January 3, 2025

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

Re: K250015
Trade/Device Name: Ormco™ EtchFree Bonding System, Ormco™ EtchFree Bonding Primer, Ormco™ EtchFree Adhesive
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket adhesive resin and tooth conditioner
Regulatory Class: Class II
Product Code: DYH
Dated: January 2, 2025
Received: January 2, 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 (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 -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
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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)*

K250015

Device Name

Ormco™ EtchFree Bonding System, Ormco™ EtchFree Bonding Primer, Ormco™ EtchFree Adhesive

Indications for Use *(Describe)*

Ormco™ EtchFree Bonding Primer is a bonding primer intended to bond orthodontic appliances such as metal brackets, ceramic brackets, and aligner attachments to enamel, in conjunction with an orthodontic sealant/enhancer, such as Ormco's Ortho Solo™ and an adhesive/cement without etching.

Ormco™ EtchFree Adhesive is a light-curing orthodontic bonding adhesive that is intended to be used for the attachment of orthodontic appliances to teeth such as metal bracket, ceramic brackets, and aligner attachments.

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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510(k) #: K250015

510(k) Summary

Prepared on: 2024-12-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Ormco Corporation
Applicant Address	200 S. Kraemer Blvd. Building E Brea CA 92821 United States
Applicant Contact Telephone	1-714-817-7237
Applicant Contact	Ms. Tara Bonny
Applicant Contact Email	tara.bonny@envistaco.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Ormco™ EtchFree Bonding System, Ormco™ EtchFree Bonding Primer, Ormco™ EtchFree Adhesive
Common Name	Bracket adhesive resin and tooth conditioner
Classification Name	Adhesive, Bracket And Tooth Conditioner, Resin
Regulation Number	21 CFR Part 872, Sec. 872.3750
Product Code(s)	DYH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K941015	Ormco Etching Solution	DYH
K110302	3M Scotchbond Universal	KLE
K880393	3M Unitek Transbond XT Light Cure Paste Adhesive	DYH

Device Description Summary

21 CFR 807.92(a)(4)

The Ormco™ Bonding System consists of a primer, a sealant, an adhesive, and bonding accessories.

• Ormco™ Bonding Primer is intended to bond orthodontic appliances such as metal brackets, ceramic brackets, and aligner attachments to enamel, in conjunction with an orthodontic sealant/enhancer, such as Ormco's Ortho Solo™ and an adhesive/cement. The primer is a clear liquid that conditions the surface of the tooth prior to the application of a bonding sealant/enhancer. Ormco Bonding Primer is designed to be used as a system along with Ortho Solo and Ormco™ Bonding Adhesive. The primer is offered in single-use vials which will be sold in kits and separately.

• Ormco™ Adhesive is a light-curing composite that is intended to be used with metal and ceramic brackets for orthodontic treatment and can also be used as aligner attachments for aligner treatment. It is a convenient off-white paste providing aesthetics when used as aligner attachments or beneath a bracket. The adhesive is designed to be used as a system along with Ormco Bonding Primer and Ortho Solo. The adhesive is offered in syringes for multi-patient use, which will be sold in kits and separately.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Ormco™ EtchFree Bonding Primer is a bonding primer intended to bond orthodontic appliances such as metal brackets, ceramic brackets, and aligner attachments to enamel, in conjunction with an orthodontic sealant/enhancer, such as Ormco's Ortho Solo™ and an adhesive/cement without etching.

Ormco™ EtchFree Adhesive is a light-curing orthodontic bonding adhesive that is intended to be used for the attachment of orthodontic appliances to teeth such as metal bracket, ceramic brackets, and aligner attachments.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Subject Primer:
The Subject Primer and Predicate Device, have the same indications for use, although expressed through a similar choice of words.

Subject Adhesive:
The Subject Adhesive and the Predicate Device have similar indications for use.

Technological Comparison

21 CFR 807.92(a)(6)

This section compares the Ormco Bonding Primer and Ormco Adhesive to the respective predicate devices with regards to indications for use, technological characteristics, and performance data. As described in this section, the differences between the subject device(s) and the predicate(s) do not raise different questions of substantial equivalence.

