K122753

AMERICAN ORTHODONTICS

DEC 14 2012

510(k) Summary

Preparation Date: August 28, 2012

Company Information:

American Orthodontics
1714 Cambridge Avenue
Sheboygan, WI 53081
Phone: 920-457-5051
Fax: 920-457-5773

Contact Information:

Trang Adams / Regulatory Affairs Specialist
1536 N. 18th Street
Sheboygan, WI 53081
Phone: 920-457-5051 Ext. 4251
Fax: 920-457-5773
E-Mail: tadams@americanortho.com

Device Information:

Trade Name: Empower Clear
Common Name: Ceramic Brackets
Classification Name: Bracket, Ceramic, Orthodontic
Classification Code: NJM
Regulation Number: 872.5470

Equivalent Legally Marketed Devices Information:

510(k) #	Product Name	Device Manufacturer
K080749	Radiance	American Orthodontics
K060837	In-Ovation C	Densply

Description of the Device:

The Empower Clear line of products is single-use devices intended for use in conjunction with comprehensive orthodontics to control the movement of individual teeth. The Ceramic Bracket combines the aesthetics of a ceramic bracket with the versatility and ease of self ligation.

These brackets are comprised of several geometries that vary from bracket to bracket, corresponding to the intended tooth. These geometries contribute to the fit of the bracket to the tooth and also impart the axial control of the energy from the archwire.

Indications for Use:

Empower Clear 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. Empower Clear brackets are intended to be single use only.

AMERICAN ORTHODONTICS

Technological Characteristics Information:
The material, Alumina Oxide [Al_2O_3], is used in the manufacturing of the Radiance brackets and In-Ovation C brackets – which is the same material used for Empower Clear.

The In-Ovation C clip material is the same as the Empower Clear clip material. The Radiance bracket does not have a clip.

The function and performance of the Empower Clear brackets are substantially equivalent to the predicate devices, as outlined in the following table.

	Device Name / Manufacturer			
Product Parameter	**Radiance / American Orthodontics**	**In-Ovation / Dentsply**	**Empower / American Orthodontics**	**Substantial Equivalence Analysis**
510(k) Number	K080749	K060837	Pending	N/A
Material	Al_2O_3	Al_2O_3	Al_2O_3	Equivalent
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 Innovation C is intended for orthodontic movement of natural teeth, excluding the mandibular bicuspid 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.	Equivalent
Single Use	YES	YES	YES	Equivalent
Non-Sterile Packaging	YES	YES	YES	Equivalent

Biocompatibility Testing:
Biocompatibility testing conducted on Empower Clear brackets indicates that the bracket material is safe for use. The bracket material, Aluminum Oxide [Al2O3], was found to be free of harmful extractables. No oral mucosa irritation or skin sensitization was detected with the material.

Summary:
The function and performance of Empower Clear bracket is similar to the predicates. There are no changes in the intended use and fundamental scientific technology. All of the materials used in the device have been used in legally marketed American Orthodontics devices. Minor differences in

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technological characteristics do not raise new types of safety and effectiveness questions.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 14, 2012

Mr. Trang Adams
Regulatory Affairs Specialist
American Orthodontics
1536 North 18th Street
SHEBOYGAN WI 53081

Re: K122753
Trade/Device Name: Empower Clear
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: October 23, 2012
Received: October 26, 2012

Dear Mr. Adams:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Susan Runner DDS, MA 2012.12.14 10:46:01 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 122753

AMERICAN ORTHODONTICS

Indications for Use Statement

510(k) Number (if known): K 122753
Unknown

Device Name:
Empower Clear

Indications for Use:
Empower Clear 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. Empower Clear brackets are intended to be single use only.

Prescription Use And/Or Over-The-Counter Use:

- Prescription use by orthodontist only
- Not available Over-The-Counter [OTC]

2012.12.1
Susan Runner DDS, MA 4 10:47:20
-05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122753

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K122753

V.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 14, 2012

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Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K122753

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off	Susan Runner DDS, MA 2012.12.14 10:46:21 -05'00'
Division Sign-Off	Susan Runner DDS, MA 2012.12.14 12:13:21 -05'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".

