December 20, 2022

Nanjing Jiahe Dental Technology Co., Ltd.
% Charles Shen
Director
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K222308
Trade/Device Name: Al Smile Aligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: November 22, 2022
Received: November 22, 2022

Dear Charles Shen:

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
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)*
K222308

Device Name
Al Smile Aligner

Indications for Use *(Describe)*
"Al Smile Aligner" is indicated for the alignment of teeth during 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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K222308

Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

5.1 Submitter & Foreign Manufacture Identification

Nanjing Jiahe Dental Technology Co., Ltd.
Room 201, Building 2, No.2 Shuanglong Street, Qinhuai District,
Naujing, Jiangsu Province, China, Zipcode 210000
Tel： (086) 400-0880468
Submitter's FDA Registration Number： N/A

5.2 Contact Person

Charles Shen
Manton Business and Technology Services
37 Winding Ridge, Oakland, NJ 07436
Tel: 608-217-9358
Email: cyshen@aol.com

5.3 Date of Summary: July 11, 2022

5.4 Device Name:

Proprietary Name:	Al Smile Aligner
Common Name:	Dental Plastic Aligner
Classification Name:	Orthodontic Plastic Brackets - Sequential Aligners
Device Classification:	II
Regulation Number:	21 CFR 872.5470
Panel:	Dental
Product Code:	NXC

5.5 Predicate Device Information:

(1) K200908, "iSMILE", manufactured by "3D Diagnostix Inc."

5.6 Device Description:

"Al Smile Aligner" consists of a custom-made series of thin, clear plastic removable orthodontic appliances (aligners) that apply gentle pressure to teeth, gradually moving them into alignment.

A dentist or orthodontist assesses the patient to determine if the patient is a good candidate. Impressions are taken by the dental clinician and submitted to Nanjing Jiahe Dental Technology Co., Ltd along with the physician's prescription.

An FDA cleared dental software used for teeth alignment was used to design a series of plastic aligners intended to gradually realign the patient's teeth in accordance to the doctor's prescription.

Once the treatment plan is reviewed and approved by a 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 "Al Smile Aligners" have the same technological characteristics as the predicate device, in that all the devices are made from commercially available plastic that is thermoformed to create a customized, patient-specific aligner. The aligners are then used for minor tooth movement by way of continuous gentle force.

5.7 Indications for Use:

"Al Smile Aligner" is indicated for the alignment of teeth during orthodontic treatment of malocclusion.

5.8 Summary of Device Testing:

As part of demonstrating substantial equivalence of "Al Smaile Aligner" to the predicate device that are subject to this 510(k) submission, we have completed a number of non-clinical performance tests. "Al Smile Aligner" meets all the requirements for overall design, biocompatibility, and performance results confirming that the design output meets the design inputs and specifications for the device.

Laboratory Testing

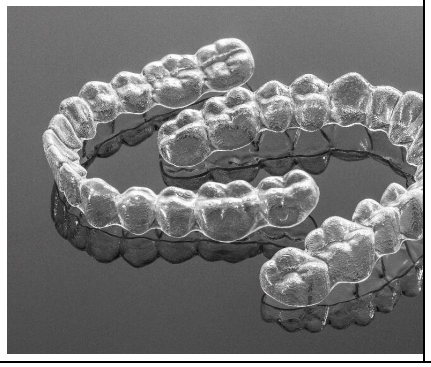
- Performance including physical, chemical, and mechanical properties
- Validate the processes used for the design and manufacture of the customized aligners.
- Additionally, mechanical property and elasticity of the thermoformed device were studied following ASTM standards such as ASTM D570, ASTM D638, ASTM D790, and ASTM D1525.

Biocompatibility Testing
The device has been tested according to Good Laboratory Practices for its biocompatibility according to ISO 10993, as follows:

- Part 3 (Ames Assay)
- Part 5 (Cytotoxicity)
- Part 10 (Oral Mucosa Irritation)
- Part 10 (Maximization for Delayed-Type Hypersensitivity)
- Part 11 (Systemic Toxicity)

5.9 Technological Comparison with Predicate Device

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Description	Subject Device	Predicate Device (K200908)	SE Decision
Brand Name	Al Smile Aligner	iSMILE	SE
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	SE
Product Code	NXC	NXC	SE
Classification	Class 2	Class 2	SE
Indication for Use	"Al Smile Aligner" is indicated for the alignment of teeth during orthodontic treatment of malocclusion.	iSMILE is indicated for the alignment of teeth during orthodontic treatment of malocclusion.	SE
Mode of Action	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays, fabricated based on doctor's prescription.	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays, fabricated based on doctor's prescription.	SE
Materials	Thermoplastic	Thermoplastic	SE
Processing	Thermoforming	Thermoforming	SE
Dimension	Customized patient specific	Customized patient specific	SE
Anatomy Location	Dental mucosal	Dental mucosal	SE
Single Use	Yes	Yes	SE
Prescription or OTC	Rx	Rx	SE
Sterile	Non-sterile	Non-sterile	SE
Software Use	Yes	Yes	SE
Product Picture			SE

Biocompatibility	Meet ISO 10993-1	Meet ISO 10993-1	SE
Performance	Bench Testing and Process Validation	Bench Testing and Process Validation	SE

Our device is essentially identical to the predicate device in terms of indications for use, design, material, and processing between our device and the predicate devices.

5.10 Substantial Equivalence Conclusion

It has been shown in this 510(k) submission that "Al Smile Aligner" and its predicate devices have the identical indications for use, similar composition and biocompatibility, similar manufacturing process, and adequate performance.

The difference between the "Al Smile Aligner" and their predicate device do not raise any question regarding its equivalence.

"Al Smile Aligner", as designed and manufactured, is equivalent to its predicate device, and therefore is substantially equivalent as its predicate device.