July 7, 2023

American Orthodontics
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K232011
Trade/Device Name: Cleo
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NJM
Dated: July 3, 2023
Received: July 6, 2023

Dear Dave Yungvirt:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K232011

Device Name
Cleo

Indications for Use *(Describe)*

The Cleo bracket line is intended to operate together with other orthodontic devices to apply forces to teeth. Under the supervision of a trained dental professional or orthodontist, this may result in changes to the position of teeth.

The Cleo bracket line is indicated for orthodontic treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist.

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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K232011

510(k) Summary

21CFR807.92

Preparation Date: 3 July 2023

Company Information:

American Orthodontics
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Sheboygan, WI 53081
Phone: 920-457-5051
Fax: 920-457-5773

Submitter Information:

Laura Richmond | Regulatory Affairs Engineer

Device Information:

Trade Name: Cleo
Common Name: Ceramic Bracket
Classification Name: Bracket, Ceramic, Orthodontic
510(k) Number: unknown
Product Code: NJM
Regulation Number (21CFR): 872.5470

Predicate Device Information:

1st Predicate Device
Product/Trade Name: Empower Clear
Classification Name: Bracket, Ceramic, Orthodontic
510(k) Number: K122753
Product Code: NJM
Regulation Number (21CFR): 872.5470

2nd Predicate Device
Product/Trade Name: Radiance
Classification Name: Bracket, Ceramic, Orthodontic
510(k) Number: K080749
Product Code: NJM
Regulation Number (21CFR): 872.5470

Description of the Device:

Device Design:

The Cleo bracket line of products are used for the orthodontic treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist. The Cleo bracket line of products are for prescription use only. The Cleo bracket line of products are intended and labeled for single-use only. American Orthodontics does not condone or support the reuse or reprocessing of single-use devices.

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The Cleo bracket line of products are single-use ceramic orthodontic brackets intended to be bonded to a tooth to hold an orthodontic archwire used to apply pressure to the tooth in order to alter the position of the tooth.

The Cleo bracket line of products are made of 99.9% alumina through the process of ceramic injection molding.

Visual placement aids (VPAs) are placed in the Cleo bracket line to help provide visual contrast at the arch wire slot and intertwin areas of the bracket. The VPA is removed from the bracket before orthodontic treatment begins; VPAs do not serve a function during the orthodontic treatment. The presence of the VPA within the bracket prior to treatment will not impact the safety and performance of the bracket during the device's intended use.

The VPAs are made of polyurethane raw material through the process of injection molding.

Indications for Use:
The Cleo bracket line is intended to operate together with other orthodontic devices to apply forces to teeth. Under the supervision of a trained dental professional or orthodontist, this may result in changes to the position of teeth.

The Cleo bracket line is indicated for orthodontic treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist.

Substantial Equivalence Discussion:
Cleo brackets have the following similarities to the legally marketed predicate Empower Clear (K122753) and Radiance (K080749):

- Same intended use, and
- Same technological characteristics through principle of operations, mechanism of action, and incorporation of similar materials.

The tables below outline the comparison of the primary predicate device (Empower Clear: K122753) and the secondary predicate device (Radiance: K080749) to American Orthodontics' device (Cleo) to show Substantial Equivalence.

Primary Predicate Device (K122753) Name and Manufacturer

Product Parameter	1st Predicate Empower Clear / American Orthodontics	Cleo / American Orthodontics
510(k) Number	K122753	Unknown
Classification Code/ Regulation Number	NJM	NJM

