October 8, 2021

Wuxi EA Medical Instruments Technologies Limited.
℅ Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
CHINA

Re: K203688
Trade/Device Name: Clear Aligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: June 28, 2021
Received: September 08, 2021

Dear Ivy Wang:

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, 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
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.

510(k) Number *(if known)*
K203688

Device Name
Clear Aligner

Indications for Use *(Describe)*
Clear Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion in patients with permanent dentition (i.e. all second molars).

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

K203688

Summary prepared date: 2021-10-06

A. Applicant:

Wuxi EA Medical Instruments Technologies Limited.
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B. Device:

Trade Name: Clear Aligner
Common Name: Sequential Aligners
Regulatory Information
Classification Name: Aligner, Sequential
Classification: Class II
Product code: NXC
Regulation Number: 21 CFR 872.5470
Review Panel: Dental

C. Predicate device:

K171674
Angel Align System
Smile Development Corp.

Reference device
K181739
Invisalign System with Mandibular Advancement Feature

Align Technology, Inc.

D. Indications for use of the device:

Clear Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion in patients with permanent dentition (i.e. all second molars).

E. Device Description:

The Proposed Device is an update device to the previous cleared Angel Align System (K171674) including added optional traction accessory.
The Clear Aligner System consists of a series of doctor-prescribed, thin, clear plastic removable orthodontic appliances (aligners) and proprietary 3D software. The aligners gently move the patient's teeth in small increments from their original state to a more optimal, treated state.
The Clear Aligners are fabricated by thin thermoformed polyurethane or thermoformed multilayer copolyester and polyurethane composite (TPU +PETG) plastic. The corrective forces are generated via differences between current teeth arrangement and each step's aligner. They are designed to move the teeth to the target position and deliver desired clinical effect.
The traction accessory, also called "Angel Button", made of thermoplastic polyurethane can be selected and will be bonded to the outer surface of the aligner by adhesive made of acrylic polyurethane.

F. Comparison to predicate device

The Clear Aligner is substantially equivalent in intended use, indications for use, mode of action, mode of use, design to the predicate Smile Angel Align (K171674). Only minor differences exist between the subject product and the predicate, which do not affect the safety or effectiveness of the subject device.
Table 1 provides a comparison of the subject and predicate device.

Table 1: Comparison to Predicate Device

Device	**Subject Device**	**Predicate Device**	**Reference Device**	**Result**
Manufacturer	Wuxi EA Medical Instruments Technologies Limited.	Smile Development Corp.	Align Technology, Inc.	-
510K number	K203688	K171674	K181739	-
Model Name	Clear Aligner	Angel Align System	Invisalign System with Mandibular Advancement Feature	-
Classification	Class II Device, NXC (21 CFR 872.5470)	Class II Device, NXC (21 CFR 872.5470)	Class II Device, NXC (21 CFR 872.5470)	Same
Classification Name	Aligner, Sequential	Aligner, Sequential	Aligner, Sequential	Same

Indications for use	Clear Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion in patients with permanent dentition (i.e. all second molars).	Angel Align System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.	The Invisalign System is intended for the orthodontic treatment of malocclusion	Same
Mode of Action	Orthodontic tooth movement occurs through forces applied by the device to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Orthodontic tooth movement occurs through forces applied by the device to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Orthodontic tooth movement occurs through forces applied by the device to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Same
Anatomical Site of Use	Oral cavity	Oral cavity	Oral cavity	Same
Mode of Use	Each aligner is worn by the patient as determined by the treating dental practitioner, generally for 2 weeks prior to being replaced by the next aligner in sequence.	Each appliance is worn by the patient as determined by the dental practitioner, generally 2 weeks prior to being replaced by the next aligner in sequence.	Aligners are worn for approximately 1-2 weeks of 20-22 hours of wear per day, after which it is replaced by the next stage aligners. This is repeated for duration as prescribed by the Dental Practitioner	Same
Description of Appliance Application	Removable	Removable	Removable	Same
Method of manufacturing	Thermoforming	Thermoforming	Thermoforming	Same
Manufacturing Method	A digital model of the patient's teeth is created from either CT scanning a PVS	A digital model of the patient's teeth is created from either CT scanning a PVS	A digital model of the patient's teeth is created from either CT scanning	Same

