Sybron Dental Specialties
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

October 11, 2018

Re: K182826
Trade/Device Name: Ormco Spark Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: October 3, 2018
Received: October 5, 2018

Dear Mark Job:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K 182826

Device Name

Ormco™ Spark™ Aligner System

Indications for Use *(Describe)*

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.

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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Department of Health and Human Services Food and Drug Administration

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K182826

510(k) SUMMARY for Ormco™ Spark™ Aligner System

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

1. Submitter Information:

Sybron Dental Specialties
1717 W. Collins Ave.
Orange CA, 92687

Primary Contact: Mey Saied
Telephone Number: 909-962-5675
Fax Number: 909-962-5694

Alternate Contact: Valerie Cimmarusti
Telephone Number: 714-516-7476
Fax Number: 909-962-5694

Date Prepared: September 12, 2018

2. Device Name:

Proprietary Name:	Ormco™ Spark™ Aligner System
Classification Name:	Aligner, Sequential
Regulation Description:	Aligner, Sequential
CFR Number:	872.5470
Device Class:	II
Product Code:	NXC

3. Predicate Device:

The Ormco™ Spark™ Aligner System is substantially equivalent (as defined in 21 U.S.C. § 360c(i)) for all regulatory purposes to the legally marketed device Invisalign System K143630 cleared on November 18, 2015, product code NXC, by Align Technology.

4. Description of Device:

The Ormco™ Spark™ Aligner System consists of a series of doctor-prescribed, custom manufactured, clear plastic removable orthodontic appliances (aligners) that incrementally move the patient's teeth from an original state to a treated state. Treatment planning, aligner design and aligner manufacture are supported by a proprietary software system. The Ormco™ Spark™ Aligner system consists of multiple interfacing software modules; Web, Design, 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. Ormco technicians use a reference Anatomy software and the Ormco™ Spark™ Aligner 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.

Several treatment options may be integrated into the Ormco Spark/Kappa aligner. 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. The aligners are individually identified and dispensed to patients and are to be worn in a specific, prescribed sequence. 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 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 are cavity spaces (that may or may not be "tooth-shaped") built into the aligner per clinician's request to address voids of missing teeth or other gaps during treatment. These treatment options are available in both the Ormco™ Spark™ Aligner as well as the Predicate Invisalign Aligner (please see Table 5.1).

Ormco also intends to trademark the Ormco Spark Aligner System as; Ormco Kappa Aligner System, Ormco Clear Aligner System, and Ormco Spark Clear Aligner System.

5. Indications for Use:

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.

6. Mode of Action:

The mechanism of action is similar to the predicate devices and supports a determination of substantial equivalence (as defined in 21 U.S.C. § 360c(i)). 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.

7. Description of Substantial Equivalence:

The Ormco™ Spark™ Aligner System is substantially equivalent (as defined in 21 U.S.C. § 360c(i)) for all regulatory purposes to the predicate device Invisalign (K143630). For purposes relevant to this regulatory filing, and as discussed in the previous subsections, technological characteristics, performance testing and clinical literature review indicate the substantial equivalence of the Ormco™ Spark™ Aligner System to the Primary Predicate, Invisalign Aligner System. There is sufficient information demonstrating that the proposed subject device provides a reasonable assurance of safety and efficacy. Both products represent new incarnations of an evolving technology with a long history of development.

a) Technological Characteristics:

The technological principle for both the subject Spark/Kappa Aligner and predicate Invisalign Aligner is the treatment of tooth malocclusions using a series of plastic appliances that incrementally moves teeth to a desired end-state. A comparison between the technological characteristics of the Ormco™ Spark™ Aligner System and that of legally marketed predicate device, Invisalign (K143630) has is summarized in Table 5.1, and demonstrates that the design, technology and composition of the Ormco™ Spark™ Aligner System are substantially equivalent (as defined in 21 U.S.C. § 360c(i)) for all regulatory purposes to the predicate devices.

b) Performance Testing:

The performance data compares the software, design, treatment characteristics and treatment process of the Spark Aligner to the predicate Invisalign Aligner. The stress relaxation, flexural and tensile strength were compared to the commercially-available Zendura Aligner material, as well as Invisalign's SmartTrack Aligner material. Comparison of mechanical testing of Spark Aligner material (TruGEN) and Invisalign Aligner material (SmarkTrack) indicates the substantial equivalence of their technological characteristics.

Bench testing of aligners was not performed due to the difficulty of evaluating these device types in a laboratory; however, translucency, staining, shelf life and shipping tests were carried on the thermoformed TruGEN™ material which showed acceptable properties for all tested samples. Additionally, several aligner features were tested and found to be acceptable including attachment dimensional accuracy, cutout effects on stability, force evaluation of attachments and bite ramp and hook evaluation at specified cycles.

