



August 30, 2024

Velmeni Inc.
c/o Mini Suri
CEO
333 West Maude Avenue
Suite 207
SUNNYVALE, CA 94085

Re: K240003
Trade/Device Name: Velmeni for Dentists (V4D)
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: August 1, 2024
Received: August 1, 2024

Dear Mini Suri:

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,

A stylized signature of "Lu Jiang" in a cursive font, overlaid on a large, semi-transparent "FDA" logo.

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

Submission Number (if known)

K240003

Device Name

VELMENI for DENTISTS (V4D)

Indications for Use (Describe)

VELMENI for DENTISTS (V4D) is a concurrent-read, computer-assisted detection software intended to assist dentists in the clinical detection of dental caries, fillings/restorations, fixed prostheses, and implants in digital bitewing, periapical, and panoramic radiographs of permanent teeth in patients 15 years of age or older. This device provides additional information for dentists in examining radiographs of patients' teeth. This device is not intended as a replacement for a complete examination by the dentist or their clinical judgment that considers other relevant information from the image, patient history, or actual in vivo clinical assessment. Final diagnoses and patient treatment plans are the responsibility of the dentist.

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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VELMENI for DENTISTS (V4D)

510(k) Summary

K240003

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the following 510(k) Summary for VELMENI for DENTISTS (V4D) is provided:

Submitter Information

Submitter: Velmeni Inc.
333 West Maude Avenue, STE 207
Sunnyvale, CA 94085
Phone: 201-289-3500

Date Prepared: June 29, 2023

Contact Person: Mini Suri, CEO
Velmeni Inc.
Phone: 201-289-3500
Email: mini@velmeni.com

Identification of the Device

Trade Name: VELMENI for DENTISTS (V4D)
Common Name: Medical image analyzer
Classification Name: Medical image analyzer
21CFR892.2070

Product Code: MYN
Device Class: Class II

Predicate Device(s)

Predicate Device(s): Overjet Caries Assist (K222746)
Reference Device: Second Opinion (K210365)
Reference Device: Denti.AI Detect (K230144)

Intended Use/ Indications for Use

VELMENI for DENTISTS (V4D) is a concurrent-read, computer-assisted detection software intended to assist dentists in the clinical detection of dental caries, fillings/restorations, fixed prostheses, and implants in digital bitewing, periapical, and panoramic radiographs of permanent teeth in patients 15 years of age or older. This device provides additional information for dentists in examining radiographs of patients' teeth. This device is not intended as a replacement for a complete examination by the dentist or their clinical judgment that considers other relevant information from the image, patient history, or actual in vivo clinical assessment. Final diagnoses and patient treatment plans are the responsibility of the dentist.

Device Description

V4D software medical device comprises of the following key components:

- Web Application Interface delivers front-end capabilities and is the point of interaction between the device and the user.
- Machine Learning (ML) Engine delivers V4D's core ML capabilities through the radiograph type classifier, condition detection module, tooth numbering module, and merging module.
- Backend API allows interaction between all the components, as defined in this section, in order to fulfill the user's requests on the web application interface.
- Queue receives and stores messages from Backend API to send to AI-Worker.
- AI-Worker accepts radiograph analysis requests from Backend API via the Queue, passes gray scale radiographs to the ML Engine in the supported extensions (jpeg and png), and returns the ML analysis results to the Backend API.
- Database and File Storage store critical information related to the application, including user data, patient profiles, analysis results, radiographs, and associated data.

The following non-medical interfaces are also available with VELMENI for DENTISTS (V4D):

- VELMENI BRIDGE (VB) acts as a conduit enabling data and information exchange between Backend API and third-party software like Patient Management or Imaging Software
- Rejection Review (RR) module captures the ML-detected conditions rejected by dental professionals to aid in future product development and to be evaluated in accordance with VELMENI's post-market surveillance procedure.

Substantial Equivalence

The proposed VELMENI for DENTISTS (V4D) has similar indications for use to, and uses the same fundamental technology as, the legally marketed predicate device to which substantial equivalence is claimed, the Overjet Caries Assist (K222746) device. Reference devices are included for comparison for detection features and image types.