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Indications for Use / Intended Use	Ceramic Brackets are intended for orthodontic movement of teeth as diagnosed by an orthodontist. It is used temporarily and is removed upon completion of orthodontic treatment. Ceramic Brackets are intended to be single use only.	The Cleo bracket line is intended to operate together with other orthodontic devices to apply forces to teeth. Under the supervision of a trained dental professional or orthodontist, this may result in changes to the position of teeth. The Cleo bracket line is indicated for orthodontic treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist.
Type and Duration of Tissue Contact	Long term use (used continuously for more than thirty days) Location - oral cavity, mucosal membrane Duration - greater than thirty days	Long term use (used continuously for more than thirty days) Location - oral cavity, mucosal membrane Duration - greater than thirty days
Material (Bracket)	Al_2O_3	Al_2O_3
Material (VPA)	Polyurethane	Polyurethane
Material (Clip)	Rh (clip coating) MP35N (clip)	N/A
Crystal Structure	Polycrystalline	Polycrystalline
Manufacturing Process	Injection Molding	Injection Molding
Color	Opaque White	Opaque White
Limits of Reuse	For Single Patient Use Only	For Single Patient Use Only
Sterile	Shipped Unsterile	Shipped Unsterile
In/Out (in)	.030 to .052	.030 to .052
Slot Depth (in)	.026 to .036	.026 to .036
Slot Height (in)	.018 to .022	.018 to .022
Slot Length (in)	.120 to .130	.116 to .156
Angle of Torque (°)	-22° to +17°	-22° to +17°
Angulation (°)	0° to +9°	0° to +9°
Rotational Offset (°)	0°	0°
Ligation Type	Clip and/or Ligature	Ligature

Secondary Predicate Device (K080749) Name and Manufacturer

Product Parameter	**2nd Predicate Radiance / American Orthodontics**	**Cleo / American Orthodontics**
510(k) Number	K080749	Unknown
Classification Code/ Regulation Number	NJM	NJM

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Indications for Use / Intended Use	Orthodontic treatment is used to correct dental deficiencies and to improve the appearance of the patient. The brackets, arch wire and elastic o-rings form a force system that is designed to gradually move teeth into a normal alignment.	The Cleo bracket line is intended to operate together with other orthodontic devices to apply forces to teeth. Under the supervision of a trained dental professional or orthodontist, this may result in changes to the position of teeth. The Cleo bracket line is indicated for orthodontic treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist.
Type and Duration of Tissue Contact	Long term use (used continuously for more than thirty days) Location - oral cavity, mucosal membrane Duration - greater than thirty days	Long term use (used continuously for more than thirty days) Location - oral cavity, mucosal membrane Duration - greater than thirty days
Material (Bracket)	Al_2O_3	Al_2O_3
Material (VPA)	Polyurethane	Polyurethane
Material (Clip)	N/A	N/A
Crystal Structure	Monocrystalline	Polycrystalline
Manufacturing Process	Milling	Injection Molding
Color	Translucent Clear	Opaque White
Limits of Reuse	For Single Patient Use Only	For Single Patient Use Only
Sterile	Shipped Unsterile	Shipped Unsterile
In/Out (in)	.045 to .068	.030 to .052
Slot Depth (in)	.028	.026 to .036
Slot Height (in)	.018 to .022	.018 to .022
Slot Length (in)	.110 to .140	.116 to .156
Angle of Torque (°)	-22° to +17°	-22° to +17°
Angulation (°)	0° to +9°	0° to +9°
Rotational Offset (°)	0°	0°
Ligation Type	Ligature	Ligature

Discussion of Differences

Indications for Use / Intended Use

There are no significant differences between the indications for use/intended use for Empower Clear, Radiance, or the Cleo Bracket. While there are minor differences in verbiage, the following is true for each device (Empower Clear, Radiance, Cleo):

1. Indicated for orthodontic treatment, which includes:
    - Use within an orthodontic system by a trained dental professional or orthodontist
    - Treatment of malocclusions and craniofacial abnormalities (i.e. misalignment/dental deficiencies/appearance of teeth)

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2. Intended to aid in the movement of teeth, which includes:
    - Application of forces

Any verbiage differences between the predicate devices and the Cleo bracket do not create significant differences between the indications for use/intended use nor do they affect the safety or effectiveness of the devices. The differences are attributed to the statements being written by different authors at a previous time. The Cleo bracket indications for use is written based off the requirements of current regulations. Additionally, all three devices are single use only, as is indicated on the label.

The table below demonstrates how each device meets the two indications listed above.

