August 1, 2024

Clear Moves Aligners
% Patsy Trisler
Regulatory Consultant
Trisler Consulting
306 Turnberry Court
Lebanon, Indiana 46052

Re: K241137
Trade/Device Name: Clear Moves Aligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: April 23, 2024
Received: April 24, 2024

Dear Patsy Trisler:

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241137

Device Name

Clear Moves Aligner

Indications for Use *(Describe)*

The Clear Moves Aligner is a series of clear, lightweight, plastic appliances indicated for the correction of dental malocclusion in patients with permanent dentition (i.e. all second molars). Clear Moves Aligner positions teeth by way of continuous gentle force.

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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SUBMITTER Name:	Clear Moves Aligners
Address:	100 Jade Block, Park View City River Edge Housing Scheme Lahore, Pakistan 54000
Contact Person: **Email:**	Muhammad Awais Mawais2487@gmail.com
Date Prepared:	June 25, 2024
DEVICE Trade Name:	Clear Moves Aligners
Common Name:	Aligner, Sequential (Clear Braces)
Classification Name **Number** **Product Code** **Regulatory Class**	Orthodontic Plastic Bracket 21 CFR 872.5470 NXC 2
Review Panel	Dental
PREDICATE / REFERENCE DEVICES	Predicate #1: K210540, Ohlendorf Appliance Laboratory: Ohlendorf Clear Aligner Predicate #2: K221097, Ordont Orthodontic Laboratories, Inc.: SmileSeries Reference Device: K062828, Dentsply Sirona: Dentsply Mouthguard and Aligner Materials
DEVICE DESCRIPTION	Clear Moves Aligners are comprised of a series of clear, thin, thermoformed removable aligner trays that are designed to correct tooth malocclusions without the use of conventional wire and bracket orthodontic technology. They are made of biocompatible thermoformable plastics, either from a copolyester or a composite of copolyester and polyurethane. They are provided non-sterile and are customized for each patient according to the dental clinician's prescription. The dental health professional (dentist/orthodontist) provides physical or scanned impressions of the patient's teeth to Clear Moves Aligners. A treatment plan using commercially available treatment planning software of either the scanned impression or a scan of the physical impression is sent to the clinician for approval. Upon approval, molds are then created with 3D-printing technology and the clear aligners are thermoformed on the molds and laser marked with patient identifying information and treatment step . The finished, customized aligners are provided to the dental health care professional who provides them to the patient, confirming fit and design. The aligner trays are held in place by pressure and can be removed by the patients at any time.
MECHANISM OF ACTION	Each aligner in the set is used for the specified period of time, usually 2-3 weeks, to exert gentle force to achieve progressive realignment of the teeth until the final correction has been achieved. The daily treatment time is approximately 22 hours,

	or except during eating, based on the clinician's prescribed treatment plan.
SUMMARY OF TECHNOLOGICAL CHARACTERISTICS	The thermoplastic materials used for the manufacture of the Clear Moves Aligers are the same materials used to make the predicate aligners. The software system used is Ortho Analyzer, 2019 ver 1.8.1.0 by 3Shape A/S (Reference device - K180941). It also is the same as used for the Predicates. It is used for management of 3D scanned orthodontic models, orthodontic diagnosis by measuring, analyzing, inspecting and visualizing 3D scanned orthodontic models, virtual planning of orthodontic treatments by simulating tooth movements, and design of orthodontic appliances based on 3D scanned orthodontic models.
INDICATIONS FOR USE STATEMENT	The Clear Moves Aligner is a series of clear, lightweight, plastic appliances indicated for the correction of dental malocclusion in adult and adolescent patients with permanent dentition (i.e. all second molars). Clear Moves Aligner positions teeth by way of continuous gentle force.
SAFETY TESTING	Biocompatibility: Testing of the plastic thermoformable materials used to make these aligners have been provided in previous 510(k) submissions to FDA. The Reference 510(k) is included because it was submitted for the copolyester material to be used for fabrication of many oral appliances using thermoforming processes.
PERFORMANCE TESTING	Bench testing was performed of each aligner thermoplastic material to validate the manufacturing process, to ensure the accuracy of the final thermoformed aligner compared to the initial digital scan. A final report was part of the 510(k) package. In vivo Animal and Human Clinical performance testing are not required for this device category.
COMPARISON TO THE PREDICATE DEVICE	The Clear Moves Aligner has the same intended use as the predicate devices. The thermoplastic materials are the same and the design phase makes the use of the same software as the predicates. The manufacturing fabrication of the clear aligner makes use of similar, industry-standard processes with the similar machines and materials. Any differences in the specific company processes do not raise new questions of safety and effectiveness.
SUBSTANTIAL EQUIVALENCE CONCLUSION	The information and data provided in this 510(k) establish that the Clear Moves Aligner is substantially equivalent to the predicate devices in the intended use, design, principle of operation, technology, including the thermoformable materials used to make the aligners. See the following SE Comparison table.

Substantial Equivalence Comparison Table

510(k) Number	Proposed Device K241137	Predicate #1 K210540	Predicate #2 K221097
Device Name	Clear Moves Aligners	Ohlendorf Clear Aligner	Ordont SmileSeries
Manufacturer	Clear Moves Aligners	Ohlendorf Appliance Laboratory	Ordont Orthodontic Laboratories, Inc.
Classification Regulation Name Product Code Class	21 CFR 872.5470 Orthodontic Plastic Bracket NXC 2	21 CFR 872.5470 Orthodontic Plastic Bracket NXC 2	21 CFR 872.5470 Orthodontic Plastic Bracket NXC 2
Indications for Use	The Clear Moves Aligner is a series of clear, lightweight, plastic appliances indicated for the correction of dental malocclusion in patients with permanent dentition (i.e. all second molars). Clear Moves Aligner positions teeth by way of continuous gentle force.	… indicated for the alignment of teeth during orthodontic treatment of malocclusion in patients with permanent dentition (i.e. all second molars). …positions teeth by way of continuous gentle force.	… indicated for the alignment of teeth during orthodontic treatment of malocclusion in patients with permanent dentition (i.e. all second molars). …positions teeth by way of continuous gentle force.
Mode of Action	The removable appliance applies gentle forces on teeth according to the plan prescribed by the doctor.	same	same
Description of Use	Each removable preformed plastic tray, prescribed by the Dr, is worn by the patient usually for a couple weeks, prior to using the next sequential aligner tray.	same	same
Material	Thermoformed copolyester or polyurethane/ copolyester composite	Thermoformed polyurethane/copolyester composite	Thermoformed copolyester
Manufacturing Process	Forming of plastic sheets on unique dental models using thermoforming machine	same	same
Software Used	Yes, for treatment planning and 3D printing of models.	same	same
Prescription Use	Rx	Same	Same
Biocompatibility	Yes, shown to meet requirements	Same	Same
Process Validation Testing	Yes, performed	Same	Same