



Ormco Corporation  
Ms. Tara Bonny  
Senior Regulatory Affairs Specialist  
1717 W. Collins Avenue  
Orange, California 92867

January 31, 2018

Re: K172845  
Trade/Device Name: Symetri Clear  
Regulation Number: 21 CFR 872.5470  
Regulation Name: Orthodontic Plastic Bracket  
Regulatory Class: Class II  
Product Code: NJM  
Dated: December 20, 2017  
Received: December 22, 2017

Dear Tara Bonny:

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](mailto: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)

K172845

Device Name

Symetri™ Clear

Indications for Use (Describe)

This device is intended for the orthodontic movement of teeth. It is used temporarily and is removed after Orthodontic treatment has been completed.

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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8. **Device Description**

Symetri Clear, is a single-use orthodontic bracket made from polycrystalline alumina. This device is intended for the orthodontic movement of teeth. It is used temporarily and is removed after Orthodontic treatment has been completed. After following standard office protocols for tooth preparation, the brackets are bonded to the teeth with an orthodontic adhesive or cement. To aid with visual placement of the bracket to the tooth surface, the bracket has a removable, color coded, plastic axis indicator that is lifted away from the bracket following tooth placement or temporary color coded labial tie wings that are removed with a toothbrush and water. To identify tooth designation, the brackets include a temporary ink dot that is removed with a toothbrush and water after the brackets have been placed on the tooth. After the brackets are placed, an archwire is then inserted / threaded through the bracket's archwire slot and is held in place with a ligature tie. These ligatures are tightened, or ligated, around the 'wings' of the bracket and over the archwire. To aid in optimal teeth movement, the individual brackets can also be ligated to other brackets or other orthodontic devices. After the teeth have moved into their proper positions, the orthodontic / dental professional will remove the brackets with the Symetri Clear Debonding Instrument / Pliers. This step is also known as debonding.

The Symetri Clear Debonding Instruments / Plier was included for informational purposes only, not for review for clearance.

9. **Indications for Use**

This device is intended for the orthodontic movement of teeth. It is used temporarily and is removed after Orthodontic treatment has been completed.

Although Symetri Clear's Indications for Use statement is not identical to the predicate devices, the minor differences in phrasing do not change the intended use.

10. **Comparison of Technology**

Symetri Clear is a non self-ligating, single-use orthodontic bracket. The bracket's design has one-piece base and bracket construction, and is made from translucent alumina. To provide optional bond strength and effective bracket debonding, the base has a laser-etched pattern. To ensure accurate placement, it uses a removable plastic component that is inserted into the horizontal and vertical slots of the bracket or temporary color which is incorporated into the labial surface instead of the plastic indicator. A temporary ink dot facilitates tooth designation. All ink is removed after the bracket has been placed on the tooth. The bracket is designed to remain intact during debonding.

As with Symetri Clear, the predicate device, Clarity ADVANCED, is also a non self-ligating, single-use orthodontic bracket which has a one-piece base and bracket construction, and is made from translucent alumina. It also includes a temporary ink dot to facilitate tooth designation but does not include a removable plastic indicator for bracket placement. Bracket placement is achieved via temporary horizontal and vertical colored ink markers. Like Symetri Clear, all ink is removed after the bracket has been placed on the tooth. It also differs from Symetri Clear in its bracket base; it is a glass-grit, mechanical-locking base with a stress concentrator for predictable squeeze debonding. The stress concentrator on the base, causes the bracket to collapse during debonding by design.

The reference predicate, Damon Clear/Damon Clear2 (K081415), is also a single-use orthodontic bracket, with a one-piece base and bracket construction, and is made from translucent alumina. Similar to Symetri Clear, it utilizes a removable plastic indicator for tooth placement and a temporary ink dot for tooth designation. Unlike Symetri Clear and Clarity ADVANCED, this bracket is self-ligating.

Clarity ADVANCED (K102803), Damon Clear / Damon Clear2 (K081415) and Symetri Clear bracket systems (K172845), all offer a hand instrument accessory designed for bracket debonding. While the debonding process is not identical, these variations do not change the indications for use.

Symetri Clear shares the same indications for use as the primary and reference predicate devices. Differences between the devices do not raise any questions of safety and effectiveness.

**11. Non-Clinical Performance Data**

Non-clinical performance data included testing results for Torque Strength (also known as Wire Torque), Double Tie Wing Strength, Bond Strength Shear (also known as Shear Test), Bond Strength Tensile (also known as Tensile Strength), Wire Drag, Debonding Removal Fracture (also known as Bracket Removal Fracture), Hook Strength and Staining. The testing analysis shows that Symetri Clear brackets perform comparably to the predicate devices.

Metal Ligation and Double Tie bench testing was also conducted, however, not compared to a predicate.

Biocompatibility assessment and testing was performed using standard risk assessment techniques and in consideration of FDA and internationally recognized guidance's.

Symetri Clear brackets were inspected and met the dimensions itemized in ISO 27020, Dentistry – Brackets and tubes for use in orthodontics.

