



September 2, 2025

Velmeni Inc.
% Ishveen Anand
Head of Regulatory & Risk
333 West Maude Avenue , STE 207
SUNNYVALE, CA 94085

Re: K250753
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, 2025
Received: August 1, 2025

Dear Ishveen Anand:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these

requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
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OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K250753

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.

This device includes a Predetermined Change Control Plan (PCCP).

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)
- K250753**

510(k) Summary

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: August 29, 2025

Contact Person: Ishveen Anand,
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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: Velmeni for Dentists (K240003)
Classification Name: Medical image analyzer
Regulatory Classification: 21 CFR 892.2070
Product Code: MYN
Device Class: Class II

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.

This device includes a Predetermined Change Control Plan (PCCP).

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.

This device includes a Predetermined Change Control Plan (PCCP).

Technological Comparison

The only difference between the proposed VELMENI for Dentists Device and its predicate device VELMENI for Dentists (K240003) is that the subject device includes a Predetermined Change Control Plan (PCCP). Both devices are identical in all other aspects, including device features, incorporated models, software version, indications for use, and indicated patient population.

The only technological difference between the predicate and proposed devices is that the proposed device includes a Predetermined Change Control Plan (PCCP). Similarities of the device with the predicate are maintained following PCCP modifications, and PCCP modifications do not incur additional differences with the predicate device.

Predetermined Change Control Plan

This submission provided a set of PCCPs that Velmeni will follow to validate the standalone updates to the identified Machine Learning Software Device functions (ML-DSF) of the device, namely the Condition Detection Modules for each radiograph type (bitewing, periapical, and panoramic) that contains the models trained for detecting predetermined conditions (caries and fillings/restorations, fixed prostheses, and implants).

The PCCPs include key components (data management, retraining, performance evaluation, update procedures, and impact assessments) that describe the plan for developing, validating, and implementing the modifications using post-market and real-world data to reduce false positives and negatives. The predefined performance and validation requirements must be met prior to the manual update of the device.

- If the modification passes the predefined evaluation criteria, controlled reports & documentation will be generated and maintained for record keeping in line with VELMENI Quality management procedure. Additionally, the device labeling will be updated to reference the updated ML-DSF model performance.
- For instances where the modification does not pass the predefined criteria, the modification will not be implemented.

Modification Description	This modification includes re-training the model and is an update to the model weights (and optionally hyperparameters) based on a combination of new and existing training and tuning data, enhancing its ability to generalize and improve performance on real-world cases while maintaining the model architecture. No changes are made to the deployment environment or inference pipeline, only the trained parameters (model weights) are updated. • Bitewing Caries Detection Model • Bitewing Fillings/restorations, Fixed Prostheses, and Implants Detection Model • Periapical Caries Detection Model • Periapical Fillings/restorations, Fixed Prostheses, and Implants Detection Model • Panoramic Caries Detection Model • Panoramic Fillings/restorations, Fixed Prostheses, and Implants Detection Model Re-training will be triggered if performance or data drift metrics are observed. Performance drift metrics include lesion or case level sensitivity, case level specificity, false positive rate per image, and DICE score. Data drift metrics including Population Stability Index (PSI) and Statistical Distribution Changes are evaluated on a quarterly basis.
Goal	The goal is to ensure the device remains safe and effective while enhancing the device diagnostic accuracy for detecting dental caries, restorations, fixed prostheses, and implants.
Testing Methods	Re-training of each Condition Detection Model with new data to maintain/improve its performance will be followed by performance testing and a comparison of the modified Condition Detection Model to the reference models i.e. most recent model version and the original cleared model version (using model-specific performance metrics) and verification and validation. The Condition Detection modification will not change the intended use/instructions for use cleared under K240003, hence, the overall standalone study protocol methodology for the modifications implemented under the approved PCCPs is aligned with the

	predicate Velmeni for Dentists cleared under K240003. The modifications do not affect the relevance of the study endpoints, which were originally chosen based on current dental practices. The acceptance criteria for Sensitivity , Specificity and Average False Positives have been updated to match the lower bounds of confidence interval demonstrated by the originally cleared models' standalone results. The new models will be evaluated on a combined test dataset with balanced ratio of historical and new data for validation to avoid overfitting historical data from repeated use. The new test data is fully independent on a site-level from training/tuning data, and the test dataset remains at least 50% US data. Since the device remains unchanged from the version cleared under K24003, the clinical test results under K240003 remain applicable and MRMC results concluded the effectiveness of the V4D software in assisting readers to identify more caries and identify more fixed prostheses, implants, and restorations correctly.
Device Update Procedure	The modified model will be locked prior to the evaluation. If the predefined PCCP criteria is met, the device will be updated manually and available globally for all the end users (global availability). After the release, the rollout is accompanied by an on-screen pop-up notification with the updated device version and link to User manual that covers the model changes and resulting performance characteristics. The latest device version will also be reflected on the Support tab for future user awareness. Additionally, the support tab will include a link to the updated User manual reflecting the modification implemented under the approved PCCP and updated standalone performance results.
Impact Assessment	These updates maintain or enhance the model's ability to generalize across different patient demographics, radiograph modalities, and clinical scenarios. This ensures that the model continues to perform reliably in aiding dental practitioners in the detection and localization of dental conditions lesions on bitewing, periapical, and panoramic radiographs. <u>Benefit-Risk Analysis:</u> Benefits: Maintained or improved performance, generalization ability, prevention of subgroup biases Risks: Model degradation, overfitting, misclassification, <u>Risk Mitigations:</u> Cross-validation, early stopping, bias monitoring, training data composition, performance evaluation

Cybersecurity	Velmeni maintains adherence to FDA guidance, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, throughout the course of model modifications under the authorized PCCP.
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Performance Data

Biocompatibility Testing:

Similar to the predicate device, 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):

Similar to the predicate device, 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:

The proposed device remains unchanged from the predicate Velmeni for Dentists cleared under K240003, hence, no additional software testing was conducted. The intended use of both the predicate device and the proposed device is identical. The only difference between the two devices is the inclusion of a set of PCCPs in the proposed device. These minor technological differences do not raise any concerns regarding safety or effectiveness for all intended users, uses, and use environments. The existing data from the previous testing remains applicable.

Animal Testing:

Similar to the predicate device, animal studies were not necessary to establish the substantial equivalence of this device.

Bench Testing and Clinical Testing:

The proposed device remains unchanged from the predicate Velmeni for Dentists cleared under K240003, hence, no additional performance testing was conducted. The intended use of both the predicate device and the proposed device is identical. The only difference between the two devices is the inclusion of a set of PCCPs in the proposed device. The planned modifications contained in the set of PCCPs do not constitute technological differences between the subject and predicate devices, and as such do not raise any concerns regarding safety or effectiveness. The existing data from the previous testing remains applicable.

Conclusion

Both the predicate device and the proposed VELMENI for dentists device share the same intended purpose. The subject and predicate devices do not have technological differences, therefore there are no new questions of safety or effectiveness. Following the information reviewed as part of this 510k, it can be concluded that the VELMENI for Dentists is substantially equivalent to the predicate device.