March 22, 2021

Ormco Corporation
Frank Ray
Director of Regulatory Affairs
200 S Kraemer Blvd
Brea, California 92821

Re: K203737
Trade/Device Name: Spark Clear Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC, PNN
Dated: December 21, 2020
Received: December 22, 2020

Dear Frank Ray:

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 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)*
K203737

Device Name
Spark™ Clear Aligner System

Indications for Use *(Describe)*
Spark™ Clear Aligner System:
The Spark™ Clear Aligner System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.

Spark™ Software System:
The Spark™ Software System is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual design of a series of dental casts, which may be used for sequential aligner trays, retainers or bracket bonding templatesor based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives.

The use of the Spark™ Clear Aligner System and Spark™ Software System requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well to have received a dedicated training in the use of the software.

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.

Section V – 510(k) Summary

for

Spark™ Clear Aligner System

K203737

1. Submitter Information:

Ormco Corporation
200 S. Kraemer Blvd,
Brea, CA 92821

Contact Person: Frank Ray
Telephone Number: (704) 587-7227
Fax Number: (704) 587-7250

Date Prepared: December 21, 2020

2. Device Name:

- Proprietary Name: Spark™ Clear Aligner System
- Manufacturer: Ormco Corporation
- Common Name: Aligner, Sequential
- Classification Name: Orthodontic Plastic Bracket
- CFR Number: 872.5470
- Device Class: II
- Product Code: NXC, PNN

3. Predicate Device (Primary):

- Proprietary Name: Invisalign System (K143630)
- Manufacturer: Align Technology, Inc.
- Common Name: Aligner, Sequential
- Classification Name: Orthodontic Plastic Bracket
- CFR Number: 872.5470
- Device Class: II
- Product Code: NXC

Reference Device:

- Proprietary Name: Ormco™ Spark™ Aligner System (K182826)
- Manufacturer: Ormco Corporation
- Common Name: Aligner, Sequential
- Classification Name: Orthodontic Plastic Bracket
- CFR Number: 872.5470
- Device Class: II
- Product Code: NXC

Reference Device #2:

- Proprietary Name: Arcad SmileStudio and Aligner System (K192244)
- Manufacturer: ArcadLab
- Common Name: Aligner, Sequential
- Classification Name: Orthodontic Plastic Bracket
- CFR Number: 872.5470
- Device Class: II
- Product Code: NXC, PNN

4. Description of Device:

The Ormco Spark™ Clear Aligner System consists of a series of doctor-prescribed, custom manufactured, thin, clear plastic removable orthodontic appliances (aligners) that gently move the participant's teeth in small increments from their original state to a more optimal, treated state.

Treatment planning, aligner design and aligner manufacture are supported by a proprietary software system. The Spark™ Clear Aligner system consists of multiple interfacing software modules; Web, Design, Anatomy, Approver, and Fabrication. The Spark Aligner Web software module is an online portal, where clinicians can create new patient profiles, plan treatments, manage patients and submit prescriptions, photos, images and digital scans to Ormco. Trained technicians use the Ormco™ Spark™ Aligner Anatomy and Design software to create a 3D model of the patient's teeth from dental scans and to generate a 3D image of a final, treated state, as well as 3D aligner transitional treatment stage models, and submits them to the clinician. The clinician uses the Approver Software to review and approve the models, then Ormco uses the Fabrication software to produce resin molds for thermoforming the aligners.

The clinician receives the aligners and provides them, in sequential "stages", to the patient, confirming fit and monitoring treatment from the placement of the first aligner to the removal of the final aligner. The trays are held in place by pressure and can be removed by the patient at any time.

