June 13, 2023

Wuxi EA Medical Instruments Technologies Limited.
℅ Breanne Butler
Regulatory Affairs Consultant
Prime Path Medtech
1321 Upland Dr. Suite 6792
Houston, Texas 77043

Re: K223517
Trade/Device Name: Clear Aligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: May 12, 2023
Received: May 15, 2023

Dear Breanne Butler:

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 ENT Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
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)*

K223517

Device Name
Clear Aligner

Indications for Use *(Describe)*
Indicated for use in alignment of teeth through orthodontic treatment of malocclusion.

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

510(k) SUMMARY - K223517

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

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Date Prepared: November 15, 2022

Proprietary Name: Clear Aligner

Common Name: Orthodontic plastic bracket.

Product Code: NXC – Orthodontic plastic bracket.

Device Classification: Class II, 21 CFR 872.5470

Predicate Device: Invisalign MAF Aligners (K181739)

Reference Predicate: Clear Aligner (K203688)

Device Description:

This premarket notification is submitted to notify the FDA of Wuxi EA Medical Technologies' intent of changes to the Clear Aligner (hereafter referred to as "Proposed Device") to the currently marketed reference device's, Clear Aligner (K203688, cleared October 8, 2021) (hereafter referred to as "Reference Device") indications for use to include mixed dentition, a wear time of at least 10 days, and mandibular repositioning features.

The Proposed Device consists of multiple stages of thermoformed plastic aligners designed to be worn in sequence to facilitate the movement of a patient's teeth to the final desired treatment position. The sequential stages of aligners introduce incremental movements that move teeth by way of gentle

continuous force and reposition the mandible to achieve a more optimal bite profile. The aligners are to be worn 20 to 22 hours a day and are to be removed for eating and for cleaning. Patients can be prescribed with more than one aligner of different materials within a single stage.

The Proposed Device is designed from digital scans of a patient's dentition submitted by a dental health professional (e.g. dentist or orthodontist). Using the scan, sequential stages of dental models are designed and approved by a physician prior to physical manufacturing. The Proposed Device includes mandibular repositioning features known as "A6" on each upper and lower aligner. A6 is intended for use in patients with growing mandibles presenting with retrognathic Class II malocclusions in permanent dentition or stable late mixed dentition.

Once the treatment plan is reviewed and approved by a dental health professional, the 3D model of each stage from the treatment plan is manufactured by 3D printing. The 3D printed models are then thermoformed over with a suitable dental thermoplastic sheet. The final manufactured aligner stages are then delivered to the patient. The patients' dental health professional then monitors their treatment from the placement of delivered initial aligner stage to the final aligner stage.

Intended Use:

The Proposed Device is indicated for use in the alignment of permanent or mixed dentition teeth through orthodontic treatment of misalignment and malocclusion, with 20 to 22 hours of daily wear for at least 10 days. The Proposed Device allows the option of forward repositioning of the mandible to a more optimal bite profile.

Comparison to Predicate and Reference Devices:

The Proposed Device is functionally equivalent to the following predicate device, Invisalign System with Mandibular Advancement Features (Invisalign MAF) (K181739, cleared October 26, 2018) (hereafter referred to as "Predicate Device"), and possesses minor differences to the previously cleared Reference Device. The following table demonstrates the functional specifications of the Proposed Device is substantially equivalent to the Predicate Device, minorly different to Reference Device, and raises no questions regarding safety and effectiveness of the device.

Table 5.1: Device Comparison

Specification	**Subject Device:** Clear Aligner (K223517)	**Predicate Device:** Invisalign MAF (K181739)	**Reference Device:** Clear Aligner (K203688)	**Comparison Result**
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	21 CFR 872.5470	Same
Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Same
Product Code	NXC	NXC	NXC	Same
Classification	Class II	Class II	Class II	Same
OTC or Rx	Rx	Rx	Rx	Same
Material	(1) Multilayer thermoformed copolyester and polyurethan composite and (2) Thermoplastic Polyurethane	Thermoplastic polyurethane-polyester composite resin	(1) Multilayer thermoformed copolyester and polyurethan composite or (2) Thermoplastic Polyurethane	Similar to Predicate (1), Same as Reference (1 & 2)