K 122753

AMERICAN ORTHODONTICS

Indications for Use Statement

510(k) Number (if known): K 122753
Unknown

Device Name:
Empower Clear

Indications for Use:
Empower Clear 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. Empower Clear brackets are intended to be single use only.

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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122753

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* * * COMMUNICATION RESULT REPORT (DEC. 14. 2012 2:39PM) * * *

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : DEC. 14. 2012 2:34PM

E MODE	OPTION	ADDRESS	RESULT	PAGE
1887 MEMORY TX		919204575773	OK	3/3

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 14, 2012

Mr. Trang Adams
Regulatory Affairs Specialist
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1536 North 18th Street
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Re: K122753
Trade/Device Name: Empower Clear
Regulation Number: 21 CFR 872.5470
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Dated: October 23, 2012
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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Myra E Browne

Subject: 510(k) Number K122753/S001

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☑ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?		✓	
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)?			✓
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank?* (If study was			✓

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)	✓
Does this device include an Animal Tissue Source?	✓
All Pediatric Patients age<=21	✓
Neonate/Newborn (Birth to 28 days)	✓
Infant (29 days -< 2 years old)	✓
Child (2 years -< 12 years old)	✓
Adolescent (12 years -< 18 years old)	✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)	✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)	✓
Nanotechnology	✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*	✓

Regulation Number	Class*	Product Code
872.5470	C. II	76 NJM

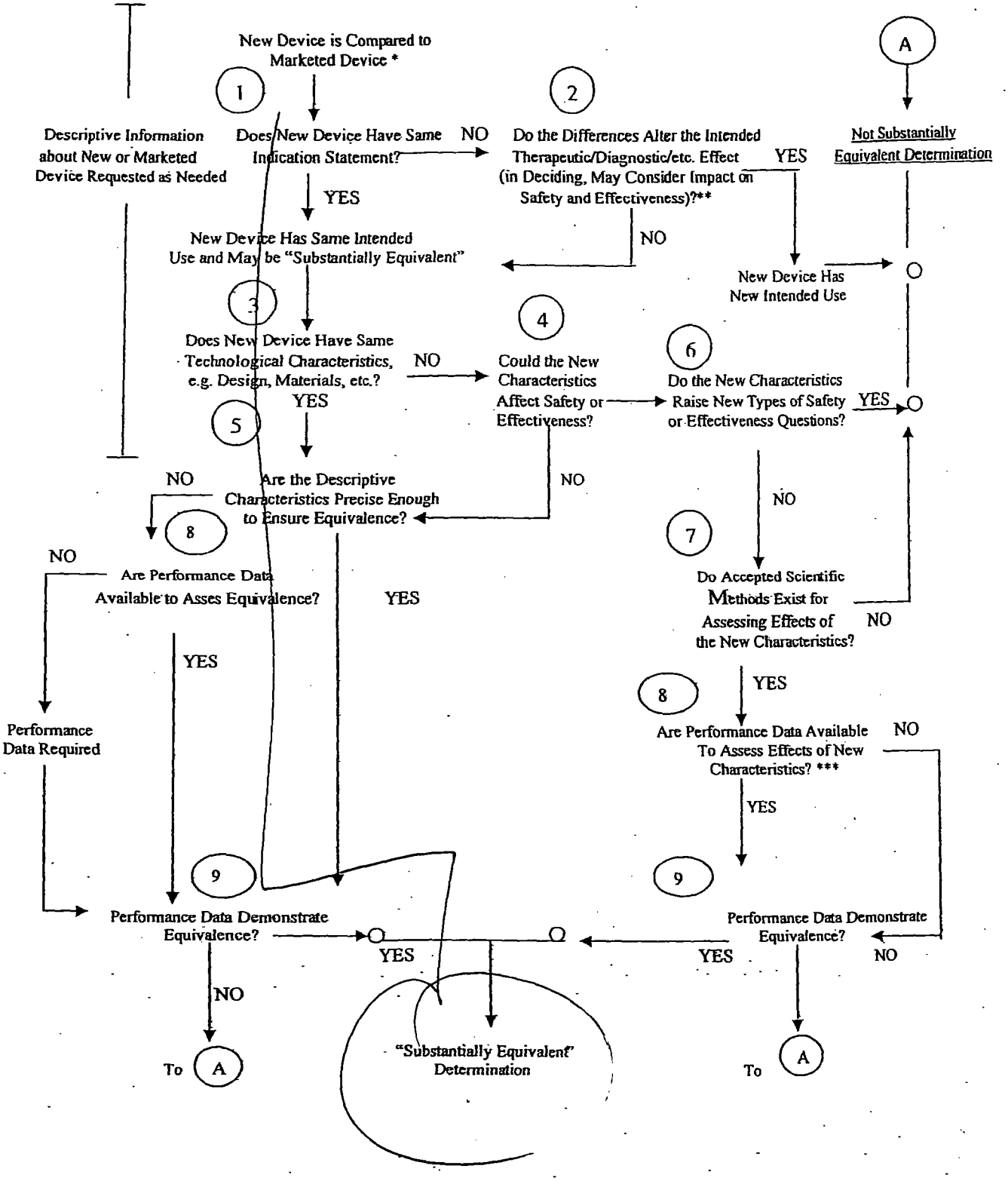
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: _____ _____ 12/13/12
(Branch Chief) (Branch Code) (Date)

