August 16, 2022

Shenzhen Meiming Dentistry Technology Co., Ltd
Fei Hu
Manager
Floor 3, Buliding D, Fuxinlin Industrial Park, Mati Pond,
Gushu Community, Xixiang Street, Baoan Dis
Shenzhen, Guangdong 518102
China

Re: K213026
Trade/Device Name: Clear Aligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: July 7, 2022
Received: July 18, 2022

Dear Fei Hu:

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,

For 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)*
K213026

Device Name
Clear Aligner

Indications for Use *(Describe)*
The Clear Aligners indicated for use in the alignment of permanent teeth (i.e. all second molars) through orthodontic treatment of misalignment and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary

510(k) number: K213026
Date of Summary Preparation: August 15, 2022

Applicant

Name: Shenzhen Meiming Dentistry Technology Co., Ltd
Address: Floor 3, Building D, Fuxinlin industrial park, Mati pond, Gushu community, Xixiang street, Baoan district, Shenzhen, Guangdong, China
Official Contact Person Information
Name: Fei Hu
Tel: 0086- 13219006323
Mail: shenzhenmeiming@gmail.com

Device

Trade name:	Clear Aligner
Common name:	Aligner, Sequential
Classification name:	Aligner, Sequential
Regulation Medical Specialty	Dental
Regulation Number	872.5470
Product Code	NXC
Classification	Class II

Predicate device

510 (K) Number: K201450
Straight T Clear Dental Aligner
Produced by Straight T, Inc.

Indication for use:

The Clear Aligners indicated for use in the alignment of permanent teeth (i.e. all second molars) through orthodontic treatment of misalignment and malocclusion.

Device Description

The Clear Aligners are intraoral thermoformed plastic aligners that are worn 22 hours per day and are designed to be used in a sequence, each aligner providing a gentle continuous force, to allow for the movement of teeth to the final desired position. The aligners are to be removed for eating and for cleaning.
The Clear Aligners are fabricated using a three-step process.
The first step is to obtain the dimensions and details of the patient's baseline dentition. This is

generally done using an oral scan data or a physical impression. This scanned data (digital CAD/CAM models or patient models) are imported into specialized dental software for treatment planning.
The second step is the printing of 3D models of the treatment plan for use in step 3 (thermoforming). In the second step, the doctor utilizes a software application to plan the treatment by creating a series of sequential models that gradually position the teeth into their final desired position. A 3D printer is used to create the molds needed for each treatment step to provide the surface around which the aligner is thermoformed.
The final step is the thermoforming of a plastic sheet material to each of the sequential treatment steps. This process is done using a standard thermoforming equipment and the appropriate material as outlined in this submission.

Software Description
Specialized orthodontic CAD/CAM software will be used to develop the treatment plans and to produce standard 3D printer files that will facilitate the manufacturing of each sequential aligner in the treatment plan. The software application used for the manufacturing validation in this submission is the 3Shape®.

Mechanism of Action
In the same manner as the predicate device, each aligner exerts gentle force to achieve progressive realignment of the teeth until the final correction has been attained. This is based on the treatment plan and proceeds over time.

Comparison with predicate
A summary comparison of features is provided in the following Table:

Device	**New Device (K213026)**	**Predicate Device** Straight T Clear Dental Aligner **(K201450)**	**Comparison**
Manufacturer	Shenzhen Meiming Dentistry Technology Co., Ltd	Straight T, Inc.	NA
Indication for use	The Clear Aligners indicated for use in the alignment of permanent teeth (i.e. all second molars) through orthodontic treatment of misalignment and malocclusion.	The Straight T Clear Dental Aligner Is indicated for use in the alignment of permanent teeth (i e all second mol ars) through orthodont ic treatment of misalignment and malocclusion.	Same
Method of use	Each preformed plastic tray is worn by the patient as prescribed by	Each preformed plastic tray is worn by the patient as prescribed by	Same

	the dental practitioner, usually a few weeks prior to using the next sequential aligners tray.	the dental practitioner, usually a few weeks prior to using the next sequential aligners tray.	
Biocompatible	Yes	Yes	Same
OTC or Rx	Rx	Rx	Same
Software Use	Yes, 3Shape K180491	Yes, 3Shape K180491	Same
Sterile	No	No	Same

There are no differences identified between new device and the predicate device for intended use, mode of action, method of use, material, biocompatibility and software, etc, thus they are substantial equivalent.

Non-clinical Test

Non-clinical tests have been conducted to verify that the Clear Aligner meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device.

Manufacturing validation accuracy testing

A manufacturing validation was performed to demonstrate the manufacturing process for Clear Aligner. Three critical aspects of the manufacturing process were assessed: digital dentition models from treatment planning, 3D printed molds, and the final thermoformed aligner.

An independent 3rd party software and digital calipers were used to perform point-to-point measurement. All translational measurements were within 0.3mm of the target input value, the predefined tolerance of the manufacturing process. There were no statistical differences in the difference in the intended and measured values observed from any of the groups. This test has met the pre-established acceptance criteria.

The results of the manufacturing validation accuracy testing support a determination of substantial equivalence.

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 Clear aligner is considered surface contacting for a duration of greater than 30 days. The testing included the following tests:

- Cytotoxicity
- Irritation
- Sensitization

The results of the testing met the requirements of the study protocol 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.

Clinical Test

No clinical study is included in this submission.

Conclusion:

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K213026, Clear Aligner is as safe, as effective, and performs as well as the legally marketed predicate device cleared under K201450.