DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 28, 2016

Ortho Organizers, Inc.
Colleen Boswell
Director, RA/QA
1822 Aston Avenue
Carlsbad, California 92008

Re: K160720
Trade/Device Name: Carriere Motion Clear Class II
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: DYW, EJF
Dated: October 26, 2016
Received: October 27, 2016

Dear Colleen Boswell:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160720

Device Name
Carriere Motion Clear Class II

Indications for Use *(Describe)*
The Carriere Motion Clear Class II orthodontic appliance is intended to provide orthodontic movement and alignment of teeth during orthodontic treatment for Class II cases with symmetrical and asymmetrical malocclusions and Class I cases with mesially positioned maxillary molars.

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.

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510(k) Summary

1. Submitter:

Ortho Organizers, Inc.
1822 Aston Avenue
Carlsbad, California 92008

Contact Person: Colleen Boswell
Telephone Number: (760) 448-8730
Fax Number: (760) 448-8616

Date Prepared: November 17, 2016

2. Device:

Name of Device: Carriere Motion Clear Class II
Common Name: Orthodontic Appliance
Classification Name: Orthodontic Plastic Bracket, per 21 CFR § 872.5470
Device Class: II
Product Code: DYW

3. Predicate Device:

Primary Predicate: *Carriere Motion Class II,* Ortho Organizers, Inc., Class I 510(k) Exempt, Product Code EJF

Reference Device: *Composite Brackets,* Ortho Specialties, Inc., K140807

4. Device Description

The **Carriere Motion Clear Class II** is a direct bond, esthetic, orthodontic appliance that attaches the maxillary canine or premolar to molar to provide a treatment solution for patients with malocclusions of primary, permanent or mixed dentition. The orthodontic appliance is a two-piece design comprised of an integrated polyethersulfone, a clear thermoplastic, anterior pad and rigid arm that connects to a 17-4 stainless steel posterior pad in a "ball and socket" relationship. The orthodontic appliance is intended to be used at the beginning of orthodontic treatment when there are no competing forces in the mouth. The device allows the distalization of the posterior segments.

The **Carriere Motion Clear Class II** corrects the posterior occlusion to a Class I platform first by rotating and uprighting the maxillary molars while distalizing the posterior segment, from canine or

premolar to molars. The orthodontic appliance independently moves each posterior segment, from canine or premolar to molar, as a unit. The anterior pad includes an integrated hook which allows for the attachment of elastics to the lower molars. The posterior pad bonds to the facial surface of the teeth and is made of 17-4 stainless steel. The pad serves as the socket in the ball and socket relationship with the plastic arm. The ball and socket has built-in stops that allow the molars to move directly to their desired position and are intended to prevent any unwanted over rotation or tipping.

The **Carriere Motion Clear Class II**'s application and removal is similar to that of a plastic orthodontic bracket. It requires orthodontic adhesive for bonding and standard orthodontic tools and techniques for debonding.

5. Statement of Intended Use:

The **Carriere Motion Clear Class II** orthodontic appliance is intended to provide orthodontic movement and alignment of teeth during orthodontic treatment for Class II cases with symmetrical and asymmetrical malocclusions and Class I cases with mesially positioned maxillary molars.

6. Summary of Technological Characteristics with the Predicate Devices

The technological characteristics of the proposed **Carriere Motion Clear Class II** are very similar to the predicate device, Carriere Motion Class II (Class I, 510(k) Exempt) and the reference device, Composite Brackets (K140807). There are no substantial technical or functional differences between the **Carriere Motion Clear Class II** appliance and the predicate and reference devices in terms of design, function, biocompatibility and intended use. See Table 1 below for technological characteristics and comparisons of the orthodontic appliances.

Table 1: Comparison of Proposed and Predicate/Reference Devices

Element	***Carriere Motion Clear Class II***	**Predicate Device Carriere Motion Class II (Class I, 510(k) Exempt)**	**Reference Device Composite Brackets (K140807)**	**Comparison**
Company	**Ortho Organizers, Inc. (O2)**	Ortho Organizers, Inc. (O2)	Ortho Specialties, Inc.	N/A
Indications for Use	**The Carriere Motion Clear Class II orthodontic appliance is intended to provide orthodontic movement and alignment of teeth during orthodontic treatment for Class II cases with symmetrical and asymmetrical malocclusions and Class I cases with mesially positioned maxillary molars.**	The Carriere Motion Class II orthodontic appliance is intended to provide orthodontic movement and alignment of teeth during orthodontic treatment for Class II cases with symmetrical and asymmetrical malocclusions and Class I cases with mesially positioned maxillary molars.	The Composite Brackets are intended for use as a clear, plastic bracket system to provide orthodontic movement of natural teeth.	Indicated for same purpose - movement of teeth.
Target Users	**Dental Professionals**	Dental Professionals trained	Dental Professionals	Same