The aligners are individually identified and dispensed to patients and are to be worn in a specific, prescribed sequence. Several treatment options may be integrated into the Ormco Spark aligner consisting of:

- Attachments: Attachments or "buttons" may be prescribed by the dental practitioner to facilitate tooth movement and aligner anchorage. The dental practitioner may choose a standard dental composite and adhesive to bond the attachments to the dentition.
- Hooks: Hooks may be designed into the aligner, then connected by an elastic to a tooth-bonded button on the opposite arch, to apply additional forces.
- Bite ramps: Bite ramps are step features built into the lingual surfaces of the upper aligner arch that used by the clinician to prevent movement of the teeth during overbite correction treatment.
- Pontics: Pontics are cavity spaces (that may or may not be "tooth-shaped") built into the aligner per clinician's request to fill voids of missing teeth or other gaps that the clinician may wish to retain during treatment.
- Posterior Bite Turbos: Posterior Bite Turbos (PBT) are designed to prevent complete closure of jaws.

Principle of Operation / Mechanism of Action:

Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a dental clinician's prescription.

5. Indications for Use:

Spark™ Clear Aligner System:

The Spark™ Clear Aligner System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.

Spark™ Software System:

The Spark™ Software System is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual design of a series of dental casts, which may be used for sequential aligner trays, retainers or bracket bonding templates based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/ desired treatment objectives.

The use of the Spark™ Clear Aligner System and Spark™ Software System requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well to have received a dedicated training in the use of the software.

6. Description of Substantial Equivalence:

The Spark™ Clear Aligner System design or technical features have not been significantly modified since its clearance in 2018 (Reference Device #1, K182826). This section provides the substantial equivalence rationale for the Spark™ Clear Aligner System and the respective predicate devices with regards to Indications for Use, Technology, and Performance Testing. The differences between the subject device and the predicates do not raise different questions of substantial equivalence.

The similarities between the Spark™ Clear Aligner System (Subject Device) and the Primary Predicate Device Invisalign System (K143630), Reference Device #1 Ormco™ Spark™ Aligner System (K182826), and Reference Device #2 Arcad SmileStudio and Aligner System (K192244) as listed in Table 12.2 below are the Intended Use of the device, Indications for Use, Mode of Action, 3D software description, and treatment process. Also, the Attachments, Hook/Cutouts, Bite Ramps, and Pontics are available options. Furthermore, Biocompatibility testing, Software testing, and Material testing processes are similar.

The difference between the Spark™ Clear Aligner System (Subject Device) and Reference Device #1 Ormco™ Spark™ Aligner System (K182826) is the material. The Thermoplastic polyurethane-polyester composite resin is the same however the composition slightly varies.

Table 5.2 below compares the Spark™ Clear Aligner System to the Primary predicate device (Invisalign System (K143630)), reference device #1 (Ormco™ Spark™ Aligner

System (K182826)), and reference device #2 (Arcad SmileStudio and Aligner System (K192244)) with respect to intended use, technological characteristics and performance testing.

Device Comparison Table:

Table 5.2

Descriptive Information	**Subject Device Spark™ Clear Aligner System**	**Predicate Device (Primary) Invisalign System (K143630)**	**Reference Device #1 Ormco™ Spark™ Aligner System (K182826)**	**Reference Device #2 Arcad SmileStudio and Aligner System (K192244)**	**Comparison**
Pictorial Representation					N/A
Regulatory Classification					
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	21 CFR 872.5470	21 CFR 872.5470	Same as Predicates
Regulation Title	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Same as Predicates
Regulation Class	II	II	II	II	Same as Predicates
Product Code	NXC, PNN	NXC	NXC	NXC, PNN	Same as Predicates
Indications for Use / Intended Use					
Indications for Use	Spark™ Clear Aligner System: The Spark™ Clear Aligner System is indicated for the alignment of teeth during orthodontic treatment of malocclusion. Spark™ Software System: The Spark™ Software System is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual design of a series of dental casts, which may be used for sequential aligner trays, retainers or bracket bonding templates based	The Invisalign System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.	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.	The Arcad SmileStudio is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual design of a series of dental casts, which may be used for sequential aligner trays or retainers, based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and	Same as Predicates The Indications for Use for the bracket is substantial equivalent to the Primary Predicate device. The Indications for Use for the software is substantial equivalent to the Reference device #2.

