April 23, 2020

Universal Orthodontic Laboratory Inc
Jiahe Li
Regulatory Affair Associate
11917 Front St.
Norwalk, California 90650

Re: K191308
Trade/Device Name: U-Aligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: April 21, 2020
Received: April 21, 2020

Dear Jiahe Li:

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 Srinivas “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

Section IV

Indications for Use Statement

510(k) Number (if known): K191308

Device Name: U-Aligner

Indications for Use:

The U-Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The U-aligner system repositions teeth by way of continuous gentle force.

Prescription Use ___X___ OR Over-The-Counter Use_____

Section V K191308

510(k) Summary

Submitter:
Universal Orthodontic Lab
11917 Front St.
Norwalk, CA 90650
Contact Person:
Jiahe Li
Regulatory Affairs Manager
Lijh0919@gmail.com
(562) 484-0500

Date Summary Prepared:
May 1st, 2019

DEVICE NAME

TRADE NAME: U-Aligner

COMMON NAME: Sequential Aligner

DEVICE CLASSIFICATION: Aligner, Sequential

CLASSIFICATION PRODUCT CODE: NXC

PREDICATE DEVICE

Primary Predicate - Custom Clear Aligner System - Derby Dental Laboratory - K173785
Reference Device - ClearCorrect System- ClearCorrect LLC - K113618

DESCRIPTION OF DEVICE

The U-Aligner system is a series of clear plastic aligners that offer a solution for patients who want an aesthetic orthodontic treatment by utilizing a set of removable aligners to correct tooth

malocclusions without the use of conventional wire and bracket orthodontic technology.

A dental health professional (e.g. orthodontist or dentist), using a standard personal computer prescribes the U-Aligner system based on an assessment of the patient's teeth, determines a course of treatment with the system, takes molds of the patient's teeth and completes a prescription form. Universal Orthodontic Lab then designs a series of plastic trays intended to gradually realign the patient's teeth in accordance with the physician's prescription using a standard dental software used for tooth alignment (Ortho System™, K180941). The prescribing physician reviews and approves the model scheme before the molds are produced. Once approved, Universal Orthodontic Lab produces trays, which are formed of clear, thin, thermoformed plastic. The trays are sent back to the dental health care professional who then provides them to the patient, confirming fit and design. Over a period, additional trays are provided sequentially to the patient by the dental health professional to gradually move the target teeth to the designed position. The dental care professional monitors treatment from the moment the first aligner is delivered to when the final aligner is delivered. The trays are held in place by pressure and can be removed by the patient at any time.

The technology is essentially identical to that used by a number of sequential aligner systems, including the two predicate devices.

INDICATIONS FOR USE

The U-Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The aligner system repositions teeth by way of continuous gentle force.

Summary of Technical Characteristics

	U-Aligner	**Primary Predicate-Custom Clear Aligner System (K173785)**	**Reference Device-ClearCorrect System (K113618)**	**Substantial equivalence**
Product Code	NXC	NXC	NXC	Yes
Device Class	Class II	Class II	Class II	Yes
Intended Use	U-Aligner is indicated for the treatment of anterior tooth malocclusions in patients with permanent dentition (i.e. all second	The Custom Clear Aligner System is indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and	ClearCorrect System is indicated for the treatment of anterior tooth malocclusions in patients with permanent dentition (i.e. all second	Yes

	molars).	malocclusion	molars).	
Indications for Use	The U-Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The U-aligner system repositions teeth by way of continuous gentle force.	The Custom Clear Aligner System is a series of clear, lightweight, plastic appliances indicated for the treatment of tooth malocclusions in patients with permanent dentition (i.e., all second molars). Utilizing a series of incremental tooth movements, it sequentially positions teeth by way of continuous gentle force.	ClearCorrect System is indicated for the treatment of anterior tooth malocclusions in patients with permanent dentition (i.e. all second molars). The Clear Correct System positions teeth by way of continuous gentle force.	Yes
Mode of Action	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays	Yes
Method of Use	Each preformed plastic tray is worn by the patient as prescribed by the dental practitioner, usually a few weeks prior to using the next sequential aligner tray	Each preformed plastic tray is worn by the patient as prescribed by the dental practitioner, usually a few weeks prior to using the next sequential aligner tray	Each preformed plastic tray is worn by the patient as prescribed by the dental practitioner, usually a few weeks prior to using the next sequential aligner tray	Yes
Material	Thermoformed polyurethane	Thermoformed polyurethane	Thermoformed polyurethane	Yes

Performance Testing

Due to the difficulty in evaluating this type of dental device in a laboratory environment, no direct performance bench testing of the aligners was performed. The use of thermoplastic materials for sequential aligners intended to treat malocclusions have been well documented in scientific literature regarding incremental tooth moving forces. The physical properties have been provided by the material manufacturer.

An internal manufacturing validation was performed to demonstrate the dimensional accuracy of the manufacturing process for U-Aligners. The results show that the pre-planned location and position of tooth structures defined by the aligner is expected compared to the final finished thermoformed aligner.

Biocompatibility Testing

The biocompatibility evaluation for the device was conducted in accordance with 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 battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

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.

Conclusion

U-Aligner is considered to be substantially equivalent to the identified legally marketed predicate in terms of indications for use, design, technological characteristics, mode of action, performance, materials and biocompatibility.