Element	*Carriere Motion Clear Class II*	Predicate Device Carriere Motion Class II (Class I, 510(k) Exempt)	Reference Device Composite Brackets (K140807)	Comparison
	trained in orthodontics	in orthodontics	trained in orthodontics	
Appliance Material	**Polyethersulfone/ 17-4 Stainless Steel**	17-4 Stainless Steel	Polycarbonate	Both thermoplastic materials (same as reference) with 17-4 stainless steel identical to predicate
Features	**Two-piece design comprised of an integrated plastic anterior pad and rigid arm that connects to a 17-4 stainless steel posterior pad in a "ball and socket" relationship.**	Two-piece design comprised of an integrated 17-4 stainless steel anterior pad and rigid arm that connects to a 17-4 stainless steel posterior pad in a "ball and socket" relationship.	One-piece design that connects to other brackets via archwires and/or elastics.	2-piece design identical to predicate vs. 1-piece bracket design of reference. The rigid arm across a posterior segment of 3-4 teeth allows teeth to be positioned into a Class II relationship with more predictability and uniformity as opposed to the reference device's reliance on multiple brackets connected via an archwire
	Translucent plastic anterior pad that bonds to the facial surface of teeth.	17-4 stainless steel anterior pad that bonds to the facial surface of teeth.	Translucent bracket pad that bonds to the facial surface of teeth.	Both thermoplastic pads (same as reference) and 17-4 stainless steel pad of predicate bonds to teeth with different retention geometries of the pad. However, the pad's use as anchorage to the tooth serves the same purpose.
	The anterior pad includes an integrated clear plastic hook for elastic activation.	The anterior pad includes an integrated 17-4 stainless steel hook for elastic activation.	The brackets are available with integrated hooks for elastic activation.	Same. All have integrated hooks for elastic activation.
	The posterior pad bonds to the facial surface of teeth and is made of 17-4 stainless steel. The pad serves as the socket in the "ball and socket" relationship with the polyethersulfone arm.	The posterior pad bonds to the facial surface of teeth and is made of 17-4 stainless steel. The pad serves as the socket in the "ball and socket" relationship with the 17-4 stainless steel arm.	The base bonds to the facial surface of teeth. Mechanical Retention eliminates the need for plastic condition pre-treatment.	Posterior pad identical with predicate and bonds to facial surface of teeth.
	Color coded for appliance identification	Color coded for appliance identification	Color coded for bracket identification	Same

Element	*Carriere Motion Clear Class II*	Predicate Device Carriere Motion Class II (Class I, 510(k) Exempt)	Reference Device Composite Brackets (K140807)	Comparison
Mode of Use	**Removable elastics (provided by clinician and worn by patient) are attached to the device and anchored to the opposing dental arch to provide vector forces required to move teeth per dental professional's technique and treatment goals.**	Removable elastics (provided by clinician and worn by patient) are attached to the device and anchored to the opposing dental arch to provide vector forces required to move teeth per dental professional's technique and treatment goals.	Archwire implementation by dental professional's technique.	Use of elastics to apply the proper amount of force to move teeth is identical with predicate. Archwire used to apply the force to move teeth with the reference device. This is not a significant difference as the forces used in both scenarios are equivalent as prescribed by the clinician.
Application	**Bonded with Orthodontic Adhesive**	Bonded with Orthodontic Adhesive	Bonded with Orthodontic Adhesive	Same
Bond Strength (lbf/MPa)	**22.05/5.28**	16.52/4.04	10.72/3.87	Higher bond strength than predicate and reference devices. All below 8.2 MPa, a value in literature that shows no risk of enamel damage.
Manufacturing Method	**Molded**	Molded	Molded, thermoformed.	Same

7. Performance Data

Biocompatibility Testing

The biocompatibility evaluation for the **Carriere Motion Clear Class II** orthodontic appliance was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," May 1, 1995 and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process" as recognized by FDA. The biocompatibility testing included the following tests:

1. Cytotoxicity
2. Sensitization
3. Irritation
4. Chemical Characterization Study (Toxicological Risk Assessment)

Bond Strength Testing

Bond strength testing was performed on the **Carriere Motion Clear Class II** orthodontic appliance and compared to the primary predicate and reference devices and was substantially equivalent to these devices.

Clinical Studies

No human clinical testing was conducted to support substantial equivalence.

8. Conclusion as to Substantial Equivalence

The similarities in design, function, safety and intended use of the **Carriere Motion Clear Class II** orthodontic appliance with the legally marketed predicate device, Carriere Motion Class II (Class I, 510(k) Exempt) and reference device, Composite Brackets (K140807), support substantial equivalence.