#	Indication	Empower Clear (Primary Predicate: K122753)	Radiance (Secondary Predicate: K080749)	Cleo
1	Indicated for orthodontic treatment, which involves: • *Use within an orthodontic system by a trained dental professional or orthodontist* • *Treatment of malocclusions and craniofacial abnormalities (i.e. misalignment/dental deficiencies/appearance of teeth)*	Ceramic Brackets are intended for **orthodontic** movement of teeth **as diagnosed by an orthodontist**. It is used temporarily and is removed upon completion of **orthodontic treatment**. Ceramic Brackets are intended to be single use only.	**Orthodontic treatment** is used to **correct dental deficiencies and to improve the appearance** of the patient. **The brackets, arch wire and elastic o-rings form a force system** that is designed to gradually move teeth into a **normal alignment**.	The Cleo bracket line is intended to **operate together with other orthodontic devices** to apply forces to teeth. **Under the supervision of a trained dental professional or orthodontist**, this may result in changes to the position of teeth. The Cleo bracket line is **indicated for orthodontic treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist.**
2	Intended to aid in the movement of teeth *(which includes application of forces)*.	Ceramic Brackets are intended for **orthodontic movement of teeth** as diagnosed by an orthodontist. It is used temporarily and is removed upon completion of orthodontic treatment. Ceramic Brackets are intended to be single use only.	Orthodontic treatment is used to correct dental deficiencies and to improve the appearance of the patient. The brackets, arch wire and elastic o-rings form a **force system** that is **designed to gradually move teeth** into a normal alignment.	The Cleo bracket line is intended to operate together with other orthodontic devices **to apply forces to teeth**. Under the supervision of a trained dental professional or orthodontist, **this may result in changes to the position of teeth**. The Cleo bracket line is indicated for orthodontic treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist.

There are no biocompatibility concerns based on the differences for indication for use.

Material

The brackets for all the predicate devices (Empower Clear: K122753 and Radiance: K080749) and the new device (Cleo) are made from the same material (Al_2O_3). The visual placement aids (VPAs) for all predicate devices and the new device are also made from the same material (polyurethane). The primary predicate Empower Clear (K122753) has additional materials (Rh and MP35N) due to the presence of the clip used to hold the orthodontic wire in place (ligation type). Rh and MP35N are not present in the final device of Cleo brackets, therefore Rh and MP35N are not evaluated as part of biocompatibility for the Cleo bracket. The difference in materials does not affect the original function or intended purpose for the brackets. The biocompatibility of the Cleo device is no worse than the tested device, primary predicate Empower Clear Brackets, which is a worst-case condition for any bracket made by American Orthodontics from alumina given the addition of the metal clip.

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Crystal Structure
Single crystal brackets (secondary predicate Radiance: K080749) are 99.9% alumina manufactured by removing material from a slab of sapphire. Devices made from polycrystalline alumina, such as primary predicate Empower Clear (K122753) and Cleo brackets, are Ceramic Injection Molded (CIM). CIM manufacturing methods require use of additional materials to properly mold and sinter the part. The final device is 99.9% polycrystalline alumina. The different crystal structure for the products do not affect the original function, intended purpose, or biocompatibility of the device.

Manufacturing Process
Single crystal (monocrystalline) brackets, such as secondary predicate Radiance (K080749), are 99.9% alumina manufactured by removing material from a slab of sapphire. Devices made from polycrystalline alumina, such as primary predicate Empower Clear (K122753) and Cleo brackets, are Ceramic Injection Molded (CIM). CIM manufacturing methods require use of additional materials to properly mold and sinter the part. The final device is 99.9% polycrystalline alumina. The different types of manufacturing steps for monocrystalline and polycrystalline products do not impact the material composition or biocompatibility as previously defined, nor do they result in any residues/contaminants that pose additional risks to the user or patient.

Color
Single crystal brackets (secondary predicate Radiance: K080749) have a translucent clear appearance due to the monocrystalline structure. Devices made from polycrystalline alumina, such as primary predicate Empower Clear (K122753) and Cleo brackets, have an opaque white appearance due to the polycrystalline structure of the devices. Below is a representative image for the appearance of primary predicate Empower Clear (K122753) and secondary predicate Radiance (K080749) brackets. The Cleo bracket line will have the same appearance as primary predicate Empower Clear (K122753). The appearance for monocrystalline and polycrystalline products do not affect the original function, intended purpose, or biocompatibility of the device.

