February 20, 2025

Ormco Corporation
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K250487
Trade/Device Name: SparkTM Clear Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: February 19, 2025
Received: February 19, 2025

Dear Prithul Bom:

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
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250487

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Declaration of Conformity

Application # K250487

Company Name	Ormco Corporation
Company Address	200 S. Kraemer Blvd. Brea CA 92821 United States
Device Trade Name	Spark™ Clear Aligner System

The subject device(s) is in conformity with the requirements of the following documents:

Organization	Designation Number and Edition/Date	Recognition #
ANSI AAMI ISO	10993-1: 2018	2-258
ANSI AAMI ISO	10993-5:2009/(R)2014	2-245
ANSI AAMI ISO	10993-10:2010/(R)2014	2-174
ANSI AAMI ISO	10993-11: 2017	2-255
ISO	7405 Third edition 2018-10 Corrected version 2018-12	4-261
ASTM	F1980-21	14-575
ANSI ADA	Standard No. 41-2020	4-295
ANSI AAMI ISO	14971: 2019	5-125
ANSI AAMI ISO	0	2-228

Additional Information (e.g., limitations on the validity of the Declaration of Conformity)

Signed for and on behalf of the applicant company:

Place and Issuance Date:	Brea, CA	2/06/2025
Full Name and Title:	Jessica Pomares; Regulatory Affairs Specialist	
Signature	*Jessica Pomares*	

510(k) Summary

Prepared on: 2025-02-06

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	714-628-8575
Applicant Contact	Ms. Jessica Pomares
Applicant Contact Email	jessica.pomares@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	21 CFR part 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
K223517	Clear Aligner	NXC
K240501	Spark™ Clear Aligner System	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. Several treatment options may be integrated into the Spark Clear Aligners, such as cutouts, hooks, and/or other attachment shapes, bite ramps, etc. to aid the aligners with teeth movement. The integrated occlusion guides on the upper and lower aligners allow the option of incrementally repositioning the mandible (lower jaw) forward to address Class II malocclusions in patients who have not reached full skeletal maturity.

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 share a similar Indications for Use