



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

March 8, 2018

Re: K173440
Trade/Device Name: Carriere SLX 3D Clear
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NJM
Dated: February 2, 2018
Received: February 5, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K173440

Device Name

Carriere SLX 3D Clear

Indications for Use (Describe)

The Carriere SLX 3D Clear orthodontic ceramic bracket system is intended to aid in the movement of teeth during orthodontic treatment.

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: February 2, 2018

2. Device:

Name of Device: Carriere SLX 3D Clear
Common Name: Orthodontic Ceramic Bracket
Classification Name: Orthodontic Plastic Bracket, per 21 CFR § 872.5470
Device Class: II
Product Code: NJM

3. Predicate Device:

Damon 4Clear, Ormco Corporation, K081415, Product Code NJM

4. Device Description

The **Carriere SLX 3D Clear** is a ceramic passive self-ligating orthodontic bracket system that directly bonds to the teeth to provide a treatment solution for patients with malocclusions of primary, permanent, or mixed dentition. Each bracket is comprised of four individual components; a polycrystalline alumina door, a polycrystalline alumina base, and two 304 stainless steel springs. The two springs are laser welded together and borne by the door. The springs are the force giving mechanism in the bracket system, providing tactile and audible feedback for the clinician when opening and closing the door. The springs also provide a mechanism to keep all four components assembled throughout treatment. Because the **Carriere SLX 3D Clear** is a passive self-ligating bracket system, wherein the door portion of the bracket opens and closes to alternatively expose and conceal the archwire slot, the door replaces the need for a conventional ligature and retains the archwire while providing minimal friction throughout the treatment process.

The bracket system is intended to be used throughout orthodontic treatment with an accompanying archwire to move the teeth to the desired occlusion by the clinician.

The **Carriere SLX 3D Clear** bracket has an integral hook design, which allows for the attachment of elastics and other alternate force giving mechanisms to assist the clinician in producing the desired tooth movement. The bonding surface of the bracket has a mechanical undercut design, allowing the bracket to retain the adhesive and bond to the facial surface of the tooth.

The application and removal of the **Carriere SLX 3D Clear** orthodontic ceramic bracket is similar to that of other orthodontic ceramic brackets. It requires orthodontic adhesive for bonding and standard orthodontic tools and techniques for de-bonding.

5. Statement of Intended Use:

The **Carriere SLX 3D Clear** orthodontic ceramic bracket system is intended to aid in the movement of teeth during orthodontic treatment.

6. Summary of Technological Characteristics with the Predicate Devices

The technological characteristics of the proposed **Carriere SLX 3D Clear** orthodontic ceramic brackets are very similar to the predicate device, Damon 4Clear (K081415). There are no substantial technical or functional differences between the **Carriere SLX 3D Clear** orthodontic ceramic bracket and the predicate device in terms of design, function, safety and intended use. Both are ceramic self-ligating brackets made of polycrystalline alumina with stainless steel springs. See Table 1 below for technological characteristics and comparisons of the orthodontic brackets.

Table 1: Comparison of Proposed and Predicate Devices

Element	<i>Carriere SLX 3D Clear (Proposed Device)</i>	<i>Damon 4Clear (Predicate Device)</i>	Comparison
<i>Company</i>	Ortho Organizers, Inc. (O2)	Ormco Corporation	N/A
<i>510(k)</i>	To be Assigned	K081415	N/A
<i>Indications for Use</i>	The Carriere SLX 3D Clear orthodontic ceramic bracket system is intended to aid in the movement of teeth during orthodontic treatment.	The Damon 4Clear is a ceramic bracket system intended to aid in the movement of patient teeth during orthodontic treatment.	Indicated for same purpose - movement of teeth.
<i>Target Users</i>	Dental Professionals trained in orthodontics	Dental Professionals trained in orthodontics	Same
<i>Appliance Material</i>	Polycrystalline Alumina / 304 Stainless Steel	Polycrystalline Alumina / Stainless Steel	Same. Both consist of ceramic materials for bracket body and door with stainless steel springs.
	Four-piece design comprised of a ceramic door and bracket with a laser welded pair of 304 stainless steel springs. The springs are borne by the door and act as the force	Three-piece design comprised of a ceramic door and bracket with a single stainless steel spring adhered to the bracket utilizing adhesive. The	4-piece design versus 3-piece bracket design of the predicate. The difference in springs is that the two springs of the proposed device are borne by the

