December 21, 2021

SoftSmile, Inc.
% Allyson Mullen
Director
Hyman, Phelps & McNamara
700 Thirteenth Street NW, Suite 1200
Washington, District of Columbia 20005

Re: K212770
Trade/Device Name: Vision
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN, LLZ
Dated: September 29, 2021
Received: September 30, 2021

Dear Allyson Mullen:

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,

Michael E. Adjodha, M.ChE.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212770

Device Name
Vision

Indications for Use *(Describe)*
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 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.

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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510(k) Summary: K212770

In accordance with 21 C.F.R. § 807.92 the following summary of information is provided:

DATE: December 13, 2021

SUBMITTER:

SoftSmile, Inc.
16192 Coastal Highway,
Lewes, DE 19958

PRIMARY CONTACT PERSON:

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SECONDARY CONTACT PERSON:

Khamzat Asabaev
CEO
T (929) 289-8777

DEVICE:

TRADE NAME: Vision
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

PREDICATE DEVICE(S):

ULab Systems UDesign Treatment Planning Software, K171295

DEVICE DESCRIPTION:

SoftSmile Vision is orthodontic planning and treatment simulation software for use by dental professionals. SoftSmile Vision imports patient 3-D digital scans and allows the user to plan the orthodontic treatment needs of the patient and develop a treatment plan. The output of the treatment plan may be downloaded as files in standard stereolithographic (STL) format for fabrication of dental casts, which may be used to fabricate by a manufacturer sequential aligner trays or retainers.

INDICATIONS FOR USE:

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 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.

TECHNOLOGY:

The proposed Vision software has similar indications for use and uses the same fundamental technology as the legally marketed predicate devices to which substantial equivalency is claimed, the ULab Systems UDesign software (K171295).

	Predicate Device **ULab Systems UDesign** **(K171295)**	**New Device** **SoftSmile, Inc. Vision** **(K212770)**
Indications for Use	The ULab Systems UDesign 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 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 the ULab Systems UDesign 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.	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 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.

	Predicate Device **ULab Systems UDesign** **(K171295)**	**New Device** **SoftSmile, Inc. Vision** **(K212770)**
Intended Use	• Used by dental professionals in orthodontic treatment planning (before, during and after treatment) • Management of patients and models • Inspection, measurement and analysis of orthodontic models • Treatment simulation • Virtual appliance preparation, handling and export • Provides device output	• Used by dental professionals in orthodontic treatment planning (before, during, and after treatment) • Management of patients and models • Inspection, measurement, and analysis of orthodontic models • Treatment simulation • Virtual preparation of dental casts, handling and export • Provides digital file
Software Environment of Use	Dental office	Dental office
Software Intended User	Dental professional	Dental professional
Intended Patient Population	Patients with malocclusion	Patients with malocclusion
Target Anatomic Area	Maxilla, Mandible	Maxilla, Mandible
Type of Patient Contact	None	None
Principle of Operation	Apply digital imaging tools for use in orthodontic case archiving, diagnosis, treatment planning and CAD design of customized appliances. The system supports the followign types of digital data: STL, JPG, BMP, PNG.	Apply digital imaging tools for use in orthodontic case archiving, treatment planning and CAD design of customized appliances. The system supports the followign types of digital data: STL, OBJ, JPG, BMP, PNG. The subject device is available in OBJ file format whereas the predicate is not.

	Predicate Device **ULab Systems UDesign** **(K171295)**	**New Device** **SoftSmile, Inc. Vision** **(K212770)**
Technical attributes	• Supported PC formats: Windows 64-bit • RAM: 4GB required; 8 GB recommended • Monitor resolution: 1024×768 24 bit color (True Color) (Recommended – 1920 x 1080 Full HD monitor) • Video Card Memory: Directx 11 or Later Compatible (Recommended – Dedicated Nvidia 1 GB) • Available HDD Space: 2 GB • CPU: Intel i3 3rd Generation Processor or Equivalent (Recommended – IntelCore i5 4th Generation or equivalent) •	Minimum Requirements: • Supported PC formats: Windows 10 64-bit • RAM: 4 GB • Monitor Resolution: 1280x800 or similar • Video Card Memory: 2 GB or more discrete graphics card • Available HDD Space: 120 GB or more • CPU: IntelCore i3, AMD FX-4300 or higher •
Management of patient/case base data	Allows creating, editing, deleting, copying patient/case data	Allows creating, editing, deleting, copying patient/case data
Collection of Input	• Surface scan for intra-oral scanner • Surface scan from STL file • 2D overlay: PNG, JPG, BMP	• Surface scan for intra-oral scanner • Surface scan from STL or OBJ file • 2D overlay: PNG, JPG, BMP
Alignment of Input	• Aligning surface scan image • Alignment of 2D overlays (e.g., ideal arch)	• Aligning surface scan image • Alignment of 2D overlays (e.g., ideal arch)
Measurement of Input	3D measurement toolbox	3D measurement toolbox

	Predicate Device ULab Systems UDesign (K171295)	New Device SoftSmile, Inc. Vision (K212770)
Analysis of Input	• Arch shape • Tooth width • Bolton • Space analysis • Overjet/overbite • Occlusion map	• Arch shape • Tooth width • Bolton • Space analysis • Overjet/overbite • Occlusion map
Treatment simulation	3D simulation	3D simulation
Virtual appliance design	• Orthodontic dental cast search • Orthodontic dental cast virtual preparation • Orthodontic dental cast design • Orthodontic dental cast export	• Orthodontic dental cast search • Orthodontic dental cast virtual preparation • Orthodontic dental cast design • Orthodontic dental cast export
Virtual appliance options	Dental casts	Dental casts

DETERMINATION OF SUBSTANTIAL EQUIVALENCE NON-CLINICAL TESTS:

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" (issued May 11, 2005) for a moderate level of concern software. The testing includes validation of implemented mitigations related to device hazards identified in the risk management procedures. All test results met acceptance criteria, demonstrating the Vision software performs as intended, raises no new or different questions of safety or effectiveness and is substantially equivalent to the predicate device.

CONCLUSION:

SoftSmile, Inc. considers the Vision software to be substantially equivalent to the predicate device.