January 30, 2020

Vitang Technology, LLC
Xiangxu Chen
Vice President of Regulatory and R&D
14662 Franklin Ave, Unit H
Tustin, California 92780

Re: K191837
Trade/Device Name: UniSmile Clear Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: October 25, 2019
Received: November 1, 2019

Dear Xiangxu Chen:

This letter corrects our substantially equivalent letter of January 29, 2020.

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 Srivinas ‘Nandu’ Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191837

Device Name
UniSmile Clear Aligner System

Indications for Use *(Describe)*
The UniSmile Clear Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition. The UniSmile Clear Aligner System 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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Vitang Technology, LLC
Traditional 510(k) Premarket Submission
Vitang UniSmile Clear Aligner System

K191837

510(k)Summary

UniSmile Clear Aligner System

Submitter Name:	Vitang Technology LLC
Submitter Address:	14662 Franklin Ave, Unit H, Tustin, CA 92780
Phone Number:	773-236-7691
Contact Person:	Xiangxu Chen
Date Prepared:	1/29/2020
Device Trade Name:	UniSmile Clear Aligner System
Common Name:	Aligner, sequential
Classification Name:	Orthodontic Plastic Bracket
Classification Number:	21 CFR 872.5470
Product Code:	NXC
Regulatory Class	2
Primary Predicate	K113618, ClearCorrect System
Reference Device	K181112, Orchestrate 3D
Device Description	The UniSmile Clear Aligner System is fabricated of clear thin thermoformed plastics in a sequential series to progressively reposition the teeth. Corrective force to reposition the teeth is delivered via minor changes into a position in each subsequent aligner.

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Indications for Use

The UniSmile Clear Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition. The UniSmile Clear Aligner System positions teeth by way of continuous gentle force.

Summary of Usage

UniSmile Clear Aligner System consists of a series of clear plastic aligners that offer a solution for aesthetic orthodontic treatment by utilizing a set of removable aligners to incrementally move the patient's teeth from an original state to a treated state that corrects tooth malocclusions.

Cases are submitted by the dental professionals and images of patient teeth structures are transformed to three-dimensional data files. Treatment planning, aligner design and aligner manufacture are supported by a software system, based on an assessment of the patient's teeth, which determines the course of treatment with the system, takes molds of the patient's teeth and completes a prescription form.

A series of plastic trays are then designed, in sequential stages, which are intended to gradually realign the patient's teeth in accordance of the treatment plan. Attachments and hooks may be designed to facilitate tooth movement and better and faster align anchorage. The dental practitioner may choose a standard dental bonding agents and composites to bond the attachments to the dentition. The aligners are individually identified and dispensed to patients and are to be worn in a specific, prescribed sequence.

The prescribing dental professional reviews and approves the model scheme before the molds are produced. Once approved, trays are produced by thermoforming plastic sheets. The trays are sent back to the dental health professional for the patient, confirming fit and design. Over a period of time, patients use these sequentially trays to gradually move the target teeth to the designed position. The dental health professional monitors treatment from the moment the first aligner is used by the patient.

Design and Manufacturing Flow chart

- This is a device that requires prescription by order of a dental practitioner.
- Based on the patient information from a dental practitioner, the treatment plan is designed with a software.
- The treatment plan is then forwarded to the dental practitioner for review.
- Once approved, the aligners are manufactured by thermal forming on digitally printed models.
- Clear aligners are delivered to the practitioner.
- Each aligner is used by the patient, with instructions.

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- Each aligner is designed for single use within a defined period of time, such as 2 weeks/aligner.
- It is not sterilized.
- It does not contain drugs or biological substances.

Software	Software is used to design treatment plans. The software used with UniSmile Clear Aligner System is the Orchestrate 3D (K181112) software, version OrthoRx 4.
Clear Aligner Materials Testing	Performance properties have been tested and approved for clear aligner applications.
Biocompatibility	Biocompatibility testing has been provided according to ISO-10993

Comparison with Predicate Device

	UniSmile Clear Aligners	**ClearCorrect System**	**Comparison**
510(k) number	K191837	K113618	
Regulation number	21 CFR 872.5470	21 CFR 872.5470	same
Device common/classification name	Aligner, sequential	Sequential Aligner	same
Product Code	NXC	NXC	
Indications for use	The UniSmile Clear Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition. The UniSmile Clear Aligner System positions teeth by way of continuous gentle force.	The ClearCorrect System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The ClearCorrect System positions teeth by way of continuous gentle force.	Same
Device Description	The UniSmile Clear Aligner System is fabricated of clear thin thermoformed plastics in a sequential series to progressively reposition the teeth. Corrective force to reposition the teeth is delivered via minor changes into a position in each subsequent aligner.	The ClearCorrect device is fabricated of clear thin thermoformed polyurethane plastic in a sequential series to progressively reposition the teeth. Corrective force to straighten the teeth is delivered via minor changes into a position in each subsequent aligner.	Same
Mode of Action	A set of removable aligners incrementally move the	Orthodontic tooth movement occurs	Same

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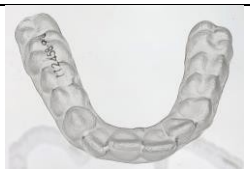
	patient's teeth from an original state to a treated state through forces applied by the appliance that corrects tooth malocclusions. The programmed displacement is based on a doctor's prescription.	through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	
Anatomy Location	Mouth, mucosal membranes	Mouth, mucosal membranes	Same
Size/Dimension	Patient and treatment progress specific	Patient and treatment progress specific	Same
Method of Manufacturing	Thermoforming	Thermoforming	Same
Material	Thermoplastic copolyester	Thermoplastic polyurethane	Similar. Both are thermoplastic forming materials that do not raise any additional questions of safety or efficacy
Material Hardness	80 ± 2 Shore D durometer	80 ± 2 Shore D durometer	Same
Material Tensile Modulus	Tensile modulus is acceptable for as an orthodontic base material	Information not available	Good for orthodontic clear aligner applications
Material Tensile Strength	Tensile strength is acceptable for as an orthodontic base material	Information not available	Good for orthodontic clear aligner applications
Biocompatibility	Passed ISO 10993-1 assessment • Cytotoxicity • Intracutaneus Intradermal reactivity • Sensitivity	Passed ISO 10993-1 asseessment • Cytotoxicity • Intracutaneus Intradermal reactivity	Same
Visual			Similar. Both are transparent plastic films

Conclusion of Substantial Equivalence

UniSmile Clear Aligner System have substantially equivalent Indications for Use as the identified predicate and reference devices.

UniSmile Clear Aligner System are substantially equivalent to the predicate device in the technological characteristics, design and device features.