Table 1. Comparison of the Proposed Device, Predicate Device and Reference Devices

Specification	Proposed Device: Velmeni For Dentists (V4D)	Predicate Device: Overjet Caries Assist K222746	Reference Device: Denti.AI Detect K230144	Reference Device: Second Opinion K210365
Manufacturer	Velmeni Inc.	Overjet Inc.	Denti.AI Technology Inc.	Pearl Inc.
Classification	892.2070	892.2070	892.2070	892.2070
Product Code	MYN	MYN	MYN	MYN

Specification	Proposed Device: Velmeni For Dentists (V4D)	Predicate Device: Overjet Caries Assist K222746	Reference Device: Denti.AI Detect K230144	Reference Device: Second Opinion K210365
Image Modality	Radiograph	Radiograph	Radiograph	Radiograph
Intended Use	To aid in clinical detection of pathologic and/or non-pathological dental features in radiographs of permanent teeth	To aid in clinical detection of pathologic and/or non-pathological dental features in radiographs of permanent teeth	To aid in clinical detection of pathologic and/or non-pathological dental features in radiographs of permanent teeth	To aid in clinical detection of pathologic and/or non-pathological dental features in radiographs of permanent teeth
Indications	Velmeni for Dentists (V4D) is a concurrent-read, computer-assisted detection software intended to assist dentist in the clinical detection of dental caries, fillings/ restorations, fixed prostheses, and implants in digital bitewing, periapical, and panoramic radiographs of permanent teeth in patients 15 years of age or older. This device provides additional information for dentists in examining radiographs of patients' teeth. This device is not intended as a replacement for a complete examination by the dentist or their clinical judgment that considers other relevant	The Overjet Caries Assist (OCA) is a radiological, automated, concurrent read, computer-assisted detection software intended to aid in the detection and segmentation of caries on bitewing and periapical radiographs. The device provides additional information for the dentist to use in their diagnosis of tooth surface suspected of being carious. The device is not intended as a replacement for complete dentist's review or their clinical judgment that takes into account other relevant information from the image,	Denti.AI Detect is a Computer-Assisted Detection (CADe) software device intended to be used by dental professionals, comprising dentists and dental specialists, while reading extraoral and intraoral 2D dental radiographs. The device aims to assist in detecting and highlighting uncategorized regions of interest (ROIs) within the teeth area, which include caries and periapical radiolucency, as a second reader. The device is also intended to aid in the measurements of mesial and distal bone levels associated with each tooth. The device is aimed	Second Opinion® is a computer aided detection ("CADe") software to identify and mark regions in relation to suspected dental findings which include Caries, Discrepancy at the margin of an existing restoration, Calculus, Periapical radiolucency, Crown (metal, including zirconia & non-metal), Filling (metal & non-metal), Root canal, Bridge, and Implants. It is designed to aid dental health professionals to review bitewing and periapical radiographs of permanent teeth in patients 12 years of age or older as a

Specification	Proposed Device: Velmeni For Dentists (V4D)	Predicate Device: Overjet Caries Assist K222746	Reference Device: Denti.AI Detect K230144	Reference Device: Second Opinion K210365
	information from the image, patient history, or actual in vivo clinical assessment. Final diagnosis and patient treatment plans are the responsibility of the dentist.	patient history, and actual in vivo clinical assessment.	to be used with images from the patients of 22 years age and older without remaining primary dentition. The device is not intended to replace a complete clinician's review or clinical judgment that considers other relevant information from the image or patient history.	second reader.
Intended Body Part	Dental/teeth	Dental/teeth	Dental/teeth	Dental/teeth
End User	Licensed Dental Professional	Dentist	Dental Professional	Dental Clinicians
Patient Population	Patients requiring dental services, all sexes, at least 15 years of age, and with permanent dentition	Patients requiring dental services, all sexes, at least 12 years of age, and with permanent dentition	Patients requiring dental services, all sexes, at least 22 years of age or older	Patients requiring dental services, all sexes, at least 12 years of age or older
Prescription or OTC	Prescription Use	Prescription Use	Prescription Use	Prescription Use
Reader Workflow	Concurrent Read	Concurrent Read	Second Read	Second Read
Image Source	JPG, JPEG, PNG or DCM, DEX, and RVG	JPG, PNG, EOP, JIF, DICOM	JPEG, JPG, TIFF, TIF, PNG, BMP, DICOM	RVG, DICOM, JPEG, TIFF, PNG

