November 27, 2025

Ortho Organizers, Inc.
Thomas Arnold
Sr. Regulatory Affairs Specialist
1822 Aston Ave.
Carlsbad, California 92008

Re: K252760
Trade/Device Name: Carriere® Motion Pro® Clear Bite Corrector
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: DYW, EJF
Dated: August 29, 2025
Received: August 29, 2025

Dear Thomas Arnold:

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,

For Michael E. Adjodha, M.ChE., 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252760

Please provide the device trade name(s).

Carriere® Motion Pro® Clear Bite Corrector

Please provide your Indications for Use below.

The Carriere® Motion Pro® Clear Bite Corrector is intended to provide orthodontic movement and alignment of teeth during orthodontic treatment for Class II and Class III cases with symmetrical and asymmetrical malocclusions and Class I cases with mesially positioned maxillary molars or mandibular crowding. The appliance is indicated for use by dental and orthodontic professionals and is applicable to any patient demographic undergoing orthodontic treatment.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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K252760 - 510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information — 21 CFR 807.92(a)(1)

Submitter:	Ortho Organizers, Inc. 1822 Aston Avenue Carlsbad, CA 92008 USA Phone: 1-760-448-8600 Establishment Registration Number: 2081322
Contact Person:	Thomas Arnold Sr. Regulatory Affairs Specialist Phone: 1-760-448-8600 Email: thomas.arnold@henryschein.com
Date Prepared:	August 29, 2025

Device Information — 21 CFR 807.92(a)(2)

Trade Name:	Carriere® Motion Pro® Clear Bite Corrector
Common Name:	Orthodontic appliance
Regulation Number:	21 CFR 872.5470
Regulation Name:	Orthodontic plastic bracket
Classification:	Class II
Product Code:	DYW (primary), EJF
Review Panel:	Dental

Legally Marketed Predicate Device(s) — 21 CFR 807.92(a)(3)

Device Trade Name:	Carriere® Motion Pro® Bite Corrector
510(k) Number:	Class I, 510(k) Exempt (Primary Predicate)
Product Code:	EJF (Bracket, Metal, Orthodontic)
Device Trade Name:	Carriere Motion Clear Class II
510(k) Number:	K160720 (Secondary Predicate)
Product Code:	DYW (primary), EJF

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Device Description — 21 CFR 807.92(a)(4)

The Carriere Motion Pro Clear Bite Corrector is a single-use, direct bond, esthetic orthodontic appliance made of 17-4 stainless steel and polyethersulfone. It attaches the maxillary or mandibular canine or 1st premolar to the molar to provide a treatment solution for patients with malocclusions of primary, permanent, or mixed dentition. The Carriere Motion Pro Clear Bite Corrector is intended to provide orthodontic movement and alignment of teeth during orthodontic treatment for Class II and Class III cases with symmetrical and asymmetrical malocclusions and Class I cases with mesially positioned maxillary molars or mandibular crowding. The appliance is indicated for use by dental and orthodontic professionals and is applicable to any patient demographic undergoing orthodontic treatment. An optional drop-in hook, manufactured from 304 stainless steel, is included and is intended to work in conjunction with the Carriere Motion Pro Clear appliance to facilitate attachment of various orthodontic auxiliaries, such as elastomeric chain, nitinol springs, ligature wire, and elastics.

Intended Use / Indications for Use — 21 CFR 807.92(a)(5)

The Carriere® Motion Pro® Clear Bite Corrector is intended to provide orthodontic movement and alignment of teeth during orthodontic treatment for Class II and Class III cases with symmetrical and asymmetrical malocclusions and Class I cases with mesially positioned maxillary molars or mandibular crowding. The appliance is indicated for use by dental and orthodontic professionals and is applicable to any patient demographic undergoing orthodontic treatment.

Comparison of Technological Characteristics — 21 CFR 807.92(a)(6)

The Carriere Motion Pro Clear Bite Corrector is substantially equivalent to the predicate devices in terms of design features, mode of use, principles of operation, manufacturing, packaging, labeling, and biocompatibility. The subject device and secondary predicate are manufactured from polyethersulfone and 17-4 stainless steel, whereas the primary predicate is manufactured from 17-4 stainless steel only. The comparison to the secondary predicate (K160720) supports the use of polyethersulfone in the subject device. Both subject device and primary predicate include an optional drop-in hook, manufactured from 304 stainless steel, which is not applicable to the secondary predicate. Any differences between the proposed device and the predicate devices are considered minor and do not raise new questions concerning safety and effectiveness.

Performance Data — 21 CFR 807.92(b)

Mechanical testing was conducted to evaluate bond strength, hook strength, connection strength, and clear bar rigidity of the subject device. Testing was performed on representative samples, and the results were compared to those of the primary predicate device and/or the secondary predicate device (K160720). The data supports Ortho Organizers' determination of substantial equivalence.

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Conclusion

Based on the indications for use, technological characteristics, and the summary of data submitted, Ortho Organizers, Inc. has determined that the subject device does not raise new questions of safety and effectiveness compared to the predicate devices. Therefore, the proposed subject device is substantially equivalent to the legally marketed predicate devices.