Final Review: _____ 12/18/12
(Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K122753

Date:	November 30, 2012
To:	The Record
From:	Myra E. Browne, M.S., Biologist
Office/Division:	ODE/DAGRID
510(k) Holder:	American Orthodontics
Device Name:	Empower Clear
Contact:	Ms. Trang Adams
Phone:	920-457-5051
Fax:	920-457-5773
Email:	tadams@americanortho.com

Purpose and Submission Summary

The 510(k) holder would like to introduce Empower Clear into interstate commerce.

Empower Clear is a ceramic orthodontic bracket that is intended to reposition teeth during orthodontic treatment.

Empower Clear is substantially equivalent (SE) to legally marketed ceramic orthodontic brackets because the information submitted by American Orthodontics , demonstrates that the device has the same indication and technological characteristics as legally marketed ceramic orthodontic brackets.

Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

Indications for Use

Empower Clear ceramic orthodontic brackets are intended for attachment to the patient's

teeth during orthodontic treatment to reposition the teeth to achieve correct dental deficiencies.

The indication of Empower Clear does not differ from that of legally marketed orthodontic ceramic brackets.

Device Description/Formulation

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		X	

The purpose of this 510(K) is to introduce a new product to market. No novel features have been introduced.

Empower Clear is an orthodontic bracket line of products that are used in conjunction with comprehensive orthodontics to control the movement of individual teeth. The ceramic bracket is a self ligating bracket system. The Empower Bracket line consists of Empower Self-ligating stainless steel brackets, Empower Reconvertible stainless steel buccal tubes and Empower Clear brackets. Empower Clear is available as interactive or passive self-ligating systems. The interactive self-ligating system offers less friction at the beginning of treatment and more control in the later stages. The passive self-ligating system offers less friction and lower force mechanics throughout treatment, no wires are actively engage by the clip. The Empower Clear brackets are made of aluminum oxide which gives the brackets a clear appearance which are desirable for esthetics.

The Empower Clear bracket system consists of 20 brackets: a group of 4 identical brackets (upper bicuspids), a second group of 4 identical brackets (lower centrals and laterals) and 12 unique brackets. Slot sizes are available in 0.018" and 0.022". The cuspid and bicuspid brackets are available with and without hooks that are used for auxiliary attachments. The three axis force system for each bracket is defined by the torque, rotation and angulation component values.