Biocompatibility testing performed on both TruGEN material and Spark aligners per *ISO10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management p*rocess included cytotoxicity, sensitization and irritation, and intracutaneous reactivity evaluation.

The performance data demonstrates substantial equivalence of the subject Spark Aligner device to the Predicate Invisalign Aligner device.

c) Clinical Performance Data:

Clinical performance testing has not been completed for the Ormco™ Spark™ Aligner System. A comprehensive scientific literature review and analysis was conducted by orthodontic specialists on behalf of Ormco (please see **Appendix A**). Research articles and reports on the predicate device covered various subjects including the efficacy of the aligner on treating different types of orthodontic malocclusions.. There is sufficient information available from scientific literature and from the predicate devices to demonstrate that orthodontic, sequential, clear aligners provide reasonable assurance of safety and effectiveness.

d) Substantial Equivalence Comparison:

The following table (Table 5.1) compares the Ormco™ Spark™ Aligner System to the predicate device, the Invisalign System (K143630), as well as the reference device ClearCorrect (K113618). There is sufficient evidence to demonstrate substantial equivalence of the proposed Spark™ Aligner device to the predicate Invisalign (K143630) device.

Table 5.1: Comparison of Proposed and Predicate Devices

Element	Proposed Ormco™ Spark™ Aligner System	Primary Predicate Invisalign System	Reference Predicate ClearCorrect
510(k) Number	Unknown	K143630	K113618
510(k) Sponsor	Sybron Dental Specialties	Align Technologies	ClearCorrect, Inc
Regulation Number	21CFR872.5470	21CFR872.5470	21CFR872.5470
Device Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket
Product Code	NXC	NXC	NXC
Device Class	Class II	Class II	Class II
Intended Use	Orthodontic tooth movement	Orthodontic tooth movement	Orthodontic tooth movement
Indications for Use	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 Invisalign System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.	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
Target users	Dental Professionals	Dental Professionals	Dental Professionals
Material	Thermoplastic polyurethane -polyester composite resin	Thermoplastic polyurethane -polyester composite resin	Thermoplastic polyurethane resin
Description of Appliance Application	Removable	Removable	Removable

Element	Proposed Ormco™ Spark™ Aligner System	Primary Predicate Invisalign System	Reference Predicate ClearCorrect
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 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	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
Software Used for Ordering Workflow	Yes	Yes	Yes
Attachments	Available	Available	Available
Hooks/Cutouts	Available	Available	Not Available
Bite ramps	Available	Available	Not Available
Pontics	Available	Available	Available
Single Use	Yes	Yes	Yes
Non-Sterile Packaging	Yes	Yes	Yes
Treatment Process	Doctor uploads Patient's dental scans into proprietary software; doctor uses software for case viewing and treatment planning; Ormco technician receives case and uses proprietary 3D software to generate models for the aligners based on the prescription (desired outcome); Doctor approves treatment plan and final treated state; manufacturer crafts and produces aligners; aligners and ships them to doctor, who then provides them to the patient, confirming fit and design.	The proprietary Invisalign System 3-D software generates the image of a final, treated state and then interpolates a series of images that represent intermediate teeth states. The dental practitioner then reviews these images to depict, edit, view, monitor, and approve an orthodontic treatment plan. The dental practitioner has the option to reject or request modifications to the set-up prior to approving it for aligner fabrication. Once the doctor approves the set-up, the series of custom-made aligners are then manufactured, packaged, and shipped to the dental practitioner to be dispensed to the patient for treatment.	Doctor sends patient scans, molds and prescription to ClearCorrect; Utilizing standard dental software used for tooth alignment, ClearCorrect 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 model scheme before the molds are produced. Once approved, ClearCorrect produces the trays, which are formed of clear, thin thermoformed polyurethane plastic. The trays are sent back to the dental health care professional, who then provides them to the patient, confirming fit and design.
Biocompatibility	Meets requirements	Meets requirements	Meets requirements

e) Substantial Equivalence Conclusion:

The Ormco™ Spark™ Aligner System is substantially equivalent (as defined in 21 U.S.C. § 360c(i)) for all regulatory purposes to the predicate device Invisalign (K143630). For purposes relevant to this regulatory filing, and as discussed in the previous subsections, technological characteristics, performance testing and clinical literature review indicate the substantial equivalence of the Ormco™ Spark™ Aligner System to the Primary Predicate, Invisalign Aligner System. Both products represent new incarnations of an evolving technology with a long history of development. There is sufficient information demonstrating that the proposed subject device provides a reasonable assurance of safety and efficacy.