October 5, 2022

ClearCorrect, LLC
Christopher Klaczyk
VP, Head of Regulatory Affairs
21 Cypress Boulevard, Suite 1010
Round Rock, Texas 78665

Re: K220140
Trade/Device Name: ClearCorrect System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: September 8, 2022
Received: September 9, 2022

Dear Christopher Klaczyk:

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, 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)*
K220140

Device Name
ClearCorrect System

Indications for Use *(Describe)*
The ClearCorrect System is indicated for the alignment of teeth during orthodontic treatment of tooth 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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510(k) Summary **K220140**

Submitter:	ClearCorrect, LLC 21 Cypress Boulevard Suite 1010 Round Rock, TX 78665
Contact Person:	Christopher Klaczyk Head of Regulatory Affairs +1 (512) 831-5128 christopher.klaczyk@clearcorrect.com
Date Prepared:	October 1, 2022
Product Code(s):	NXC (21 CFR 872.5470)
Device Class:	II (21 CFR 872.5470)
Classification Panel:	Dental Devices (DHT1B)
Classification Name:	Orthodontic plastic bracket (21 CFR 872.5470)
Common Name	Aligner, Sequential
Proprietary Name:	ClearCorrect System
Predicate Device(s):	K143630, Invisalign System, Align Technologies
Reference Device(s):	K210320, ClearCorrect System, ClearCorrect, LLC K203737, Spark Clear Aligner System, Ormco Corporation
Device Description:	The aligners of the ClearCorrect System are a sequential series of clear thermoformed orthodontic appliances that, when worn in the prescribed sequence and duration, progressively reposition the teeth. The aligner is an orthodontic appliance intended for intra-oral use. Individual devices will be used between 20 – 22 hours per day for a period ranging from one to three weeks. The corrective forces to align teeth are primarily generated by the difference between the starting tooth position and the planned tooth position defined by the appliance. Features can be added to the aligner that engage with composite resin tooth attachments to improve aligner retention and/or to apply force in directions that cannot be achieved by engaging with tooth surfaces alone.

Indications For Use: The ClearCorrect System is indicated for the alignment of teeth during orthodontic treatment of tooth malocclusion.

Materials: The ClearCorrect aligners are produced from multi-layer polymer film having the trade name ClearQuartz™. The film consists of one layer of elastomeric polyurethane sandwiched between two layers of rigid co-polyester.

Technological Characteristics: A comparison of the indications and relevant technological characteristics between the subject and primary predicate devices is provided in the table that follows.

Performance Data:

- Package integrity via simulated transport test per ISTA 2A
- Validation of shelf life per ASTM F1980
- Biocompatibility per the ISO 10993 series standards
- Water absorption testing per ISO 62
- Tensile performance testing per ISO 527-3
- Flexural performance testing per ISO 178
- Impact performance testing per ISO 8256
- Tear resistance testing per ISO 6383-1
- Fatigue resistance testing per ASTM D7774
- Stress relaxation testing
- Dimensional stability per internal methods
- Usability testing per IEC 62366-1
- Software development per IEC 62304

Conclusions: The Indications for Use and the technological characteristics of the subject device are largely the same as the primary predicate device. The material of construction and the treatment planning software are identical to the reference predicate device. The subject devices have been determined to be substantially equivalent to the identified predicate devices.

Feature	Subject Device ClearCorrect System	Primary Predicate Device Invisalign System (K143630)	Reference Device ClearCorrect System (K210320)	Reference Device Spark Clear Aligner Sys. (K203737)	Equivalence Discussion
Indications for Use	The ClearCorrect System is indicated for the alignment of teeth during orthodontic treatment of tooth malocclusion.	The Invisalign System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.	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.	The Spark™ Clear Aligner System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.	**Equivalent** The indication for the Subject Device is a subset of the indications for the Primary Predicate Device. And the K203737 Reference Predicate Device.
Mode of Action / Operating Principle	The aligner is an orthodontic appliance intended for intra-oral use. Individual devices will be used between 20 – 22 hours per day for a period ranging from one to three weeks The corrective forces to align teeth are primarily generated by the difference between the starting tooth position and the planned tooth position defined by the tray. Features can be added to the aligner that engage with composite resin tooth attachments to improve aligner retention and/or to apply force in directions that cannot be achieved by engaging with tooth surfaces alone.	The corrective forces to align teeth are primarily generated by the difference between the starting tooth position and the planned tooth position defined by the tray.	The aligner is an orthodontic appliance intended for intra-oral use. Individual devices will be used between 20 – 22 hours per day for a period ranging from one to three weeks The corrective forces to align teeth are primarily generated by the difference between the starting tooth position and the planned tooth position defined by the tray. Features can be added to the aligner that engage with composite resin tooth attachments to improve aligner retention and/or to apply force in directions that cannot be achieved by engaging with tooth surfaces alone.	Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	**Equivalent** The mode of operation of the Subject Device is largely equivalent to that of the Primary Predicate Device and is identical to that of the K210320 Reference Predicate Device.

