August 6, 2021

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

Re: K210320
Trade/Device Name: ClearCorrect System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: May 3, 2021
Received: May 5, 2021

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)*
K210320

Device Name
ClearCorrect System

Indications for Use *(Describe)*
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.

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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5. 510(k) Summary K210320

Submitter: ClearCorrect, LLC
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Contact Person: Christopher Klaczyk
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Date Prepared: July 30, 2021

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): K113618, ClearCorrect System, ClearCorrect LLC

Reference Device(s): K182826, Ormco™ Spark™ Aligner System, Sybron Dental Specialties

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 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 retainers of the ClearCorrect System are clear thermoformed appliances intended to keep the teeth from relapsing after they have been treated with aligners. Retainers are an optional component of aligner therapy. Retainers are typically prescribed for use at the conclusion of aligner treatment but can be prescribed at other times should there be a need to interrupt aligner treatment.

The engager templates of the ClearCorrect System are clear thermoformed appliances used to accurately apply composite resin attachments to the teeth as needed to achieve the desired tooth movement. The use of engagers and engager templates is an optional component of aligner treatment. Cavities are formed in the film having the desired shape, orientation and tooth position of the engager attachments to be bonded to the patient's teeth. At the time of use, the clinician fills the cavities in the engager template with light-curing composite resin. The engager template is then placed onto the patient's teeth and the resin cured. Once the resin is cured, the engager template is removed and discarded.

Picture of Device

Indications For Use:

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.

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.

The ClearCorrect retainers are produced from single-layer rigid polyurethane film.

The ClearCorrect engager templates are produced from single-layer rigid PETG film.

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

Performance Data: Assessment of the risks associated with the subject device presented in this submission indicate that the following studies establish the substantial equivalence of the subject device to the identified predicate and reference devices:

- 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: Based upon our assessment of the design and applicable performance data, the subject devices have been determined to be substantially equivalent to the identified predicate devices.

Feature	Subject Device ClearCorrect System	Primary Predicate Device ClearCorrect System (K113618)	Reference Device Ormco™ Spark™ Aligner System (K182826)	Equivalence Discussion
Indications for Use	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 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 Ormco™ Spark™ Aligner System is indicated for the alignment of teeth during orthodontic treatment of malocclusion in patients with permanent dentition (i.e. all second molars). The Ormco™ Spark™ Aligner System positions teeth by way of continuous gentle force.	**Identical** The indication for the Subject device is the same as for the Primary Predicate device.
Target Patient Population	Adults (> 21 y.o.) Adolescents (12 – 21 y.o. having permanent second molars)	Adults (> 21 y.o.) Adolescents (12 – 21 y.o. having permanent second molars)	Adults (> 21 y.o.) Adolescents (12 – 21 y.o. having permanent second molars)	**Identical**
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 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. 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.	**Identical**

Feature	Subject Device ClearCorrect System	Primary Predicate Device ClearCorrect System (K113618)	Reference Device Ormco™ Spark™ Aligner System (K182826)	Equivalence Discussion
Aligner Material	Thermoplastic polyurethane-polyester composite resin, tradename ClearQuartz	Thermoplastic polyurethane film	Thermoplastic polyurethane-polyester composite resin.	**Equivalent** The Subject device has a multilayer construction of polyurethane and co-polyester resins. The Reference Device also has a multilayer construction of polyurethane and co-polyester resins.
Retainer Material	0.030" rigid polyurethane film	0.030" rigid polyurethane film	Not relevant	**Identical** The Retainer of the ClearCorrect System is unchanged from the previously cleared device.
Engager Template Material	0.5 mm (0.02") rigid PETG film	0.5 mm (0.02") rigid PETG film	Not relevant	**Identical** The Engager Template of the ClearCorrect System is unchanged from the previously cleared device.
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.	Not relevant	**Identical** The status of the Subject devices is identical to that of the Primary Predicate devices.
Singe Use/ Reuse	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 Primary Predicate devices.
Packaging	**Primary:** LDPE bag containing one or two appliances as defined by the prescribed treatment plan. **Secondary:** 20 pt C1S SBS paperboard box	**Primary:** LDPE bag containing one or two appliances as defined by the prescribed treatment plan. **Secondary:** 20 pt C1S SBS paperboard box	Not relevant	**Identical** The packaging for the Subject devices is identical to that of the Primary Predicate devices.