**12. Predicate, Predicate Reference and Proposed Device Comparison**

<b>Element</b>	<b>Clarity™ ADVANCED (K102803)</b>	<b>Damon Clear / Damon Clear2 (K081415)</b>	<b>Symetri™ Clear (K172845)</b>
<b>510(k)</b>	K102803	K081415	K172845
<b>Trade Name</b>	Clarity ADVANCED Ceramic Brackets	Damon Clear / Damon Clear2	Symetri Clear
<b>Target Users</b>	Licensed Orthodontic / Dental Professionals	Licensed Orthodontic / Dental Professionals	Licensed Orthodontic / Dental Professionals
<b>Device Description</b>	Clarity ADVANCED is a single-use polycrystalline alumina	Damon Clear / Damon Clear2 is a single-use polycrystalline alumina	Symetri Clear is a single-use polycrystalline alumina

<b>Element</b>	<b>Clarity™ ADVANCED (K102803)</b>	<b>Damon Clear / Damon Clear2 (K081415)</b>	<b>Symetri™ Clear (K172845)</b>
	orthodontic twin bracket.	orthodontic self-ligating bracket.	orthodontic twin bracket.
<b>Indications for Use</b>  (Identical to 510k)	Clarity ADVANCED Ceramic Brackets are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth.	Damon 4Clear* is a bracket system intended to aid in the movement of patient teeth during orthodontic treatment.  * Name at time of submission.	This device is intended for the orthodontic movement of teeth. It is used temporarily and is removed after Orthodontic treatment has been completed.
<b>Common Name</b>	Orthodontic Ceramic Bracket	Orthodontic Ceramic Bracket	Orthodontic Ceramic Bracket
<b>Classification Name</b>	Bracket, Ceramic, Dental	Bracket, Ceramic, Dental	Bracket, Ceramic, Dental
<b>Class</b>	II	II	II
<b>Product Code</b>	NJM	NJM	NJM
<b>Material</b>	Alumina (Al <sub>2</sub> O <sub>3</sub> )	Alumina (Al <sub>2</sub> O <sub>3</sub> )	Alumina (Al <sub>2</sub> O <sub>3</sub> )
<b>Clarity</b>	Translucent	Translucent	Translucent
<b>Bracket Design</b>	1-Piece Base and Bracket Construction	1-Piece Base and Bracket Construction and a slide	1-Piece Base and Bracket Construction
<b>Ligation</b>	Non Self-Ligating	Self-Ligating	Non Self-Ligating
<b>Manufacturing Method</b>	CIM	CIM	CIM
<b>Hooks</b>	CIM Hooks	CIM Hooks	CIM Hooks
<b>In/Out</b>	.020”-.045”	.035” - .059”	.020” - .045”
<b>Torque</b>	+17° thru -17°	+2° thru -11°	+17° thru -17°
<b>Angulation</b>	Up to +8°	Up to +9°	Up to +8°
<b>Rotation</b>	Up to 2°	0°	Up to 2°
<b>Bracket Identification and Placement</b>	Temporary color coded placement indicator system to aid in bracket positioning  Temporary colored dot to indicate Upper/Lower, Left/Right	Color coded plastic jig to aid in visual placement  Temporary colored dot to indicate Upper/Lower, Left/Right	Color coded plastic axis indicator or temporary color coded labial tie wings to aid in visual placement  Temporary colored dot to indicate Upper/Lower, Left/Right

Element	Clarity™ ADVANCED (K102803)	Damon Clear / Damon Clear2 (K081415)	Symetri™ Clear (K172845)
<b>Material Composition for Bracket Identification and Placement</b>	Unknown	Bracket Identification – Blue*: -Polypropylene Copolymer - Copper, [29H, 31H-Phthalocyaninato(2-)-N29, N30, N31 - Titanium Dioxide Bracket Identification – Red*: -Polypropylene Copolymer -Iron Oxide -Zinc Stearate Bracket Identification – Temporary Acrylic Paint* -Polyethylene Glycol Octylphenyl Ether <i>*Per an independent accredited medical research service company, the finished device is considered to have met biological evaluation and risk assessment requirements (ISO 10993 and ISO 14971).</i>	Bracket Identification – Blue*: -Polypropylene Copolymer - Copper, [29H, 31H-Phthalocyaninato(2-)-N29, N30, N31 - Titanium Dioxide Bracket Identification – Red*: -Polypropylene Copolymer -Iron Oxide -Zinc Stearate Bracket Identification – Temporary Acrylic Paint* -Polyethylene Glycol Octylphenyl Ether <i>*Per an independent accredited medical research service company, the finished device is considered to have met biological evaluation and risk assessment requirements (ISO 10993 and ISO 14971).</i>
<b>Bracket Base</b>	Micro-crystalline, mechanical bonding, surface for optimal bond strength	Laser etch pattern strategically cut onto the bottom of the bracket for optimal bond strength between the bracket and tooth	Laser etch pattern strategically cut onto the bottom of the bracket for optimal bond strength between the bracket and tooth
<b>Single Use</b>	Yes	Yes	Yes
<b>Non-Sterile Packaging</b>	Yes	Yes	Yes
<b>Debonding Hand Instrument Accessory</b>	Unitek Self-Ligating Bracket Debonding	Damon Clear / Damon Clear 2 Debonding	Symetri Clear M <sup>c</sup> Laughlin, Bennett & Trevisi – Debonding

Element	Clarity™ ADVANCED (K102803)	Damon Clear / Damon Clear2 (K081415)	Symetri™ Clear (K172845)
<i>*Included for informational purposes only, not for review for clearance</i>	Instrument (REF: 804-170)	Instrument (REF: 866-4019)	Instrument / Pliers (REF: 866-4025)

13. **Clinical Performance Data**

Clinical performance testing has not been performed for Symetri Clear.

14. **Conclusion as to Substantial Equivalence**

Based upon similarities in the indications for use and technology, biocompatibility testing and performance testing, Symetri Clear brackets have been shown to be substantially equivalent to Clarity ADVANCED brackets (K102803) and to Damon Clear/Damon Clear2 brackets (K081415).