April 4, 2024

Space Maintainers Laboratories (SML)
℅ Na Zhang
Consultant/Project Manager
DeviceMC LLC.
1 Bay Street
Rancho Mission Viejo, California 92694

Re: K240038
Trade/Device Name: Clear Moves Aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: January 3, 2024
Received: January 5, 2024

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.

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,

FDA 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)*

K240038

Device Name

Clear Moves Aligners

Indications for Use *(Describe)*

The Clear Moves Aligners are indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The Clear Moves Aligners position 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.

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510(k) Summary

SUBMITTER

Date Prepared: April 1, 2024

Submitter: Space Maintainers Laboratories(SML)

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Official Contact: Scott Veis
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DEVICE

Trade/Proprietary Name:	Clear Moves Aligners
Common Name:	Aligners, Sequential
Classification Name :	Orthodontic Plastic Bracket
Classification Regulations:	21CFR 872.5470
Product Code:	NXC
Device Classification:	Class II
Classification Panel:	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PRIDICATE DEVICE

Primary Predicate Device: K223141 STR8 Clear Aligners STR8 Oral Care

DEVICE DESCRIPTION

The Clear Moves Aligner is a series of clear, light weight thermoformed plastic aligners designed to be worn in sequence to facilitate the movement of the teeth to the final desired position. The sequential aligners introduce incremental movements that move teeth by way of gentle continuous force. The aligners are to be worn 20 to 22 hours a day and are to be removed for eating and for cleaning. Generally the typical wear time for each aligner is a two weeks duration prior to being replaced by the next aligner in sequence.

A digital or traditional mold impression of the patient's dentition is provided by a dental health professional (e.g. orthodontist or dentist). From the digital data of the patient's dentition, a specialized orthodontic CAD/CAM software is used to develop treatment plan. Using the software, dental technicians design a series of intermediate models

corresponding to each stage of treatment, gradually realigning the patient's teeth according to the dental health profession's prescription.

The prescribing doctor reviews and approves the model scheme and treatment plan before the molds/models are produced.

Once approved, the specialized orthodontic software is used to generate standard format 3D files which are used to physically produce each model/mold in the treatment plan for aligner fabrication. Space Maintainers Laboratories produces the aligner trays by thermal forming a plastic sheet over each model in the treatment plan. The trays are provided to the dental health care professional who provides them to the patients in sequential stages, confirming fit and design. The dental health professional monitors treatment from the moment of the first aligner is delivered to when the final aligner is finished and treatment is complete. The aligners are held in place by pressure and can be removed by the patient at any time.

INDICATIONS FOR USE

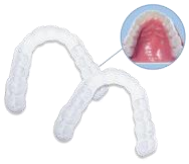
The Clear Moves Aligners are indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The Clear Moves Aligners position teeth by way of continuous gentle force.

COMPARISON OF TECHNOLOGICAL WITH THE PREDICATE DEVICE

The subject device is substantial equivalent in intended use and technological characteristics to predicate devices mentioned above. Below is a summary table comparing the subjective device with the primary predicate and an additional reference predicate device.

Features	**Submission Device**	**Predicate Device**	**Substantial Equivalent Comparison**
Manufacture	Space Maintainers Laboratories (SML)	STR8 Oral Care	N/A
Trade Name	Clear Moves Aligners	STR8 Clear Aligners	N/A
510(k) Number	N/A	K223141	N/A
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	Same
Classifications	Class II	Class II	Same
Product Code	NXC	NXC	Same
Indications for Use	The Clear Moves Aligners are indicated for the	The STR Clear Aligner is indicated for the Alignment of teeth during orthodontic	Same, slight difference in wording will

	treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). The Clear Moves Aligners position teeth by way of continuous gentle force.	treatment of malocclusions by way of continuous gentle forces	not affect the intended use/indications for use
Mode of Actions	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastics trays	Each performed Plastic tray is worn in sequence by the patient as prescribed by the dental practitioner. Orthodontic movement occurs through continuous gentle forces applied to the dentition as each tooth follows the programmed displacement based on the doctor's prescription	Same
Material	Zendura FLX (copolyester and poly urethane composite)	Zendura FLX (copolyester and poly urethane composite)	Same
Biocompatible	Yes	Yes	Same
Software	Guidemia Ortho+ (K162850)	Treatment Planning System (K213916)	Different, does not affect substantial equivalence
Software Design Process	The standard ortho dental software uses a scan of tooth impression or a digital scan to generate the image of a final, treated state and then interprets a series of images that represent intermediate teeth states. Once the dental practitioner approves the treatment plan, the software converts the	Standard dental software for tooth alignment uses digital scan(untreated state) to generate the image of a final provisional treated state and then interprets a series of images that represent intermediate teeth states. The dental practitioner then review these images and has option to reject or request modifications to the set-up prior to approving for aligner fabrication. Once the dental practitioner	Similar, does not affect substantial equivalence

