December 20, 2019

CDB Corporation
Leah Lehman
Quality & Regulatory Manager
9201 Industrial Blvd
Leland, North Carolina 28451

Re: K191823
Trade/Device Name: Clear-Aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: November 18, 2019
Received: November 19, 2019

Dear Leah Lehman:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K191823

Device Name
Clear-Aligners

Indications for Use *(Describe)*
The Clear-Aligner system is indicated for the treatment of malocclusion in patients with permanent dentition. The 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.

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

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510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21CFR 807.92.

Submitter: CDB Corporation
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Establishment Registration No.: 1054415

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Date Prepared:	December 19, 2019
510k Submission:	K191823
Device Name:	Clear-Aligners
Common Name:	Sequential Aligner
Classification Name:	Orthodontic Plastic Bracket
Regulation Number:	21 CFR 872.5470
Product Code:	NXC
Classification Panel:	Dental Products Panel 76
Classification:	Medical Device, Class II

Indications for Use:

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

Predicate Devices:

Clear Correct, Clear Correct Inc., K082556 (primary predicate)
Invisalign, Align Technology, K981095 (reference device)

Device Description:

A dental health care professional (e.g. orthodontist or dentist), using a standard personal computer prescribes the Clear-Aligner system based on an assessment of thee patient's teeth, determines a course of treatment with the system, takes molds of the patient's teeth, and completes a prescription form. Utilizing standard dental software used for tooth alignment, CDB then designs a series of plastic trays intended to gradually realign the patient's teeth in accordance with the physician's prescription. The prescribing physician reviews and approves the treatment plan before the molds are produced. Once approved, CDB produces the trays, which are formed of clear, thin, thermoformed, copolyester plastic. The trays sent back to the dental health care professional, who then provides them to the patient, confirming fit and design. Over a period of months, additional trays are provided sequentially to the patient by the dental health professional to gradually move the target teeth to the desired 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. This technology is essentially identical to that used by a number of sequential alignment systems, including the predicates referenced in **Table 1**.

Technological Characteristics:

Treatment of tooth malocclusions via a series of plastic appliances that incrementally moves teeth to a desired end-state is the technological principle for both the subject and predicate devices. A comparison between technological characteristics of the Clear-Aligners and that of legally marketed predicate devices has been performed. The results of this comparison demonstrate that the design, technology, materials, and composition of the Clear-Aligners are substantially equivalent to the predicate devices.

Mechanism of Action:

The mechanism of action is similar to the predicate devices and supports a determination of substantial equivalence. Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a dental health professional's prescription.

Performance Testing:

Bench testing was performed to ensure the accuracy of the final product carried through the entire process from the initial scan through treatment planning and manufacturing of the model to the final thermoformed aligner. Functional characteristics tested and the standard by which they were tested include the following, all pre-established specification and acceptance criteria:

- Fit of the aligner against the treatment plan as determined by dental health professional
- Process consistency from the treatment plan file to 3D printed mold to final aligner was measured against internal acceptance criteria derived by considering all sources of variation

The acceptance results observed during the verification and validation testing that has been conducted on these devices has shown that they are capable of performing to their stated intended use and specification requirements.

Further testing was not performed given there is sufficient information available from the scientific literature and from the predicate devices to demonstrate that sequential aligners provide reasonable assurance of substantial equivalence.

Biocompatibility Testing:

The biological evaluation for the device was conducted in accordance with the US FDA Docket Number FDA-2013-D-0350, “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 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 the determination of substantial equivalence.

Software Consideration

There are two areas in the Clear-Aligner process where software is used; they are the ordering process and treatment planning. The software usage in these areas is considered of moderate concern. Software testing has been performed to verify the function of the Clear-Aligners, which supports a substantial equivalence decision.

Substantial Equivalence Comparison:

The following table compares the Clear-Aligner system to the predicate devices, Clear Correct (primary predicate) and the Align System (reference device), with respect to intended use, technological characteristics, and principles of operation.

Table 1. Predicate Device Information Comparison

Feature	Clear-Aligners	Clear Correct	Align System
	Submission Device	**Primary Predicate**	**Reference Device**
510(k) Number	K191823	K082556	K981095
Manufacturer	CDB Corporation	Clear Correct Inc.	Align Technology
Regulation Number	872.5470	872.5470	872.5470
Device Classification	Aligner, Sequential	Aligner, Sequential	Aligner, Sequential
Product Code	NXC	NXC	NXC
Device Class	II	II	II
Indications for Use	The Clear-Aligner system is indicated for the treatment of malocclusion in patients with permanent dentition. The Clear-Aligner system positions teeth by way of continuous gentle force.	The Clear Correct System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The Clear Correct System positions teeth by way of continuous gentle force.	The Align System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The Align System positions teeth by way of continuous gentle force.
Mode of Action	Alignment of teeth by sequential use of preformed plastic trays.	Alignment of teeth by sequential use of preformed plastic trays.	Alignment of teeth by sequential use of preformed plastic trays.
Material	Thermoformed Copolyester	Thermoformed Polycarbonate	Thermoformed Polycarbonate
Material Properties	Demonstrates sufficient tensile strength, elasticity, ductility, chemical resistance, and clarity for use as a clear tray aligner	Demonstrates sufficient tensile strength, elasticity, ductility, chemical resistance, and clarity for use as a clear tray aligner	Demonstrates sufficient tensile strength, elasticity, ductility, chemical resistance, and clarity for use as a clear tray aligner
Software Used for Ordering Workflow	Yes	Yes	Yes
OTC or Rx	Rx	Rx	Rx

Substantial Equivalence Conclusion:

The conclusion drawn from the data included in this submission demonstrates that the Clear-Aligner system is substantially equivalent to the predicate devices in indications for use, design, technological characteristics, mechanism of action, performance, materials, and biocompatibility.