Element	<i>Carriere SLX 3D Clear (Proposed Device)</i>	<i>Damon 4Clear (Predicate Device)</i>	Comparison
<i>Features</i>	giving mechanism of the design.	spring is borne by the bracket and act as the force giving mechanism of the design.	door vs. borne by the bracket.
	Ceramic pad that bonds to the facial surface of the teeth. Pad utilizes mechanical undercuts that are formed in the ceramic material	Ceramic pad that bonds to the facial surface of the teeth. Pad utilizes mechanical undercuts that are laser cut into the ceramic material.	Both ceramic pads utilize mechanical undercuts for adhesive retention with the difference being the pads achieve the undercuts through different manufacturing processes. However, the pads' use as anchorage to the tooth serves the same purpose.
	Select brackets contain an integrated ceramic hook for accessory attachment.	Select brackets contain an integrated ceramic hook for accessory attachment.	Same
	The door is actuated open and closed to alternatively expose and conceal the archwire slot. The door is held in either position by the spring mechanism.	The door is actuated open and closed to alternatively expose and conceal the archwire slot. The door is held in either position by the spring mechanism.	Same
	Self-Ligating	Self-Ligating	Same
	Color coded for bracket identification	Color coded for bracket identification	Same
<i>In/Out</i>	.025" - .046"	.3" - .0445"	Both bracket systems utilize similar but not identical in/out values. Specific in/out values vary based on prescription and tooth position.
<i>Torque</i>	-17° through +17°	- 11° through + 22°	Both bracket systems utilize similar but not identical torque values. Specific torques vary based on prescription and tooth position.
<i>Angulation</i>	Up to + 9°	Up to + 9°	Same
<i>Rotation</i>	Up to + 12°	0°	Rotation provided on the upper molar brackets only. Predicate device does not have a molar offering.
<i>Mode of Use</i>	An archwire (provided by clinician and worn by patient) is inserted into the device	An archwire (provided by clinician and worn by patient) is inserted into the	Same

Element	<i>Carriere SLX 3D Clear</i> (Proposed Device)	Damon 4Clear (Predicate Device)	Comparison
	and provides the light orthodontic forces required to move teeth per the dental professional's technique and treatment goals.	device and provides the light orthodontic forces required to move teeth per the dental professional's technique and treatment goals.	
<i>Application</i>	Bonded with Orthodontic Adhesive	Bonded with Orthodontic Adhesive	Same
<i>Bond Strength</i> (lbf/MPa.)	23.31/7.63	33.45/10.15	Lower bond strength than predicate device to ensure a more comfortable de-bond pressure than predicate. Proposed device is below 8.2 MPa, a value in literature that shows no risk of enamel damage.
<i>Manufacturing Method</i>	Ceramic injection molded and assembled	Ceramic injection molded and assembled	Same

7. Performance Data

Biocompatibility Testing

The biocompatibility evaluation for the **Carriere SLX 3D Clear** orthodontic ceramic bracket system was conducted in accordance with 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

The biocompatibility testing conducted met the requirements of the tests.

Bond Strength Testing

Bond strength testing was performed on the **Carriere SLX 3D Clear** orthodontic ceramic bracket and compared to the predicate device and was substantially equivalent to the device.

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 SLX 3D Clear** orthodontic ceramic bracket with the legally marketed predicate device, Damon 4Clear (K081415), support substantial equivalence.