April 24, 2023

STR8 Oral Care
℅ Elisabeth Miller
Regulatory Affairs Consultant
Prime Path Medtech
1321 Upland Dr.
Suite 6792
Houston, Texas 77043

Re: K223141
Trade/Device Name: STR8 Clear Aligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: February 21, 2023
Received: February 21, 2023

Dear Elisabeth Miller:

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 -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
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Office of Product Evaluation and Quality
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223141

Device Name
STR8 Clear Aligners

Indications for Use *(Describe)*
The STR8 Clear Aligner is indicated for the alignment of teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.

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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Section 5. 510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter: STR8 Oral Care

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Date Prepared: September 2022

Proprietary Name: STR8 Clear Aligners

Common Name: Sequential Clear Aligner

Product Code: NXC – Orthodontic plastic bracket

Device Classification: Class II, 21 CFR 872.5470

Predicate Device: uLab Systems Dental Aligner (K211510)

Classification Name: Aligner, Sequential

Device Description:

STR8 Clear Aligners are thermoformed plastic aligners designed to be worn in sequence to facilitate the movement to 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.

STR8 Clear Aligners are designed from digital scans of a patient's dentition. Using the scan, specialized orthodontic CAD/CAM software will be used to develop the treatment plans that consist of sequential dental models wherein the teeth are gradually realigned with each step. For this 510(k), ArchForm Treatment Planning System (K213916) will be used for this application. ArchForm is approved for use in the management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options. The specialized orthodontic treatment planning software has a 510k clearance for the intended use under FDA Classification Product Code PNN, regulation 872.5470.

Once the treatment plan is reviewed and approved by a STR8 Oral Care dental health professional, each 3D model from the treatment plan is manufactured. The aligner trays are then manufactured by thermoforming a dental thermoplastic sheet over each model. The aligners are then provided to the patient by the prescribing dental professional group.

Indications for Use:

The STR8 Clear Aligner is indicated for the alignment of teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.

Comparison to Predicate Devices:

STR8 Clear Aligners are functionally equivalent to the following predicate device: uLab Systems Dental Aligner Kit (K211510).

Table 1. Predicate Device Comparison

Specification	***Subject Device:*** *STR8 Clear Aligners*	***Predicate Device:*** *uLab Systems Dental Aligner Kit (K211510)*	***Comparison Result***
Regulation Number	21 CRF 872.5470	21 CRF 872.5470	Same
Classification Name	Aligner, Sequential	Aligner, Sequential	Same
Product Code	NXC	NXC	Same
Classification	Class II	Class II	Same
OTC or Rx	Rx	Rx	Same
Material	Zendura FLX (copolyester and polyurethane composite)	Zendura A (thin thermoformed polyurethane) or Zendura FLX (copolyester and polyurethane composite)	Similar (Zendura A) or Same (Zendura FLX)
Biocompatible	Yes	Yes	Same
Sterile	No	No	Same
Device Description	A series of customized removable clear plastic orthodontic aligners that sequentially position teeth by way of continuous gentle force.	A series of customized removable clear plastic orthodontic aligners that sequentially position teeth by way of continuous gentle force.	Same
Patient Removable?	Yes	Yes	Same
Indication for Use	The STR8 Clear Aligner is indicated for the alignment of teeth during	The uLab Systems Dental Aligner is indicated for the alignment of teeth during	Same

	orthodontic treatment of malocclusions by way of continuous gentle forces.	orthodontic treatment of malocclusions by way of continuous gentle forces.	
Intended Use	Orthodontic Tooth Movement	Orthodontic Tooth Movement	Same
Principles of Operation	Each preformed 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.	Each preformed 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
Aligner Design Process	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 reviews these images and has the option to reject or request modifications to the set-up prior to approving for aligner fabrication. Once the dental practitioner approves the treatment plan, the software converts the files to produce a series 3D models used to produce thermoformed aligners.	Standard dental software, including the uLab Systems uDesign. K171295, 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 reviews these images and has the option to reject, make or request modifications to the set-up prior to approving it for aligner fabrication. Once the dental practitioner approves the treatment plan, the software converts the files to produce the series of 3D models used to produce thermoformed aligners.	Same

Comparison for Indications for the Use to Predicate Device:

Based on the above comparison, the indications for use of the STR8 Clear Aligners in this submission is the same as the uLab Systems Dental Aligner Kit (K211510) as they are both indicated for the alignment of teeth during orthodontic treatment of malocclusions by way of continuous gentle forces. Thus, the STR8 Clear Aligners can be considered substantially equivalent to its predicate device.

Comparison of Technical Characteristics to Predicate Device

Based on the above comparison, the design, construction, and performance characteristics of the STR8 Clear Aligners is similar to that of the uLAB Systems Dental Aligner Kit (K211510).

The only difference between the subject device (STR8 Clear Aligner) and predicate device (uLab Systems Dental Aligner Kit) is the material. The material differences come from the additional material (Zendura A) used for the predicate device. The expansion of material does not increase the risk associated with manufacturing, and the subject device and predicate device do share an exact material, Zendura FLX.

Thus, the STR8 Clear Aligners can be considered substantially equivalent to its predicate device.

Non-Clinical Performance Testing

The use of thermoplastic materials for sequential aligners intended to treat malocclusions has been well documented in scientific literature regarding incremental tooth moving forces. However, durability testing was completed on these aligners. Real world use was simulated to ensure that the aligner material and manufacturing process produced aligners that were suitable for their prescribed period of use.

An internal manufacturing validation was performed to establish the dimensional accuracy of the manufacturing process for the STR8 Clear Aligners. The submitted intraoral scans, digital dentition models, from treatment planning, 3D printed molds and the final thermoformed aligners were all assessed quantitatively or qualitatively in the validation. Thus, the robustness of the process was demonstrated from 3D printing through thermoforming.

All measurements were within 0.3 mm of the target input value, the predefined tolerance of the manufacturing process. Furthermore, throughout the qualitative assessment of the aligners no performance, cosmetic, or other detectable issues were identified. This validation has met the pre-established acceptance criteria to demonstrate that the STR8 manufacturing process yields dimensional accurate products that meet product specifications.

The dental thermoplastic material used for STR8 Clear Aligners is a well-establish and commonly used thermoplastic, Zendura FLX. Biocompatibility testing for the aligner

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

Additional cytotoxicity testing according to ISO 10993-5:2009 was performed on final manufactured STR8 Clear Aligners.

Clinical Performance Testing

The technical characteristics, indications for use, material, manufacturing, and sterilization processes are the same to the predicate device and therefore, no clinical studies were deemed necessary to demonstrate the safety and effectiveness of the subject device.

Conclusion

Based on the similarities in indications for use, technological characteristics, and materials the STR8 Clear Aligners are substantially equivalent to the uLab Systems Dental Aligner Kit (K211510)