	on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of the Spark™ Clear Aligner System and Spark™ Software System requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well to have received a dedicated training in the use of the software.			analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The Arcad Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The Arcad Aligner System positions teeth by way of continuous gentle force. The use of the Arcad Aligner System and SmileStudio requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well to have received a dedicated training in the use of the software.	
Intended Use	Orthodontic tooth movement	Orthodontic tooth movement	Orthodontic tooth movement	N/A	Same as Predicates
Description of Appliance Application	Removeable	Removeable	Removeable	N/A	Same as Predicates
Intended User	Dental Professional	Dental Professional	Dental Professional	N/A	Same as Predicates
Technological Characteristics					
Mode of Action	Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a	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.	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.	N/A	Same as Predicates

	doctor's prescription.				
3-D Software Description	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.	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.	The Ormco™ Spark™ 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.	N/A	Same as Predicates
Attachments	Available	Available	Available	N/A	Same as Predicates
Hook/Cutouts	Available	Available	Available	N/A	Same as Predicates
Bite ramps	Available	Available	Available	N/A	Same as Predicates
Pontics	Available	Available	Available	N/A	Same as Predicates
Single Use	Yes	Yes	Yes	N/A	Same as Predicates
Non-Sterile Packaging	Yes	Yes	Yes	N/A	Same as Predicates
Treatment Process	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	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	The Ormco™ Spark™ 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	N/A	Same as Predicates

	needed for the manufacturing of series of custom-made aligners.	practitioner approves the treatment plan, the software converts the files to produce the series of custom-made aligners.	for the manufacturing of series of custom-made aligners.		
Material	Thermoplastic polyurethane-polyester composite resin	Thermoplastic polyurethane-polyester composite resin	Thermoplastic polyurethane-polyester composite resin	N/A	Same as Predicates
Material Properties	Demonstrates sufficient flexural strength, stress retention, stain resistance, and transparency for use as a clear aligner.	Demonstrates sufficient flexural strength, stress retention, stain resistance, and transparency for use as a clear aligner.	Demonstrates sufficient flexural strength, stress retention, stain resistance, and transparency for use as a clear aligner.	N/A	Same as Predicates
Performance testing					
Biocompatibility testing	Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system).	Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system).	Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system).	N/A	Same as Predicates
Software testing	IEC 62304: 2015-06 CONSOLIDATED VERSION Edition 1.1 - Medical device software – Software life-cycle processes.	N/A	IEC 62304: 2015-06 CONSOLIDATED VERSION Edition 1.1 - Medical device software – Software life-cycle processes.	N/A	Same as Predicate #2
Material testing	ASTM D790-10: 2010-04-01 Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials.	N/A	ASTM D790-10: 2010-04-01 Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials.	N/A	Same as Predicate #2

Non-Clinical Test Data:

Performance bench testing according to international standards for Aligners, Sequential has been conducted to determine conformance in regards to:

- Biocompatibility has been completed for the applicable components.
- Comparative performance testing of the functions of the Proposed device compared to the cleared stand-a-lone device.

Furthermore, the performance of the Spark™ Clear Aligner System has been verified utilizing the following standards:

- ISO 10993-1:2018: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5:2009: Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-6:2016: Biological evaluation of medical devices - Part 6: Tests for local effects after implantation.
- ISO 10993-10:2010: Biological evaluation of medical devices -Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11:2017: Biological evaluation of medical devices—Part 11: Tests for systemic toxicity.
- ISO 7405:2018 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry.
- ISO 14971:2007: Medical devices - Application of risk management to medical devices.
- IEC 62304:2015-06: Medical device software – Software life-cycle processes.
- IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices.
- ASTM D790-10: 2010: Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials.
- ASTM F1980-16: 2016: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

Clinical Performance Data:
Clinical data is not needed to characterize performance and establish substantial equivalence. The non-clinical test data characterize all performance aspects of the device based on well-established scientific and engineering principles. Clinical testing has not been conducted on this product.

Conclusion as to Substantial Equivalence:
Based on a comparison of intended use, indications, material composition, technological characteristics, principle of operation, features and performance data, the Spark™ Clear Aligner System is deemed to be substantially equivalent to the predicate device.