-Lesion Fraction of 0.599 Comparing these results with the results from the readers study shows a decrease in the absolute number of false positives per image.

VCA's standalone performance was assessed against the following potential subject and image confounders: age, sex, number of lesions per image, image quality, imaging sensor model, effective resolution, bit-depth, and image size. We observed very good generalizability for all confounders with the exception of image sensor model, with all reported confidence intervals including 0.74, the average AFROC FOM calculated on the full dataset. We did observe a somewhat lower average AFROC FOM of 0.608 for the Schick 33 sensor. However, when we performed a sub-analysis of the reader study results for the Schick 33 images (n=28), we found a lower unaided reader performance for this sensor versus the mean performance across all sensors, and an improvement in mean AFROC FOM performance for aided (0.706) versus unaided (0.614) reads that was very similar to what was seen for the entire study dataset alleviating any concerns.

Animal Testing

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

Clinical Data (Reader Study)

A fully crossed randomized, multiple reader multiple case (MRMC) controlled study was performed to determine whether the diagnostic accuracy of readers aided by VCA is superior to reader accuracy when unaided by VCA, 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.

The dataset was 226 adult radiographs collected from 10 US sites that were ground-truthed by three US board-certified dentists. The patients in the dataset were 55% female and 45% male, with 49% having age 22-40, 38% age 41-60, 11% age 61-75, and 6% over age 76. Image sensors included in the study were: DEXIS Platinum, DEXIS Titanium, Gendex GXS-700, Kodak RVG, 6100, RVG 5200, RVG 6200, and Schick 33.

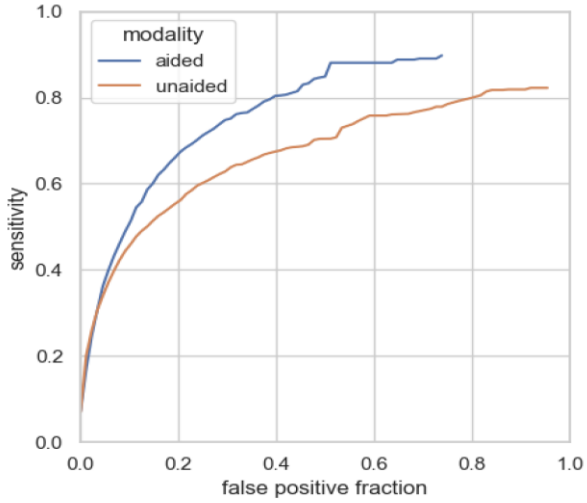
The overall average AFROC FOM for reads aided by VCA was 0.739 as compared to 0.667 for unaided reads (Table 3). The difference was 0.072 (95% CI: 0.047, 0.097; $p < 0.0001$), thus rejecting the null hypothesis. This demonstrates that the performance of readers assisted by VCA was better than that of readers who were unassisted, thus meeting the primary study objective. The improvement in aided reader performance over unaided reader performance was seen for each of the 21 readers

Table 3: Overall Image-based AFROC FOM for Aided vs Unaided reads

	Aided	Unaided	Difference
Overall, average FOM	0.739	0.667	0.072
95% Confidence Interval	(0.705, 0.773)	(0.633, 0.701)	(0.047, 0.097)

The image-based - AFROC Curve for aided and unaided reads is shown below in Figure 1.

Figure 1: Image-based- AFROC Curve of aided (blue) and unaided (orange) reading modalities.



Sensitivity was significantly increased for aided versus unaided reads for both the reader-averaged and the lesion-based analyses. The Non-Lesion Fraction (NLF) is a measure of the average number of false positive lesions expected per image. NLF was reduced in aided reads for both normal (no lesions) and abnormal (one or more lesions) images. The False Positive Fraction (FPF) is a measure of how many normal images have at least one false positive. Although the FPF is slightly increased for aided reads (0.33) versus unaided reads (0.29), this difference is small and not statistically significant (95% CI [-0.03, 0.12]). Furthermore, the device did demonstrate an overall improvement in reader performance as demonstrated by the primary endpoint analysis.

Conclusion

The predicate Logicon Caries Detector (P980025) and the proposed Videa Caries Assist device have the same intended use, as they are both computer-assisted detection devices that accept dental radiographs as inputs and use Supervised Deep Learning to identify and highlight ROIs. Although there are technological differences, as discussed above these differences in technological characteristics do not raise different questions of safety and effectiveness, as overall functionality as a reading aid for dental radiographs and utility within the associated

clinical workflows offered to the dental professionals by Videa Caries Assist and Logicon Caries Detector are the same.

Software testing verified the device functioned as intended. The results of the Standalone Performance Assessment and Clinical Performance Assessment demonstrate that the performance of Videa Caries Assist is comparable to that of Logicon Caries Detector. Therefore, Videa Caries Assist can be found substantially equivalent to Logicon Caries Detector.