January 7, 2026

AMV Consulting, LLC.
℅ Na Zhang
Consultant/Project Manager
DeviceMC LLC.
1 Bay Street
Rancho Mission Viejo, California 92694

Re: K252507
Trade/Device Name: SmileInspector
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN, LLZ
Dated: August 7, 2025
Received: August 8, 2025

Dear Na Zhang:

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.

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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252507

Please provide the device trade name(s).

SmileInspector

Please provide your Indications for Use below.

The SmileInspector software is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis , treatment simulation and virtual design of a series of dental casts , which maybe used for sequential aligner trays or retainers, based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives.

The use of SmileInspector requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well to have received a dedicated training in the use of software.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K252507 - 510(k) Summary

SUBMITTER

Date Prepared: December 30, 2025

Submitter: AMV Consulting, LLC.

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Bothell, WA 98011
USA

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DEVICE

Trade/Proprietary Name:	SmileInspector
Common Name:	Orthodontic Software
Classification Name :	Orthodontic Plastic Bracket
Classification Regulations:	21CFR 872.5470
Primary Product Code:	PNN
Additional Product Code:	LLZ
Device Classification:	Class II
Reviewing Panel	Dental

PREDICATE DEVICE

Predicate Device:	K212770	Vision	SoftSmile, Inc.

COMMON/USUAL NAME: Orthodontic Software
CLASSIFICATION NAMES: Orthodontic Plastic Bracket
REVIEW PANEL: Dental
PRIMARY PRODUCT CODE: PNN
ADDITIONAL PRODUCT CODE: LLZ
CLASSIFICATION REGULATION: 21 C.F.R. § 872.5470
CLASS: II

DEVICE DESCRIPTION

SmileInspector is an orthodontic planning and treatment simulation software for utilized by dental professionals. SmileInspector allows users to upload 3D digital scans of patient's dentitions as software input, analyzing, inspecting, measuring, and simulating tooth movements, and allows the user to plan the orthodontic treatment needs of the patient and develop a virtual treatment plan. The output of the treatment plan may be downloaded as files in standard stereolithographic file format (STL) for fabrication of dental casts, which may be used to manufacture sequential aligner trays or retainers.

INDICATIONS FOR USE

The SmileInspector software is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis , treatment simulation and virtual design of a series of dental casts , which maybe used for sequential aligner trays or retainers, based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives.

The use of SmileInspector requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well to have received a dedicated training in the use of software.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO THE PREDICATE DEVICE

The subject device is substantially equivalent in intended use and technological characteristics to the predicate devices shown above. Below is a summary table comparing the subject device with the predicate.

Features	Submission Device	Predicate Device	Substantial Equivalence
Manufacture	AMV Consulting, LLC.	SoftSmile, Inc.	N/A
Trade Name	SmileInspector	Vision	N/A
510(k) Number	K252507	K212770	N/A
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	same
Classifications	Class II	Class II	Same
Product Code	PNN, LLZ	PNN, LLZ	Same
Indications for Use	The SmileInspector software is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis , treatment simulation and virtual design of a series of dental casts , which may be used for sequential aligner trays or retainers, based on 3D models of the patient's dentition before the start of an orthodontic	The SoftSmile Vision is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual design of a series of dental casts, which may be used for sequential aligner trays or retainers, based on 3D models of the patient's dentition before the start of an orthodontic	Same, slight difference in wording does not affect the intended use/indications for use

	treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of SmileInspector requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well to have received a dedicated training in the use of software.	treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of SoftSmile Vision requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well to have received a dedicated training in the use of the software.	
Technical attributes	Minimum Requirements: • Supported PC formats Windows 10+, macOS 12+ • RAM: 8GB (16GB recommended) • GPU Integrated or dedicated GPU supporting WebGL 2.0 • CPU Intel i5 or higher (or equivalent Apple Silicon)	Minimum Requirements: • Supported PC formats Windows 10 64-bit • RAM: 4GB • Monitor Resolution 1280 x 800 or similar • Video Card Memory 2GB or more discrete graphics card • Available HDD Space 120 GB or more • CPU IntelCore i3, AMD FX-4300 or higher	Similar, does not affect substantial equivalence
Principle of Operation	Apply digital imaging tools for use in orthodontic case archiving, treatment planning and CAD design of customized appliances. The system supports the following types of digital data: STL, OBJ, PLY, DICOM	Apply digital imaging tools for use in orthodontic case archiving, treatment planning and CAD design of customized appliances. The system supports the following types of digital data: STL, OBJ, JPG, BMP, PNG	Similar, does not affect substantial equivalence
Collection of Input	• Surface scan for intra-oral scanner • Surface scan from STL or OBJ file • CBCT scans DICOM format	• Surface scan for intra-oral scanner • Surface scan from STL or OBJ file • 2D overlay: PNG, JPG, BMP	Similar, does not affect substantial equivalence

Alignment of Input	• Aligning surface scan image • Aligning intraoral scans with CBCT for hybrid planning	• Aligning surface scan image • Alignment of 2D overlays (e.g., ideal arch)	Similar, does not affect substantial equivalence
Measurement of Input	3D measurement toolbox	3D measurement toolbox	same
Analysis of Input	• Arch shape • Tooth width • Bolton Analysis • Space analysis • Overjet/overbite • Occlusion map	• Arch shape • Tooth width • Bolton Analysis • Space analysis • Overjet/overbite • Occlusion map	Same
Treatment Simulation	3D simulation	3D simulation	Same
Virtual appliance options	Dental casts	Dental casts	Same
Patient's Case Management	Allows creating, editing, deleting, copying patient/case date	Allows creating, editing, deleting, copying patient/case date	Same
Environment of Use	Dental Office	Dental Office	Same
Intended User	Dental Professional	Dental Professional	Same
Target Patient Population	Patients with malocclusion	Patients with malocclusion	Same

Discussion:

The indications of use of the subject device and predicate device are equivalent . Minor differences in wording do not alter intended therapeutic use of the subject device. Both the subject and reference devices are software-only devices intended for use by dental professionals in orthodontic treatment planning for management of patients and orthodontic models, inspection, measurement and analysis of the models, treatment simulation, preparation and export of a series of virtual dental casts.

Both the subject and predicated device have very similar technological characteristics in design, construction and performance characteristics. Any differences in technological characteristics were assessed and addressed through risk analysis and verification and validation testing that supports these difference do not raise any new questions of safety and effectiveness. Software and integration verification and validation testing were performed in accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" for a moderate level of concern software. The testing includes validation of implemented mitigations related to device hazards identified in risk management procedures. All test results met acceptance criteria, demonstrating the SmileInspector software performs as intended and is substantially equivalent to predicate device.

Non-Clinical PERFORMANCE DATA

The following performance data were provided or relied upon in support of the substantial equivalence determination.

Software Verification and Validation

Software verification and validation testing was conducted on the subject device and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff " Guidance for the Content of Premarket Submission for Software Contained in Medical Device." The document level for the subject device is determined to be Basic Documentation level for a moderate level of concern of software based on the risks of the software functions in the context of software's intended use.

The testing includes validation of implemented mitigations related to device hazards identified in the risk management procedures. Software verification and validation was conducted to ensure the functionality and compatibility of all system components and to support the safety and effectiveness of the proposed devices.

Cybersecurity risks have been addressed in accordance with FDA Guidance Document " *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*". The software's vulnerability and exploitability were assessed and will continue to be monitored throughout the software life cycle .

All testing results met acceptance criteria, demonstrating that SmileInspector software performs as intended and is substantially equivalent to the predicate device.

CONCLUSIONS

The subject device has the same intended use and similar technological characteristics as to the predicate device. The minor technological differences between the subject device and its predicate device do not have an effect on substantial equivalence. The SmileInspector software is deemed to be substantially equivalent to the predicate device.