Cloud Hosted Software	Yes	Yes	Yes	Yes
Data Input	Digital intraoral files of bitewing and periapical radiographs and digital extraoral files of panoramic radiograph	Digital files of bitewing and periapical radiographs	Intraoral (bitewing and periapical) Extraoral (panoramic)	Digital intraoral files of bitewing and periapical radiographs
Model	Machine Learning	Machine Learning	Machine Learning	Machine Learning
Tooth Numbering	Yes	Yes	Unknown	Unknown
Detection	Caries, restorations, fixed prostheses, and implants	Caries	Caries and periapical radiolucency	Caries, margin discrepancy-MD, calculus, periapical radiolucency-PR, crown, bridges, implants, root canals, and fillings
Segmentation	Yes	Yes	Regions of Interest (ROIs)	No
Bounding Boxes	Yes	Unknown	Unknown	Yes

Technological Characteristics

As shown in Table 1 above, the proposed VELMEDI for DENTISTS (V4D) device and the predicate device have similar indications for use and uses the same fundamental technology (i.e., machine learning technology). Differences in technological characteristics include that each device uses its own proprietary algorithm to analyze digital radiographs. The proposed device's output is not limited to caries but includes restorations, fixed prostheses, and implants. Reference devices were identified because they demonstrate the Agency's familiarity with computer-assisted technology and the ability to identify and detect conditions beyond caries and in radiographs other than bitewing and periapical. The differences in technological characteristics do not raise new or different questions of safety or effectiveness.

The proposed device and the predicate device are technologically equivalent as follows:

- Both devices are designed to process digital bitewing and periapical radiographs.
- Both devices use neural network-based computer algorithms.
- Both devices mark detections within the user interface with a graphical overlay on the radiograph.
- Both devices produce near-instantaneous detection results.
- Both devices are for prescription use.
- Both devices utilize cloud-hosted solutions.

The proposed device and the predicate device are technologically different as follows:

- The proposed device can detect other dental features (i.e., restorations, fixed prostheses, and implants) in addition to dental caries. The ability to detect other dental features has been cleared in other devices within this same regulation and product code.
- The proposed device is capable of making detections in panoramic radiographs in addition to the bitewing and periapical radiographs. The ability to detect dental features in panoramic radiographs has been cleared in other devices within the same regulation and product code.
- The proposed device will be used on patient images from 15 years old or older with permanent teeth. The use of the device in patients as young as 12 years of age with permanent teeth has already been cleared within the predicate device.
- Once suspected findings are detected in a radiograph, the proposed device overlays the radiograph with segmentation on the radiograph or alternatively a bounding box outlining the detected regions of suspected caries, restorations, fixed prosthesis, and implants, while predicate device does so with segmented polygons outlining the detected regions of suspected caries or fills suspected caries.
- The proposed device utilizes a different list of compatibility of image types as compared to the predicate device.

Performance Data

Biocompatibility Testing:

There are no direct or indirect patient-contacting components of the proposed device. Therefore, patient contact information and biocompatibility testing are not applicable for this device.

Electrical Safety and Electromagnetic Compatibility (EMC):

The proposed device is a software-only device. It contains no electric components, generates no electrical emissions, and uses no electrical energy of any type. Therefore, electrical safety and EMC testing is not applicable for this device.

Software Verification and Validation Tests:

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 Submission for Device Software Functions." Verification of the software was conducted to ensure that the product works as designed. Validation was conducted to validate the design and the performance of the device to meet user needs and intended uses. VELMENI FOR DENTISTS (V4D) passed all verification and validation software tests. Overall, the VELMENI for DENTISTS (V4D) was found to be safe and effective for all intended users, uses, and use environments.

Animal Testing:

Animal studies were not necessary to establish the substantial equivalence of this device.

Bench Testing and Clinical Testing:

Velmeni Inc. conducted performance testing according to FDA's Guidance for Industry and Food and Drug Administration Staff, "Computer-Assisted Detection Devices Applied to Radiology Images and Radiological Device Data- Premarket Notification (510(k)) Submissions," as part of the development of VELMENI for DENTISTS (V4D). Performance testing included standalone testing and clinical reader evaluation.