	files to produce the series of patient specific aligners.	approves the treatment plan, the software converts the files to produce a series 3 D models used to produce thermoformed aligners	
Manufacture Method	Thermoforming	Thermoforming	Same
Rx or OTC	Rx	Rx	Same
Sterility	Non-sterile	Non-sterile	Same
Design			Similar, does not affect substantial equivalence

Substantial Equivalence Discussion:

The indications of use of the Clear Moves aligners is same as the predicate device. Slight difference in wording will not affect the intended use of the devices as they are both intended for correcting dental malocclusion patients with permanent dentition.

The subjective has very similar technological characteristics as to the predicate device in material, principle of operation, manufacturing process, design and clinical application. The only difference compared to Clear Moves Aligner with the predicate device is the software used to treatment planning and creation of models/mold. However both software are FDA cleared, under product code PNN for its intended use, which will not affect substantial equivalence of safety and effectiveness.

Therefore, the Clear Moves Aligner is considered to be substantially equivalent to the predicate device based on a comparison of intended use and technological characteristics.

Non-Clinical PERFORMANCE DATA

Non-clinical testing have been conducted to verify that the Clear Moves Aligner meets all design specification which supports the conclusion that it's substantially equivalent (SE) to the predicate device.

Software used for treatment planning and creation of models/mold for Clear Moves Aligner is Guiemia Ortho +,manufactured by Guidemia Technologies, LLC. It is a 510(K) clearance (K162850) software under product code PNN for intended use.

An internal manufacturing validation was performed to demonstrate the dimensional accuracy of the manufacturing for Clear Moves Aligner. The critical aspects of the manufacturing process were assessed for accuracy. The final aligner fitness was evaluated according to the in-house fitness acceptance criteria.

Translational measurement were within 0.150mm (150microns) of the target input value, the predefined tolerance of the manufacturing process. The testing results are within the acceptance criteria to demonstrate dimensional accuracy. Additionally, the final aligner fitness evaluation by a trained physician demonstrate all the aligners including in the study passed and were deemed an excellent fit .

The biocompatibility evaluation determined that Clear Moves Aligner and the predicate devices are composed of the same material, fabricated by the similar manufacturing processes, and has identical method of use, which can conclude that Clear Moves Aligners are biocompatible for its intended use.

Biocompatibility testing for the aligner material, the only patient contacting material, was conducted by the material manufacture in accordance with International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".

- Test for *in vitro* cytotoxicity : Elution Method ISO10993-5
- Skin Irritation Test in New Zealand White Rabbits ISO10993-10
- Sensitization Test in Guinea Pigs ISO10993-10
- Subacute/Subchronic Toxicity Testing ISO 10993-11
- Genotoxicity ISO 10993-3

Additional cytotoxicity testing according to ISO 10993-5:2009 was performed on the final manufactured Clear Moves Aligner .

- Test for *in vitro* cytotoxicity : Minimal Essential Media (MEM) Elution ISO10993-5

Non-Clinical physical properties of the device material have been tested by the material manufacture complying with the following standard

- Tensile Strength at Break(MPa) ASTM D638
- Tensile Stress at Yield (MPa) ASTM D638
- Elongation at Break (%) ASTM D638
- Elongation at Yield (%) ASTM D638
- Elastic Modulus (MPa) ASTM D638
- Flexural Strength ASTM D790
- Flexural Elastic Modulus ASTM D790

CLINICAL PERFORMANCE DATA

The clinical performance of sequential aligners (product code NXC) has been well established since the first device of this category was cleared by the FDA in 1998. The Clear Moves aligners have equivalent indication and method of use to its predicate, therefore there was no clinical testing necessary to support this device.

CONCLUSIONS

The subject device has very similar technological characteristics (i.e. design, function, principle of operation, materials, biocompatibility and sterilization) to the predicate device . The intended use and indications for use of the subject device are the same as the predicate device.

In conclusions, the subject device is substantially equivalent based on a comparison of intended use, and technological characteristics. Therefore, the device is considered to be safe and effective for its intended use.