Specification	**Subject Device:** Clear Aligner (K223517)	**Predicate Device:** Invisalign MAF (K181739)	**Reference Device:** Clear Aligner (K203688)	**Comparison Result**
Material Properties	Acceptable material properties established for use as an aligner.	Acceptable materials properties established for use as an aligner.	Acceptable materials properties established for use as an aligner.	Same
Material Testing	Tested for performance in accordance with internal design specification and with the applicable performance standards.	Tested for performance in accordance with internal design specification and with the applicable performance standards.	Tested for performance in accordance with internal design specification and with the applicable performance standards.	Same as Reference Device
Biocompatible	Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system).	Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system).	Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system).	Same
Sterile	Non-sterile	Non-sterile	Non-sterile	Same
Device Description	Sequential thermoformed plastic aligners	Sequential thermoformed plastic aligners	Sequential thermoformed plastic aligners	Same
Patient Removable?	Yes	Yes	Yes	Same
Indication for Use	Indicated for use in alignment of teeth through orthodontic treatment of malocclusion.	Indicated for the orthodontic treatment of malocclusion.	Indicated for the alignment of teeth during orthodontic treatment of malocclusion in patients with permanent dentition (i.e. all second molars).	Similar
Intended Use	Orthodontic tooth movement	Orthodontic tooth movement	Orthodontic tooth movement	Same
Mode of Action	Continuous gentle force applied to teeth following the prescribed and approved treatment	Continuous gentle force applied to teeth following the prescribed and approved treatment	Continuous gentle force applied to teeth following the prescribed and approved	Same

Specification	Subject Device: Clear Aligner (K223517)	Predicate Device: Invisalign MAF (K181739)	Reference Device: Clear Aligner (K203688)	Comparison Result
	plan to achieve orthodontic movement.	plan to achieve orthodontic movement	treatment plan to achieve orthodontic movement	
Lower Jaw Adjustment Mechanism	Mandibular repositioning features known as "A6"	Mandibular Advancement Features also known as "Precision Wings"	N/A	Same as predicate device

Comparison of Indications for Use to Predicate Devices and Previously Cleared Devices:
The Proposed Device in this submission is the same as the Predicate Device as they are both indicated for use in the alignment of teeth and mandibular repositioning through orthodontic treatment of malocclusion. It can be used for both permanent and mixed dentition with a wear time 20 to 22 hours a day for at least 10 days. The differences between the indications for use of the Proposed Device, Predicate Device, and the previously cleared Reference Device do not raise questions of substantial equivalence. The Proposed Device guides patients' teeth and mandible to their desired treated position by way of continuous gentle forces in sequential aligner stages. Thus, the Proposed Device can be considered substantially equivalent to the Predicate Device and Reference Device.

The difference between the Proposed Device in this submission and the Reference Device is the inclusion of mandibular repositioning and of teeth for treatment of malocclusion. The Proposed Device additionally differs from the Predicate Device in allowing the use of multiple aligner materials. The Thermoplastic Polyurethane material of the Proposed Device is the same as the Reference Device and the Copolyester and Polyurethane Multilayer material is similar to the Predicate Device and raises no questions in the safety or effectiveness of the Proposed Device, demonstrating substantial equivalence to the Predicate Device.

Comparison of Technological Characteristics to Predicate Devices:
Based on the above comparison, the design, construction, and performance characteristics of the Proposed Device are similar to the Predicate Device and Reference Device. Thus, Proposed Device can be considered substantially equivalent to the 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. An internal manufacturing validation was performed to test the manufacturing process for Proposed Device. The robustness of the process was demonstrated from 3D printing through thermoforming.

The thermoplastic materials used for the Proposed Device has passed the required testing for material characterization. Material testing was conducted on the aligner materials according to internal design specification and with the applicable performance standards. Biocompatibility testing for the aligner materials, the only patient contacting aspect, was conducted in accordance with International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."

Clinical performance testing:

Retrospective clinical data has been provided the Proposed Device. The data collected for the study showed that successful alignment of teeth through orthodontic treatment of misalignment and malocclusion with at 20 to 22 hours of daily wear for at least 10 days was achieved when using the Proposed Device.

Conclusion:

Based on similarities in indications for use, technological characteristics, non-clinical and clinical performance data, the Proposed Device is substantially equivalent to the Predicate Device, Invisalign MAF (K181739) and the previously cleared Reference Device, Angel Align System (K203688).