October 11, 2024

Ormco Corporation
Samantha Britt
Principal Specialist, Regulatory Affairs
200 S. Kraemer Blvd.
Brea, California 92821

Re: K240501
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
Dated: September 16, 2024
Received: September 16, 2024

Dear Samantha Britt:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
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Respiratory, ENT, and Dental Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240501

Device Name

Spark™ Clear Aligner System

Indications for Use *(Describe)*

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

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #: K240501

510(k) Summary

Prepared on: 2024-10-09

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Ormco Corporation
Applicant Address	200 S. Kraemer Blvd. Brea CA 92821 United States
Applicant Contact Telephone	714.817.7252
Applicant Contact	Ms. Samantha Britt
Applicant Contact Email	samantha.britt@envistaco.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Spark™ Clear Aligner System
Common Name	Orthodontic plastic bracket
Classification Name	Aligner, Sequential
Regulation Number	872.5470
Product Code(s)	NXC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K203737	Spark™ Clear Aligner System	NXC
K203688	Clear Aligner	NXC

Device Description Summary

21 CFR 807.92(a)(4)

The 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 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 aligners 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 Spark Clear Aligners consisting of:

- Attachments: Attachments are small protuberances of tooth-colored dental bonding material and may be prescribed by the dental clinician to act as anchor points on the teeth to focus the forces of the aligner to help with teeth movement.
    - o Templates: Attachments are placed onto the teeth via Templates. The dental practitioner may choose a standard dental composite, to fill into the Template themselves, and adhesive to bond the attachments onto the dentition. The option for composite material to be prefilled into the Template during manufacturing is also available via Prefilled Attachment (PFA) Templates.
- Hooks & Cutouts: Hooks and Cutouts may be designed into the aligner to accommodate elastics for aiding in applying additional aligner forces. Integrated Hooks are an optional alternative to the traditional Hooks.
- Bite ramps: Bite ramps are step features built into the lingual surfaces of the upper and lower aligner arch that are used by the clinician to prop open the bite temporarily so that certain teeth have a clearer path for movement without interference.
- 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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Subject Device and Predicate Device have the same indications for use.

Technological Comparison

21 CFR 807.92(a)(6)

This section provides the substantial equivalence rationale for Spark™ Clear Aligner System and the predicates with regards to Indications for Use, Technology, and Performance Testing. As described in this section, the differences between the Subject Device and the Predicate Device do not raise different questions of substantial equivalence.

Details of the similarities between Subject and Predicate Devices:
The similarities between Subject Device and the Predicate Device are the Indications for Use/ Intended Use, technological characteristics, and mode of action. Biocompatibility testing and material testing processes are similar to the Predicate Device.
The Subject Device's Integrated Hook and analogous feature on the Reference Device share a rounded design and same protrusion height. Therefore, the two features are similar in safety, due to similar shape and profile, with respect to the risk of causing irritation in the oral mucosa from the surface protrusions.

Details of the differences between Subject and Predicate Devices:
There are no major differences between the Subject Device and predicates. However, there are two minor differences between Subject Device and Predicate Device. The Predicate Device includes Templates which are used by the dental clinician to place attachments onto the teeth at specific locations. The composite material is filled into the Template in the field, whereas the Subject Device includes an optional Prefilled Attachment (PFA) Template. Additionally, the Subject Device includes Integrated Hooks, an optional alternative to the Predicate Device's traditional Hooks, that accommodate elastics for aiding in applying additional aligner forces.

Conclusion:
Based on a comparison of intended use, indications for use, technological characteristics, materials, principle of operation, features, and performance data, the Spark™ Clear Aligner System is deemed to be substantially equivalent to the Predicate Device as it satisfies all criteria of substantial equivalence and does not raise new concerns regarding substantial equivalence: (1) Indications for Use, (2) Technological Characteristics, and (3) Performance Data. Spark™ Clear Aligner System does not introduce a fundamentally new scientific technology and the nonclinical tests demonstrate that the device is substantially equivalent.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-Clinical performance bench testing according to international standards and FDA recognized consensus standards for Aligner, Sequential Device has been conducted to determine conformance in regards to:

• ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
• ISO 14971:2019-12 Third Edition: Medical devices — Application of risk management to medical devices

Biocompatibility testing were completed on the Template accessory, such as Cytotoxicity, Sensitization, and Irritation, and on the Aligner materials (TruGEN materials), such as Cytotoxicity, Sensitization, Irritation, and Acute Systemic & Pyrogenicity, in accordance with the following standards:

• ISO 10993-1 2018-08 Fifth Edition: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

• ISO 10993-5 2009-06-01 Third Edition: Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
• ISO 10993-10 Third Edition 2010-08-01:Biological evaluation of medical devices -Part 10: Tests for irritation and skin sensitization
• ISO 10993-11 2017-09 Third Edition: Biological evaluation of medical devices—Part 11: Tests for systemic toxicity
• ISO 7405 Third Edition 2018-10, Corrected version 2018-12: Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
• ANSI ADA Standard No. 41-2020: Evaluation of Biocompatibility of Medical Devices Used in Dentistry

Performance Testing Clinical:
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:
Based on a comparison of intended use, indications for use, 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.