April 17, 2023

Zhejiang Yinchili Medical Technology Co., Ltd.
℅ Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K223454
Trade/Device Name: Custom-made Invisible Aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: January 16, 2023
Received: January 17, 2023

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., 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.

510(k) Number *(if known)*
K223454

Device Name
Custom-made Invisible Aligner

Indications for Use *(Describe)*
The Custom-made Invisible Aligners is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). The Custom-made Invisible Aligners 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.

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K223454

510(K) Summary

(As requirement by 21 CFR 807.92)

A. Applicant:

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Date of summary prepared: 2023-03-30

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B. Device:

Trade Name: Custom-made Invisible Aligners
Common Name: Sequential Aligners
Model: YCL-C
Regulatory Information
Classification Name: Aligner, Sequential
Classification: Class II
Product code: NXC
Regulation Number: 21 CFR 872.5470
Review Panel: Dental

C. Predicate device:

K203624 (Primary Predicate)
Custom-made Invisible Aligners
Zhejiang Yinchili Medical Technology Co., Ltd.

Reference device
K181739
Invisalign System with Mandibular Advancement Feature
Align Technology, Inc.

D. Indications for use of the device:

The Custom-made Invisible Aligners is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). The Custom-made Invisible Aligner positions teeth by way of continuous gentle force.

E. Device Description:

The Custom-made Invisible Aligners System is a series of dental aligners that fabricated of clear, thin thermoformed plastic to progressively reposition the teeth. The product is made from a composite multilayer material with thermoplastic polyurethane and polyethylene terephthalate-1, 4-cyclohexanedimethanol ester (TPU+PETG). Corrective force to reposition the teeth is delivered via minor changes into a position in each subsequent aligner. They are designed to move the teeth to the target position and deliver desired clinical effect.

F. Comparison to predicate device

The Custom-made Invisible Aligners is substantially equivalent in intended use, indications for use, mode of action, mode of use, design, and manufacturing to the predicate device. 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
510K number	K223454	K203624	K181739	-
Model Name	Custom-made Invisible Aligners	Custom-made Invisible Aligners	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	The Custom-made Invisible Aligners is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). The Custom-made Invisible Aligner positions teeth by way of continuous gentle	The Custom-made Invisible Aligners is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). The Custom-made Invisible Aligner positions teeth by way	The Invisalign System is intended for the orthodontic treatment of malocclusion.	Same

	force.	of continuous gentle force.		
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 22 hrs/day (or full time except for eating and hygiene) for 2 weeks prior to being replaced by the next aligner in sequence. This is repeated for a duration as prescribed by a Dental Professional.	Each aligner is worn by the patient as determined by the treating dental practitioner, generally for 22 hrs/day (or full time except for eating and hygiene) for 2 weeks prior to being replaced by the next aligner in sequence. This is repeated for a duration as prescribed by a Dental Professional.	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
Application	Removable	Removable	Removable	Same
Raw Material Used	Multilayer TPU (Thermoplastic polyurethane) + PETG (Polyethylene terephthalate-1, 4-cyclohexanedimethanol ester)	Thermoplastic copolyester (polyethylene terephthalate-ethylene glycol copolyester)	The Invisalign System uses either: 1. Multilayer aromatic thermoplastic polyurethane /copolyester. or 2. thermoformed polyurethane	Same with the reference device.
Method of Manufacturing	Thermoforming	Thermoforming	Thermoforming	Same
OTC or Rx	Rx	Rx	Rx	Same

Sterile	No	No	No	Same
Biocompatibility	In compliance with ISO 10993, tests including Cytotoxicity Oral Mucosa Irritation Sensitization Sub chronic systemic toxicity Genotoxicity	In compliance with ISO 10993, tests including Cytotoxicity Oral Mucosa Irritation Sensitization	In compliance with ISO 10993	Similar. Both are in compliance with ISO 10993
Design			Not available	Similar. Both are transparent plastic films.

G. Non-clinical Test

1) Performance Testing

Bench testing has demonstrated that the device is in compliance with pertinent standards and specifications, the expectations of the dental community and the product labeling. Performance testing was performed to the subject device including thickness, appearance, odor, density, water absorption, dissolution, color stability, tear resistance, wear resistance, Tensile modulus of elasticity to demonstrate its effectiveness.

Manufacturing validation accuracy testing

Manufacturing accuracy validation were conducted to the Custom-made Invisible Aligners. Aligners from 12 different patient case were evaluated at the beginning, middle and end throughout the sequence. The accuracy of 3D molding and aligner molding are checked and meet the pre-established specification. The suitability, function and form of the aligner were checked and comparing it to the treatment design in the software, and the results were complied with the pre-established specifications and acceptance criteria.

Shelf life – 3 years

A 3-year shelf life was determined by accelerated aging testing. Performance testing were conducted after 81 days of accelerated aging under 60℃. The test results showed conformity with the pre-established specifications and acceptance criteria.

2) 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
- Sub chronic systemic toxicity
- Genotoxicity

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

3) Software Verification and Validation Testing

Software verification and validation testing were conducted on the software that facilitates ordering and processing of the Custom-made Invisible Aligner to support that the device is as safe and effective as the predicates. Documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

H. Clinical Test Conclusion

No clinical study is included in this submission.

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 K203624.