Similarities Between Subject Device(s) and Predicate(s):

• Ormco™ Bonding Primer
The primer is similar to the Predicate Device, as both products have the same intended use which is to bond orthodontic appliances. Both products are biocompatible and have the appropriate bond strength necessary to bond orthodontic appliances. The Indications for Use is also similar, as it is to prepare the surface of the tooth prior to the application of a bonding agent and adhesive. Both products use a brush to apply the product onto the surface of the tooth and do not require to be light cured. Physically, both products are clear liquids.
• Ormco™ Adhesive
The adhesive is an orthodontic composite that is similar to the Predicate Device. They are both off-white, light curing adhesives which use photoinitiation. Both bond to prepared enamel. They can be used with metal and ceramic brackets and can be used as aligner attachments. They are a one component system, which eliminates any chairside mixing. They use a resin and glass filler system to create adhesives with high bond strength and exceptional handling properties. Both resin matrices include the use of Bis-GMA and Bis-Hema. Both are packaged in a non-sterile 4-gram syringe which can be used on multiple patients.

Differences Between Subject Device(s) and Predicate(s):
• Ormco™ Bonding Primer
There are no major differences between the Subject Device and the Predicate Device, although there are two minor differences. The two devices have different composition characteristics; however, they function in an equivalent manner. The Predicate Device has indications to bond to dentin while the Subject Device does not.
• Ormco™ Adhesive
There are no major differences between the Subject Device and the Predicate Device, although there are some minor differences. Both composites use different types of fillers which serve the purpose of increasing viscosity, bracket retention, and bond strength. The fillers used in each formulation differ in particle size, shape, and material. The Subject Device uses an additional photoinitiator to diphenyliodonium hexafluorophosphate found in both formulations. The Predicate Device is packaged in a 4-gram syringe and in a 0.2-gram unit dose, whereas the Subject Device is only offered in a 4-gram syringe. The Predicate can be stored in a wider temperature range (2°C-27°C), and the Subject Device should only be stored in ambient temperature (16°C-27°C). The Subject Device has a curing time of 10 seconds when used with ceramic brackets and as aligner attachments, and a cure time of 20 seconds when used with metal brackets. The Predicate has a curing time of 3 seconds when used with ceramic brackets and as aligner attachments, and a cure time of 6 seconds when used with metal brackets. The difference in curing times can be attributed to the different curing guns and light intensity from each brand. All differences between the two devices do not affect safety or efficacy.

Conclusion:
Based on a comparison of intended use, indications for use, technological characteristics, materials, principle of operation, features, and performance data, the Subject Primer, and Subject Adhesive, are substantially equivalent to their respective Predicate Devices. All criteria of substantial equivalence were met and do not raise new concerns regarding substantial equivalence: (1) Indications for Use, (2) Technological Characteristics, and (3) Performance Data. The Subject Devices do 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 'Adhesive, Bracket and Tooth Conditioner, Resin' have been conducted to determine conformance in regard to:

o ISO 29022 First Edition 2013-06-01: Dentistry - Adhesive - Notched-edge sheer bond strength test
o ISO 11405:2015 Dentistry - Testing of Adhesion to Tooth Structure
o ASTM F2503-23 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
o ASTM F1980-16 Standard Guide for Accelerating Aging of Sterile Barrier Systems for Medical Devices
o ISO 15223-1 Fourth edition 2021-07 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
o ANSI AAMI ISO 14971:2019 Medical devices – Applications of risk management to medical devices
Biocompatibility testing was completed on the combined Bonding System, such as Cytotoxicity, Acute System Toxicity, Sensitization, Irritation, Mutation and Genotoxicity in accordance with the following standards:
o 4-261 ISO 7405 Third Edition 2018-10 Corrected Version 2018-12: Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
o 4-295 ADA ANSI Standard No. 41-2020: Evaluation of Biocompatibility of Medical Devices Used in Dentistry
o ANSI AAMI ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity carcinogenicity and reproductive toxicity
o ANSI AAMI ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
o ANSI AAMI ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
o ANSI AAMI ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
o ISO 10993-12 Fifth edition 2021-01 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
o ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation
o ISO 10993-2 Third edition 2022-11 Biological Evaluation of medical devices - Part 2: Animal welfare requirements

Performance Testing - Bench:
Several tests were carried out, such as Knife Shear, Wire Shear, Hardness, Viscosity and Working Time, to name a few. All results were deemed acceptable.

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.

Based on a comparison of intended use, indications for use, material composition, technological characteristics, principles of operation, features and performance data, the Ormco™ Bonding System is deemed to be substantially equivalent to the predicate device(s).