



Food and Drug Administration  
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August 26, 2016

OraCrew Inc.  
c/o Ms. Angela Blackwell  
Senior Consultant  
Blackwell Device Consulting  
210 E Flamingo Rd #217  
Las Vegas, Nevada 89169

Re: K150830

Trade/Device Name: CompleClear Plastic Orthodontic Bracket and Wire Appliance  
Regulation Number: 21 CFR 872.5470  
Regulation Name: Orthodontic Plastic Bracket  
Regulatory Class: Class II  
Product Code: DYW, DZC  
Dated: August 24, 2016  
Received: August 26, 2016

Dear Ms. Blackwell:

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,

**Michael J. Ryan -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)

Device Name

CompleClear Plastic Orthodontic Bracket and Wire Appliance

Indications for Use (Describe)

CompleClear appliances are intended for use as a clear, plastic bracket and archwire system to provide orthodontic movement of natural teeth.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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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.\***

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**510k Summary**  
**March 2, 2016**  
**CompleClear Plastic Orthodontic Bracket and Wire Appliance**

**Name and address:**

Oracrew Inc  
210 E Flamingo Rd #314  
Las Vegas, NV 89169  
(760) 237-0163

**Contact person:**

Dr. Pawan Gautam  
210 E Flamingo Rd #314  
Las Vegas, NV 89169  
(760) 237-0163

**Name of device:** CompleClear Plastic Orthodontic Bracket and Wire Appliance

**Classification Name:** orthodontic plastic bracket and wire

**CFR:** 21 CFR 872.5470 and 872.5410

**Product Code:** DYW and DZC

**Classification:** II and I

**Device Description:** CompleClear Plastic Orthodontic Bracket and Wire Appliance is an orthodontic appliance consisting of a polysulfone bracket with two separate components (tooth component and wire component) and an orthodontic wire pre-attached to the wire component of the bracket. The tooth and the wire components are capable of mechanically interlocking to form a detachable and re-attachable bracket assembly. The tooth component of the bracket is cemented to the tooth, like regular orthodontic brackets. The wire components are pre-attached at specific positions along the orthodontic wire. The orthodontic wire is customized for each patient by creating various bends and rotations along the wire. This configuration of the customized wire, results in a specific position and orientation of the wire components of the bracket system along the customized wire. This customized orthodontic wire along with the series of pre-attached wire components constitutes the 'aligner'. When the wire components of the 'aligner' are engaged on to the corresponding tooth component cemented on the tooth, the orthodontic wire is activated like a spring. The tooth is gently moved to its desired position due to the elastic recoil of the wire.

The two component bracket assembly of the present device allows moment arms for mesiodistal rotation, labio-lingual inclination and mesio-distal angulations (tip) similar to conventional bracket-wire used in orthodontics.

The treatment uses a series of aligners, each incorporating a predefined amount to tooth movement toward the final desired end goal. The amount of tooth movement incorporated, the type of tooth movement incorporated and the final desired end goal are all determined and approved by the provider.

**Indications for Use:** CompleClear appliances are intended for use as a clear, plastic bracket and archwire system to provide orthodontic movement of natural teeth.

**Predicate Device:** K110796 Biomers SimpliClear Rectangular Orthodontic Wire and K140807 Ortho Specialties Incorporated Composite Brackets

**Substantial Equivalence:**

CompleClear is substantially equivalent to Ortho Specialties Composite Brackets and Biomers Rectangular Orthodontic Wire in indications for use, materials, aesthetic features, mode of use, physical properties, application and manufacturing methods.

Company	CompleClear	Composite Brackets K140807	SimpliClear Rectangular Orthodontic Wire K110796
Indications for Use	CompleClear Appliances are intended for use a clear plastic bracket and archwire system to provide orthodontic movement of natural teeth.	The Composite Brackets are intended for use as a clear, plastic bracket system to provide orthodontic movement of natural teeth.	An orthodontic archwire used to provide force to the teeth to effect movement in orthodontic treatment.
Material	Bracket is polysulfone Archwire is glass fibers with a polysulfone coating	Polycarbonate	Polymer composite resin with glass fibers and a USP Class VI polymer coating
Aesthetic Features	Clear (translucent) bracket system Clear wire	Clear (translucent) bracket system	Clear wire
Mode of Use	Patient-specific Aligner (Archwire pre-attached to outer half of brackets) made to fit stone model under dental professionals orders	Archwire implementation by dental professionals technique	Archwire implementation by dental professionals technique
Application	Tooth half of bracket bonded to teeth and aligner snapped into place	Bracket bonded to tooth	Wire placed with ligatures
Bracket Manufacturing Method	Molded, thermoformed	Molded, thermoformed	

Wire manufacturing method	Composite of polymer and glass fibers with a polymer coating on the outside		Composite of polymer and glass fibers with a polymer coating on the outside
Biocompatibility	Meets the requirements of ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-10:2010 and ISO 10993-11:2006	Meets the requirements of ISO 10993	Meets the requirements of ISO 10993

**Physical testing:** Mechanical testing showed the force which could be applied by deflection of the wire was within the range of other orthodontic forces. The force required to break the melt and remove the wire from the bracket was significantly higher than the force which could be applied by the wire. The force necessary to snap the aligner away from the cemented brackets was also significantly higher than the orthodontic forces applied to the teeth. This ensures integrity of the aligner during function and also that aligner does not detach until the dentist or patient intends to remove it. A tool is normally used to remove the aligner. Since the wire in the aligner acts more like a spring friction testing was not appropriate.

Shear bond strength testing of the brackets adhered to teeth was carried out on both CompleClear and Ortho Specialties' brackets. There was no statistical difference in them.

**Conclusion:** The CompleClear Plastic Orthodontic Bracket and Wire Appliance is substantially equivalent to the Composite Brackets (K140807) and the SimpliClear rectangular orthodontic wire (K110796) in manufacturing, materials, biocompatibility, application and indications for use and shear bond strength.