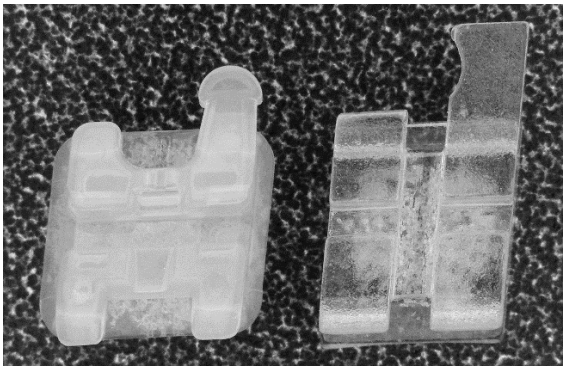

Figure 1 Color and Appearance of primary predicate Empower Clear: K122753 (left) and secondary predicate Radiance: K080749 (right) brackets.

In/Out
The Cleo line of brackets have the in/outs design to align with the Mini Master line of brackets sold by American Orthodontics. The in/outs for these brackets range from .030 inches to .052 inches. The in/out range is the same as our primary predicate Empower Clear (K122753). Our secondary predicate (Radiance: K080749) was designed to have a consistent slot depth across all the brackets due to the

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manufacturing process of the brackets. The in/out range for our products does not affect the original function or intended purpose of the device.

Slot Depth
Slot depth is related to the in/out of the bracket. The Cleo line of brackets have a slot depth range of .026 inches to .036 inches. This slot depth range is the same as the primary predicate Empower Clear (K122753) line of brackets. There is a slot depth range for these brackets because the brackets have been designed to have a specified in/out. The slot depth for secondary predicate Radiance (K080749) is .028 inches. These brackets have been designed to have the same slot depth for all brackets due to the manufacturing process. It is noted that the slot depth for the secondary predicate Radiance (K080749) brackets is within the range of the primary predicate Empower Clear (K122753) and the Cleo brackets.
The slot depth range for our products does not affect the original function or intended purpose of the device.

Slot Length
The slot length range for the Cleo line of brackets is .116 inches to .156 inches. The slot length range is larger than either of the predicate devices (primary predicate Empower Clear: K12275 .120-.130; secondary predicate Radiance: K080749 .110-.140) However, a longer slot length is beneficial to the bracket for rotational control of the bracket. This is so because the wire is in contact with more of the bracket. The slot length range for the Cleo line of brackets does not affect the original function or intended purpose of the device.

Ligation Type
The difference in the ligation type is the primary reason for having two predicate devices for the Cleo line of brackets. The Cleo line of brackets is designed to have the wire held in place with an elastic ligature placed under the tie wing and over the arch wire. This method of ligation is the same for our secondary predicate, Radiance (K080749). Primary predicate Empower Clear (K122753) brackets is also able to hold a wire in place with an elastic ligature placed under the tie wing and over the arch wire. However, the primary method of ligation for the primary predicate Empower Clear (K122753) line of bracket is a clip that retains the wire by the clip closing over the slot. The different methods of ligation do not affect the original function, intended purpose, or biocompatibility of the device.

Performance Testing:
Clinical Performance Testing
No clinical performance testing has been conducted.

Non-Clinical Performance Testing
The following non-clinical performance tests were conducted:

1. Analysis of Dimensions and Angles (See section 18)

Conclusion:
The Cleo bracket line of products have the following similarities to the legally marketed predicate Empower Clear (K122753) and Radiance (K080749):

- Same intended use, and

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- Same technological characteristics through principle of operations, mechanism of action, and incorporation of similar materials.

In-house testing performed has demonstrated the efficacy and suitability to the intended purpose of the Cleo bracket line. Results of bench testing indicates that the Cleo bracket line is similar to the predicate Empower Clear and Radiance devices.

Any slight differences do not affect the original function or intended purpose of the device.

Information contained in this 510(k) does not raise new questions or safety and effectiveness and, demonstrates it is at least as safe and effective as the predicate.