- **Standalone Performance**

Standalone performance of the Velmeni for Dentists (V4D) was evaluated on a total of 600 Bitewing images, 597 Periapical images and 600 Panoramic images. Standalone performance was compared to ground truth established by consensus labels of three US licensed dentists, and non-consensus labels were adjudicated by an oral radiologist.

Standalone testing included images from the following sensor manufacturers: Dexis, Dexis platinum, and Kavov used for bitewing and periapical image type and Kavov, Carestream, Planmeca sensor used for panoramic image type.

Standalone study assessed sensitivity, specificity and dice coefficient.

Table 2, Lesion-Level Sensitivity for Caries

Caries	
View	Lesion-Level Sensitivity(95% CI ¹)
Bitewing Views	72.8% (68.0%, 77.4%)
Periapical Views	70.6% (64.1%, 76.6%)
Panoramic Views	68.3% (64.9%, 71.8%)

¹ Two-sided bootstrap 95% CI based on images with one or more caries and resampling of subjects.

² Image classification for Sensitivity: TP = image with all lesions correctly identified. FN = image with at least one lesion not identified.

Table 3, Lesion-level and case-level sensitivity for caries, fixed prosthesis, implants and restorations and dice coefficient for lesion segmentation.

Assessment	Results		
	Bitewing Views	Periapical Views	Panoramic Views
Lesion-level Sensitivity (95% CI¹)			
Fixed Prosthesis	92.1% [90.0%, 94.1%]	81.0% [76.6%, 85.4%]	74.5% [71.5%, 77.3%]
Implant	81.1% [67.6%, 92.1%]	94.5% [90.0%, 98.2%]	79.6% [69.7%, 87.4%]
Restoration	88.1% [86.1%, 90.1%]	76.8% [72.0%, 81.4%]	72.6% [70.6%, 74.6%]
Case-level Sensitivity² (95% CI¹)			
Caries	59.5% [51.7%, 66.9%]	57.5% [50.0%, 65.1%]	45.0% [39.7%, 50.5%]
Fixed Prosthesis	81.1% [75.7%, 86.3%]	71.7% [62.5%, 79.9%]	44.3% [38.0%, 50.6%]
Implant	75.0% [59.1%, 88.9%]	91.7% [84.8%, 97.2%]	60.0% [45.0%, 74.4%]
Restoration	71.6% [67.0%, 76.2%]	68.1% [61.2%, 74.5%]	27.2% [23.3%, 31.2%]

False Positives Per Image Mean (95% CI¹)			
Caries	0.24 [0.19, 0.29]	0.27 [0.22, 0.32]	0.33 [0.28, 0.38]
Fixed Prosthesis	0.03 [0.01, 0.05]	0.01 [0.00, 0.02]	0.06 [0.04, 0.08]
Implant	0.00 [0.00, 0.01]	0.00 [NA, NA]	0.01 [0.00, 0.02]
Restoration	0.15 [0.11, 0.19]	0.10 [0.07, 0.13]	0.62 [0.54, 0.70]
Case-level Specificity³ (95% CI¹)			
Caries	88.0% [84.4%, 91.2%]	84.7% [81.4%, 87.9%]	96.8% [94.6%, 98.6%]
Fixed Prosthesis	98.2% [96.4%, 99.7%]	99.7% [99.2%, 100.0%]	97.7% [96.0%, 99.2%]
Implant	100.0% [NA, NA]	100.0% [NA, NA]	100.0% [NA, NA]
Restoration	93.3% [89.1%, 96.9%]	95.1% [92.8%, 97.2%]	83.3% [75.0%, 90.6%]
DICE Score Mean (95% CI¹)			
Caries	81.96% (80.81%, 83.10%)	82.77% (81.41%, 84.13%)	77.07% (76.25%, 77.89%)
Fixed Prosthesis	97.09% (96.84%, 97.33%)	96.23% (95.78%, 96.69%)	91.47% (91.24%, 91.71%)
Implant	94.20% (92.44%, 95.97%)	95.47% (94.60%, 96.34%)	88.67% (87.22%, 90.11%)
Restoration	90.45% (90.06%, 90.84%)	81% (88.97%, 90.64%)	81.49% (81.19%, 81.78%)

¹ Two-sided 95% CI obtained by bootstrapping analysis of subjects.

² Image classification for Sensitivity: TP = image with all lesions correctly identified. FN = image with at least one lesion not identified.

