January 11, 2024

Clevaligner Ltd
% Ora Msika
QA/RA Manager
Rs Ness
Hamelacha street 45
Netanya, 4250574
Israel

Re: K233616
Trade/Device Name: Clevaligner Software (V1.0.0)
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN, LLZ
Dated: November 10, 2023
Received: November 13, 2023

Dear Ora Msika:

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., 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

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.

Submission Number *(if known)*

K233616

Device Name

Clevaligner Software (V1.0.0)

Indications for Use *(Describe)*

The Clevaligner software is intended for use as a medical device standalone software, 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 Clevaligner Software 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.

510(k) SUMMARY

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

DATE: November 10, 2023

SUBMITTER

Clevaligner LTD
King George St 20
9426208
Jerusalem
Israel

CONTACT PERSON

Jonathan Tabet
Chief Technology Officer (CTO)
Email:
jonathan@clevaligner.com
King George St 20
9426208
Jerusalem
Israel
T: +972-534719048

DEVICE

PROPRIETARY NAME: Clevaligner Software V1.0.0

COMMON NAME: Orthodontic Software

CLASSIFICATION REGULATION NAMES: Orthodontic plastic bracket

CLASSIFICATION REGULATION: 21 C.F.R. § 872.5470

DEVICE CLASS: II

PRIMARY PRODUCT CODE: PNN: Orthodontic Software (Under 21 C.F.R. 872.5470)

ADDITIONAL PRODUCT CODE: LLZ: System, Image Processing, Radiological (under 21 C.F.R. 892.2050)

PREDICATE DEVICE

For the planned and proposed 510(k), the Clevaligner Software will have a primary predicate device as SoftSmile, Inc. Vision (K212770).

DEVICE DESCRIPTION

Clevaligner Software imports patient 3-D digital scans and provides the orthodontic treatment planning of the patient under dental professional supervision.
The Clevaligner Software performs the automatic segmentation of the 3-D digital scans, achieves an automatic design of an ideal arch form, which is approved by orthodontists using a 2D software interface.
The Clevaligner Software provides an initial to ideal final stage treatment plan, with each step of the treatment plan path presented in the 3D software interface.
Every 3D digital model from the path treatment plan, generated by the Clevaligner Software, can be exported for fabrication of orthodontic appliances, either to an orthodontic laboratory or directly to orthodontic appliance manufacturers for further use in orthodontic treatment.

INDICATIONS FOR USE

Clevaligner Software is intended for use as a medical device standalone software, 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 Clevaligner Software 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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed Clevaligner Software has the same indication for use as the legally marketed predicate device to which substantial equivalency is claimed, the SoftSmile,

Inc. Vision (K212770).

The proposed Clevaligner Software has identical intended use, operational and functional features as the cleared software, SoftSmile, Inc. Vision (K212770).

Clevaligner Software uses the same fundamental technology as the legally marketed predicate software, to which substantial equivalency is claimed, the SoftSmile, Inc. Vision. The subject device supports in addition PLY file format whereas the predicate does not.

Table 1 Substantial Equivalence Justification: comparison of technological characteristics with the predicate device

	Clevaligner Software	**SoftSmile, Inc. Vision (K212770) (Primary Predicate)**
Indication for use	The Clevaligner Software is intended for use as a medical device standalone, 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 Clevaligner Software 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.
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	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

	Clevaligner Software	**SoftSmile, Inc. Vision (K212770) (Primary Predicate)**
	• Virtual preparation of dental casts handling and export • Provides digital file	• 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, treatment planning and CAD design of customized appliances. The system supports the following types of digital data: STL, OBJ, JPG, PNG and PLY. The subject device supports PLY file format whereas the predicate does not.	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.
Technical attributes	Minimum Requirements: • Operating System (OS): Windows 10, 64-bit, Mac OS 10 • Browser system: Chrome Version 110, Safari 16 • RAM: 8 GB • Monitor Resolution: 1920x1440 or similar • Graphic Card Memory: Video Card Memory: 2 GB or more discrete graphics card Available HDD Space: 80 GB • CPU: IntelCore i3, AMD FX4300 or higher • Network:8MB/s	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

	Clevaligner Software	**SoftSmile, Inc. Vision (K212770) (Primary Predicate)**
Collection of Input	• Surface scan for intra-oral scanner • Surface scan from STL or OBJ file • 2D overlay: PNG, JPG	• 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
Analysis of Input	• Arch shape • Tooth width • 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 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

PERFORMANCE DATA

NON-CLINICAL TESTS

Software testing has been conducted in accordance with the software life cycle processes, as defined in IEC 62304.
Software and integration verification and validation testing were performed in accordance with the FDA Guidance Document "General Principles of Software Validation; Final Guidance for Industry (issued June 11, 2002).

Software verification and validation testing was conducted to ensure that all user needs and performance requirements according to the design inputs are fulfilled. Software verification and validation was conducted to ensure the functionality of the software and to support the safety and effectiveness of the proposed software. The verification and validation of the software has been completed prior to release of the Clevaligner 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 Clevaligner Software performs as intended, raises no new or different questions of safety or effectiveness and is substantially equivalent to the predicate device.

The described approach for testing also includes testing of cybersecurity requirements determined in the cybersecurity analysis.

A cybersecurity analysis was performed in accordance with the FDA Guidance Document "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions", issued on September 27, 2023. Clevaligner Software monitors vulnerabilities of the software during lifetime and analyses them in the risk management.

The documentation level for the software was assessed per the FDA Guidance (Guidance for the Content of Premarket Submissions for Device Software Functions" issued June 14, 2023) and determined to be Basic Documentation level, based on the risks of the software functions in the context of the software intended use.

The test data to verify the performance of Clevaligner Software have been provided, where the results of this testing, combined with the comparison to the predicate device, support substantial equivalence and do not raise any new issues of safety or effectiveness.

All test results have been reviewed and approved, demonstrating Clevaligner Software is substantially equivalent in terms of safety and effectiveness to the predicate software.

CLINICAL TESTING

Clinical testing has not been performed and is not required since the proposed device, Clevaligner Software, is a stand-alone medical device software which is used without direct patient contact.

However, an aligner manufacturing validation was performed, in order to demonstrate that the digital aligners treatment planned proposed by the Clevaligner Software, matches the fabrication

of aligner trays or retainers 3D printed from subsequent thermoforming steps with an acceptable level of accuracy.

CONCLUSIONS

The proposed Clevaligner Software is intended to provide virtual design of dental casts, which may be used for sequential aligner trays or retainers such as the predicate device.

Both devices create customized dental appliances based on computer models of the patient's pre-treatment and post-treatment dentition.The minor technological differences between this device and its predicate device raise no new issues of safety or effectiveness. Thus, the Clevaligner Software is found to be substantially equivalent to in terms of safety and effectiveness to the predicate device.