October 11, 2024

Progressive Aligners Inc.
Fouad Alaeddin
Chief Financial Officer
135 Columbia
Aliso Viejo, California 92656

Re: K241153
Trade/Device Name: Progressive Orthodontics App
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN, LLZ
Dated: September 26, 2024
Received: September 27, 2024

Dear Fouad Alaeddin:

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
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OHT1: Office of Ophthalmic, Anesthesia,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241153

Device Name

Progressive Orthodontics App

Indications for Use *(Describe)*

The Progressive Orthodontics App is indicated for use as a front-end software tool for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options, which may be used for sequential aligner trays or retainers. These applications are based on 3D scans 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 Progressive Orthodontics App requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as 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) **K241153**

510(k) Summary

Submitter: Progressive Aligners Inc.
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Submission Correspondent: Fouad Alaeddin, CPA, CFO and Regulatory Affairs
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Date Prepared: October 10, 2024

Proprietary Name:	Progressive Orthodontics App
Common/Usual Name:	Orthodontic Software
Classification Name:	Orthodontic Plastic Bracket
Product Code:	PNN, LLZ
Device Class:	Medical Device, Class II
Regulation Number:	21 CFR 872.5470
Predicate Device:	Orchestrate 3D Orthodontic Software (K181112)

Device Description:

The Progressive Orthodontics App is an orthodontic appliance design and treatment simulation software. This software is for use by dental professionals in a healthcare facility to assist in diagnosis and design solutions for patients. Digital scans (3D) of a patient's dentition can be loaded into the software and the dental professional can then review different treatment plans and simulations for each individual patient and decide on the most appropriate treatment. This is a software only device. Physical outputs such as aligners are not included in the scope of the clearance.

Indication of Use:

The Progressive Orthodontics App is indicated for use as a front-end software tool for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options, which may be used for sequential aligner trays or retainers. These applications are based on 3D scans 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 Progressive Orthodontics App requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the Software .

Comparison to Predicate Device:

The proposed Progressive Orthodontics App has similar indications for use and uses the same fundamental technology as the legally marketed predicate device to which substantial equivalency is claimed, the Orchestrate 3D Orthodontic Software (K181112)

	Predicate Device **Orchestrate 3D Orthodontic Software** **(K181112)**	**Subject Device** **Progressive Orthodontics App** **(K241153)**
Indication of Use	The Orchestrate 3D Orthodontic Software is indicated for use as a front-end software tool for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options, including dental casts, which may be used for sequential aligner trays or retainers. These applications are 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 Orchestrate 3D requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.	The Progressive Orthodontics App is indicated for use as a front-end software tool for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options, which may be used for sequential aligner trays or retainers. These applications are based on 3D scans 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 Progressive Orthodontics App requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software .

	Predicate Device Orchestrate 3D Orthodontic Software (K181112)	**Subject Device Progressive Orthodontics App (K241153)**
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 digital file	• 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 appliances • 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	• Stand Alone Software Module • Imports Digital Patient Scans • Can be used to design Dental Casts • Useful for Diagnosis, treatment planning, and CAD design • Virtual Planning of tooth movement • Supports STL Files	Stand Alone Software Module • Imports Digital Patient Scans • Can be used to design Dental appliances • Useful for Diagnosis, treatment planning, and CAD design • Virtual Planning of tooth movement • Supports STL Files
Technical attributes	• OS: Windows 10 64-bit • RAM: 8 GB • Monitor resolution: 1280X800 • Video Card Memory: 1 GB • Available HDD Space: 10 GB • CPU: Intel compatible 2.6 GHz/Dual or Quad core 2.6 GHz • Mouse: Any Mouse with scrolling wheel or button	• OS: Windows 10 64-bit, 11 64-bit • RAM: 10 GB or higher • Monitor Resolution: 1280x800 • Video Card Memory: 2 GB • Available HDD Space: 10 GB or more • CPU: IntelCore i5 2.6 GHz • Mouse: Any mouse with scrolling wheel or button

	Predicate Device Orchestrate 3D Orthodontic Software (K181112)	New Device Progressive Orthodontics App (K241153)
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	3D measurement toolbox	3D measurement toolbox
Analysis of Input	• Arch shape Occlusion Map • Overjet/overbite	• Arch shape Occlusion Map • Tooth width Overjet/Overbite
Treatment simulation	3D simulation	3D simulation
Virtual Appliance Design	• Treatment Plans • Dental Casts	• Treatment plans • Appliances designs

NON-CLINICAL TESTS:
Software and integration verification and validation testing were performed in accordance with the FDA Guidance Document, “Content of Premarket Submissions for Device Software Functions” (issued June 14, 2023) and FDA Guidance Document, “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (issued September 27, 2023)”and IEC 62304 – Software Life Cycle Processes. All test results met acceptance criteria, demonstrating the Progressive Orthodontics software performs as intended, raises no new questions of safety or effectiveness and is substantially equivalent to the predicate device.

CONCLUSION:
Progressive Aligners, Inc. considers the Progressive Orthodontics App to be substantially equivalent to the predicate device.

Comparison of Indications for Use to Predicate Device:
Based on the above comparison, the indications for use of the Progressive Orthodontics App is similar to that of the Orchestrate 3D Orthodontic Software, except for the dental casts that are not produced by the Progressive Orthodontics App. This difference is not critical to the intended use and does not constitute a new intended use, Therefore, the Progressive Orthodontics App can be considered substantially equivalent to its predicate device.

Comparison of Technological Features to Predicate Device:
Based on the above comparison, the design, construction, and performance characteristics of the Progressive Orthodontics App is similar to that of Orchestrate 3D Orthodontic Software. Therefore, the Progressive Orthodontics App can be considered substantially equivalent to its predicate device.

Summary of Performance Data and Substantial Equivalence:
Utilizing FDA Guidance document "Content of Premarket Submissions for Device Software Functions" (issued June, 14, 2023), and "The 510(k) Program:Evaluating Substantial Equivalence in Premarket Notifications {510(k)} ," the Progressive Orthodontics App underwent appropriate integration, verification, and validation testing. The software passed the testing and performed per its intended use.

Conclusion:
Based on comparison of indications for use, technological features, performance testing, and software verification and validation testing, the Progressive Orthodontics App have been shown to be appropriate for its indications for use and is substantially equivalent to the legally marketed predicate device.