³ Image classification for Specificity: FP = image without a positive lesion that has at least one false positive. TN = image without a positive lesion that has no false positives.

Subgroup analyses were performed among types of caries (primary and secondary caries; for caries-level sensitivity only), sex, age category, sensor, and study site.

● Clinical Performance

Velmeni evaluated the performance of Velmeni for Dentists (V4D) in a multi-reader fully crossed reader improvement study. 12 US licensed dentists were asked to evaluate 600 bitewing images (total caries 315), 597 periapical images (total caries 271) and 600 panoramic images (total caries 853). Ground truth was established by the consensus labels of three US licensed dentists, and non-consensus labels were adjudicated by an oral radiologist. Half of the data set contained unannotated images, and the second half contained radiographs that had been processed through the V4D model. Radiographs were presented to readers in alternating groups. In Session 1, readers were asked to outline suspected caries, fixed prosthesis, implant, and restorations and to review predictions from the V4D model. Each reader was asked to provide a rating of 25 - 100 for their confidence in the annotation (25 for lowest confidence, up to 100 for highest confidence). A 4-week washout period was utilized to limit recollection bias. Following the washout, the readers were presented with the same data set but with alternate grouping. i.e., if a reader saw a radiograph in the

unpredicted state in session 1, they were presented with the same radiograph with V4D predictions in session 2, and vice versa. Results were compared against a consensus ground truth, and the sensitivity, specificity, and weighted alternative free response receiver operating characteristic (wAFROC) were evaluated to characterize the performance of the readers with (assisted) and without (unassisted) viewing the model annotations.

Findings were first summarized at the lesion level and then at the case (view) level. The V4D software demonstrated clear benefit for bitewing and periapical views in all features. The panoramic view demonstrated benefit though the absolute benefit for caries sensitivity was smaller due to lower overall reader performance. In addition, for the panoramic view, there was a benefit in restoration sensitivity that was somewhat offset by a drop in image-level specificity.

Table 4: wAFROC AUC at lesion- level for Caries Detection by Reader Mode

View	Measure	Results		
		Aided	Unaided	Difference (95% CI)
Bitewing	wAFROC AUC	0.848	0.794	0.054 (0.035, 0.073)
Periapical ¹	wAFROC AUC	0.814	0.721	0.093 (0.066, 0.120)
Panoramic	wAFROC AUC	0.615	0.579	0.036 (0.022, 0.050)

¹ Excludes reader 1784 for Periapical View since the reader did not have all results for all aided assessments.

Table 5 Sensitivity and Specificity

Assessment	Measure	Results		
		Aided (95% CI)	Unaided (95% CI)	Difference (95% CI)
Bitewing				
Caries	Lesion-Level Sensitivity	80.3%	67.5%	12.8% (9.9%, 15.9%)
	Mean FPs per Image	0.18	0.18	0.00 (-0.03, 0.03)
	Case-level Sensitivity	69.5%	51.5%	18.1% (13.7%, 22.5%)
	Case-level Specificity	85.7%	88.5%	-2.8% (-6.0%, 0.3%)
Fixed Prosthesis	Lesion-Level Sensitivity	95.7%	90.2%	5.5% (3.6%, 7.6%)
	Mean FPs per Image	0.04	0.13	-0.08 (-0.11, -0.05)
	Case-level Sensitivity	89.6%	82.7%	6.8% (3.0%, 10.6%)
	Case-level Specificity	97.9%	98.7%	-0.8% (-2.7%, 0.8%)
Implant	Lesion-Level Sensitivity	93.2%	61.3%	32.0% (21.4%, 41.3%)
	Mean FPs per Image	0.00	0.00	0.00 (-0.01, 0.00)
	Case-level Sensitivity	91.1%	59.2%	31.8% (21.2%, 42.9%)
	Case-level Specificity	100.0%	99.9%	0.1% (0.0%, 0.2%)
Restoration	Lesion-Level Sensitivity	90.8%	74.1%	16.7% (14.3%, 19.2%)
	Mean FPs per Image	0.15	0.29	-0.14 (-0.18, -0.09)
	Case-level Sensitivity	77.8%	52.7%	25.1% (21.3%, 29.1%)
	Case-level Specificity	92.5%	94.0%	-1.4% (-5.6%, 2.5%)