Feature	Subject Device ClearCorrect System	Primary Predicate Device Invisalign System (K143630)	Reference Device ClearCorrect System (K210320)	Reference Device Spark Clear Aligner Sys. (K203737)	Equivalence Discussion
Aligner Material	Thermoplastic polyurethane-polyester composite resin, tradename ClearQuartz	Thermoplastic polymer	Thermoplastic polyurethane-polyester composite resin, tradename ClearQuartz	Thermoplastic polyurethane-polyester composite resin, tradename TruGEN	**Identical** The Subject Aligner material is identical to that of the Reference Devices per K210320 and K203737.
Sterilization	Provided in non-sterile condition. Not intended to be sterilized before use.	Provided in non-sterile condition. Not intended to be sterilized before use.	Provided in non-sterile condition. Not intended to be sterilized before use.	Provided in non-sterile condition. Not intended to be sterilized before use.	**Identical** The status of the Subject devices is identical to that of the Reference Device per K210320.
Singe Use/ Reuse	Repeated use by a single patient	Repeated use by a single patient	Repeated use by a single patient	Repeated use by a single patient	**Identical** The use profile of the Subject devices is identical to that of the Reference Device per K210320.
Packaging	**Primary:** LDPE bag containing one or two appliances as defined by the prescribed treatment plan. **Secondary:** 20 pt C1S SBS paperboard box	Unknown	**Primary:** LDPE bag containing one or two appliances as defined by the prescribed treatment plan. **Secondary:** 20 pt C1S SBS paperboard box	Unknown	**Identical** The packaging for the Subject devices is identical to that of the Reference Device per K210320.

Feature	Subject Device ClearCorrect System	Primary Predicate Device Invisalign System (K143630)	Reference Device ClearCorrect System (K210320)	Reference Device Spark Clear Aligner Sys. (K203737)	Equivalence Discussion
Treatment Planning Software Description	ClearCorrect technicians using the ClearCorrect Cut and Stage software use a scan of a PVS impression or the output of an intra-oral scanner of the patient's untreated oral anatomy and the prescription details to derive the desired final patient tooth positions. Using this desired state, the software interprets a series of intermediate states that adhere to defined maximum tooth motions and clinician instructions. The technician further refines these intermediate states manually as necessary to facilitate the desired outcome. The dental practitioner then reviews these images and has the option to reject or request modifications to the set-up prior to approving it for aligner fabrication. Once the dental practitioner approves the treatment plan, the software converts the files to produce the series of custom-made aligners	The Align 3-D Software uses a scan of a PVS impression or a digital scan (which represents an untreated state) to generate the image of a final, treated state and then interprets a series of images that represent intermediate teeth states. The dental practitioner then reviews these images and has the option to reject or request modifications to the set-up prior to approving it for aligner fabrication. Once the dental practitioner approves the treatment plan, the software converts the files to produce the series of custom-made aligners	ClearCorrect technicians using the ClearCorrect Cut and Stage software use a scan of a PVS impression or the output of an intra-oral scanner of the patient's untreated oral anatomy and the prescription details to derive the desired final patient tooth positions. Using this desired state, the software interprets a series of intermediate states that adhere to defined maximum tooth motions and clinician instructions. The technician further refines these intermediate states manually as necessary to facilitate the desired outcome. The dental practitioner then reviews these images and has the option to reject or request modifications to the set-up prior to approving it for aligner fabrication. Once the dental practitioner approves the treatment plan, the software converts the files to produce the series of custom-made aligners	The Spark™ Clear Aligner System 3-D software uses scanned teeth data, landmarks and the clinician's prescription to design a corrected case setup for the clinician's review. The output files from this software are sent to the clinician, who may suggest improvements or approve as-is for manufacture. The software is used to produce pre-molds and molds needed for the manufacturing of series of custom-made aligners.	**Identical** The software used by technicians internal to ClearCorrect is identical to that used with the Reference Predicate Device. The software is functionally equivalent to the software of the Primary Predicate.

Feature	Subject Device ClearCorrect System	Primary Predicate Device Invisalign System (K143630)	Reference Device ClearCorrect System (K210320)	Reference Device Spark Clear Aligner Sys. (K203737)	Equivalence Discussion
Clinician Interface Software Description	The ClearCorrect Doctor Portal is used by the clinician to initiate new treatment cases coordinating the provision of dental records, the prescription, and any other treatment instructions. Doctor Portal also allows the clinician to manage existing cases and address any actions associated with those cases. The ClearCorrect ClearPilot™ allows the clinician to view, comment and approve the orthodontic treatment plan. ClearPilot also allows the clinician to monitor treatment progress against the plan and to share the plan with the patient.	ClinCheck Software is an electronic prescription form and process used to depict, edit, view, monitor and approve an orthodontic treatment plan. Treatment Plan File: • The plan downloads to other computing devices (e.g., tablets) The plan is deleted upon exiting application	The ClearCorrect Doctor Portal is used by the clinician to initiate new treatment cases coordinating the provision of dental records, the prescription, and any other treatment instructions. Doctor Portal also allows the clinician to manage existing cases and address any actions associated with those cases. The ClearCorrect ClearPilot allows the clinician to view, comment and approve the orthodontic treatment plan. ClearPilot also allows the clinician to monitor treatment progress against the plan and to share the plan with the patient.	Unknown	**Equivalent** The combination of Subject device clinician interface software provides the same functionality as the Primary Predicate Device ClinCheck software and is identical to that of the Reference Device.