	impression or directly from an intraoral scan of the patient's teeth. From the digital model, following a dental practitioner's prescription, the software generates model transforms describing the provisional final, treated state and then interpolates a series of model transforms that represent intermediate states of alignment. The resulting computer "setups" relay this information to rapid prototyping machines that produce physical positive models. The aligners are produced by thermoforming on each physical model to fabricate the sequence of aligners.	impression or directly from an intraoral scan of the patient's teeth. From the digital model, following a dental practitioner's prescription, the software generates model transforms describing the provisional final, treated state and then interpolates a series of model transforms that represent intermediate states of alignment. The resulting computer "setups" relay this information to rapid prototyping machines that produce physical positive models. The aligners are produced by thermoforming on each physical model to fabricate the sequence of aligners.	a PVS impression or directly from an intraoral scan of the patient's teeth. From the digital model, following a dental practitioner's prescription, the software generates model transforms describing the provisional final, treated state and then interpolates a series of model transforms that represent intermediate states of alignment. The resulting computer "setups" relay this information to rapid prototyping machines that produce physical positive models. The aligners are produced by thermoforming on each physical model to fabricate the sequence of aligners.	
Material	The clear aligner uses either 1. Multilayer thermoformed copolyester and polyurethane composite or 2. Thermoformed	Thermoformed polyurethane	The Invisalign System uses either: 1. Multilayer aromatic thermoplastic polyurethane /copolyester. or 2. thermoformed	Same with the reference device.

	polyurethane		polyurethane	
Traction accessory	Yes Thermoformed polyurethane	No	No	Different. Same material as aligner, no new concerns raised.
OTC or Rx	Rx	Rx	Rx	Same
Sterile	No	No	No	Same
Biocompatibility	In compliance with ISO 10993	In compliance with ISO 10993	In compliance with ISO 10993	Similar. Both are in compliance with ISO 10993

G. Non-clinical Test

1) Biocompatibility Testing

The biocompatibility evaluation for the device was conducted in accordance with "Use of International Standard ISO 10993-1, Biological evaluation and testing within a risk management process –Guidance for Industry and Food and Drug Administration Staff" as recognized by FDA. The aligner is considered mucosal membrane contacting for a duration of greater than 30 days. The testing included the following tests:

- Cytotoxicity
- Irritation
- Sensitization
- Acute Toxicity
- Subchronic toxicity
- Genetic Toxicity

The results of the testing met the requirements of the study protocols and the material is considered non-cytotoxic, non-sensitizing and is not an intracutaneous irritant. The results of the studies further support a determination of substantial equivalence.

2) Software validation & risk analysis

The software system used in the process of clear aligner manufacturing has been verified and validated as per FDA Guidance "General Principles of Software Validation; Final Guidance for Industry and FDA Staff".

A Risk Analysis was performed according to ISO 14971:2019 and documentation was included in the 510(k) to assess the performance and safety of subject device.

3) Performance Testing

Verification and validation testing were conducted to demonstrate the Clear Aligner showed conformity with pre-established specifications and acceptance criteria. The shear and tensile strength testing performed for the Angel button were tested according to EA internal specifications and the

results passed the pre-defined acceptance criteria.
A 3-year shelf life accelerated aging testing were conducted and the test results showed conformity with the pre-established specifications and acceptance criteria.

H. Clinical Test Conclusion

Real-world data was submitted to demonstrate that the traction accessory was effective to aid the movement of teeth and that an analysis of adverse events was provided that showed less than 0.001 ‰ of adverse events were occurred since 2019.

I. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K171674.