Assessment	Measure	Results		
		Aided (95% CI)	Unaided (95% CI)	Difference (95% CI)
Periapical¹				
Caries	Lesion-Level Sensitivity	73.4%	48.7%	24.8% (19.8%, 29.8%)
	Mean FPs per Image	0.19	0.08	0.11 (0.08, 0.14)
	Case-level Sensitivity	59.0%	33.6%	25.5% (19.6%, 31.3%)
	Case-level Specificity	84.2%	94.5%	-10.3% (-13.0%, -7.6%)
Fixed Prosthesis	Lesion-Level Sensitivity	91.1%	80.0%	11.1% (8.0%, 14.5%)
	Mean FPs per Image	0.01	0.04	-0.02 (-0.03, -0.01)
	Case-level Sensitivity	82.7%	67.1%	15.7% (10.6%, 20.9%)
	Case-level Specificity	99.7%	99.5%	0.2% (-0.2%, 0.6%)
Implant	Lesion-Level Sensitivity	95.9%	79.5%	16.4% (12.7%, 20.3%)
	Mean FPs per Image	0.00	0.01	-0.01 (-0.01, 0.00)
	Case-level Sensitivity	93.8%	77.5%	16.3% (12.2%, 21.0%)
	Case-level Specificity	99.9%	100.0%	-0.1% (-0.4%, 0.0%)
Restoration	Lesion-Level Sensitivity	90.6%	80.3%	10.3% (8.2%, 12.4%)
	Mean FPs per Image	0.07	0.05	-0.02 (0.00, 0.03)
	Case-level Sensitivity	83.9%	69.4%	14.5% (11.2%, 17.7%)
	Case-level Specificity	94.9%	97.6%	-2.7% (-4.9%, -0.8%)
Panoramic				
Caries	Lesion-Level Sensitivity	27.2%	15.1%	6.5% (4.5%, 8.6%)
	Mean FPs per Image	0.21	0.30	-0.09 (-0.13, -0.06)
	Case-level Sensitivity	11.5%	8.5%	3.0% (0.6%, 5.5%)
	Case-level Specificity	95.1%	94.6%	0.5% (-1.7%, 2.4%)
Fixed Prosthesis	Lesion-Level Sensitivity	88.8%	80.5%	8.2% (6.1%, 10.3%)
	Mean FPs per Image	0.07	0.18	-0.10 (-0.13, -0.07)
	Case-level Sensitivity	70.5%	67.0%	3.5% (0.5%, 6.3%)
	Case-level Specificity	97.6%	99.0%	-1.4% (-2.8%, -0.1%)
Implant	Lesion-Level Sensitivity	88.3%	79.6%	8.7% (0.2%, 15.9%)
	Mean FPs per Image	0.01	0.01	0.00 (-0.01, 0.01)
	Case-level Sensitivity	77.1%	77.1%	0.0% (-10.4%, 10.0%)
	Case-level Specificity	100.0%	100.0%	0.0% (NA, NA)
Restoration	Lesion-Level Sensitivity	73.0%	57.4%	15.6% (14.3%, 16.9%)
	Mean FPs per Image	0.73	1.02	-0.29 (-0.37, -0.22)
	Case-level Sensitivity	26.7%	19.6%	7.1% (4.8%, 9.5%)
	Case-level Specificity	85.8%	96.2%	-10.4% (-16.5%, -4.8%)

¹ Excludes reader 1784 for Periapical View since the reader did not have all results for all aided assessments.

Subgroup analysis was also performed for readers' experience, gender, age, imaging sensors, collection sites and primary and secondary caries.

Conclusion

Velmeni Inc. has the same intended use as the predicate device, specifically to detect pathological and/or non-pathological conditions on dental radiographs for use by trained dental professionals. While there are some small differences in technological characteristics between the proposed device, VELMENI for DENTISTS (V4D), and the predicate device, these differences do not raise different questions of safety and effectiveness. The results of the stand-alone and MRMC reader studies demonstrate that the performance of V4D is as safe, as effective, and performs equivalent to that of the predicate device, and VELMENI has demonstrated that the proposed device complies with applicable Special Controls for Medical Image Analyzers. Therefore, VELMENI for DENTISTS (V4D) can be found substantially equivalent to the predicate device.