Empower Clear orthodontic brackets use a colored dot identification system to facilitate placement of the brackets on the teeth via the location of one or two colored dots on the bracket tie wings. Each colored dot is approximately 0.015" in diameter. These dots are made of food coloring purchased by (b) (4) and are brushed away at the patients' initial brushings after placement. In addition to these dots the brackets contain Visual Positioning Aids in arch wire slots to assist wit the bracket alignment during bonding. These Visual Positioning Aids are removed with a scaler prior to final placement of the brackets so that the wire can be placed.

The chemical composition of Empower Clear is as follows:

Chemical	%
Aluminum oxide	99.99
Impurities which may exist as: Si, Fe, Na, K, Ca and/or Mg	0.01

(b) (4) [redacted]

Contact History

The reviewer contacted the submitter via telephone on October 19, 2012, and spoke to Ms. Trang Adams to request additional information regarding the chemical composition, 510(k) summary, physical properties, removal of the brackets, etc. The additional information was received on October 26, 2012. The company did not submit the revised 510(k) summary with the biocompatibility information included. The revised summary was received on December 12, 2012. There are no outstanding issues.

Deficiencies

No deficiencies have been identified.

Labeling

The labeling for Empower Clear has been provided which includes instructions for use and an appropriate prescription statement as required by CFR 21.801.109. No unsubstantiated claims are purported. Labeling includes the proper bonding and debonding instructions.

Sterilization/Shelf Life/Reuse:

Empower Clear will be provided non-sterile and is not intended to be sterilized before use.

Biocompatibility

The formulation of Empower Clear includes no new components. This basic formulation is known to be biocompatible for this intended use. The company did submit cytotoxicity testing, oral mucosa testing and sensitization testing. The results of these tests demonstrate that Empower Clear is acceptable for its intended use as a ceramic orthodontic bracket.

Software

Empower Clear contains no software.

Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Empower Clear is not a mechanical or electrical device. Therefore, mechanical safety, electrical safety, EMC, and thermal safety are not applicable.

Performance Testing - Bench

Engineering performance test results are provided in Section, Device Comparison.

Performance Testing - Animal

Animal test results were not provided for Empower Clear. This type of information is not needed for the assessment of safety and effectiveness of this product.

Performance Testing - Clinical

Human test results were not provided for Empower Clear. This type of information is not needed for the assessment of safety and effectiveness of this product.

Device Comparison

Predicate Device: Radiance Ceramic Orthodontic Bracket (K080749) of American Orthodontics.

Physical Property	(b) (4)
Tensile strength (MPa)	
Density (grams/cubic centimeter)	
Melting point	
Vickers Hardness	
Transparency	

Empower Clear orthodontic brackets are comparable to other legally marketed orthodontic ceramic brackets on the market, especially the Radiance Orthodontic Bracket (K080749) also manufactured by American Orthodontics. Both Radiance and Empower Clear brackets are made of 99.99% aluminum oxide, and both have (b) (4) The difference between the two products is that the Radiance material is monocrystalline, whereas Empower Clear is polycrystalline. In addition, Radiance brackets do not have a clip, and Empower Clear brackets have a clip. Both brackets have the visual placements aids for positioning and alignment, the Radiance aid is colored + and the Empower's aid is only in the slot with a -.

The physical properties of Empower Clear appear to be adequate for its intended use.

No new technological characteristics have been introduced in Empower Clear that could affect its safety or effectiveness.

Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	X		If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision: **SE**

Recommendation

Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Ceramic Bracket
Regulatory Class: Class II
Product Code: NJM

Myra E. Browne

Digitally signed by Myra E. Browne
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Myra E. Browne, 0.9.2342.19200300.100.1.1=1300013790
Date: 2012.12.14 10:30:45 -05'00'

Myra E. Browne, M. S., Biologist
Reviewer

Date

Susan Runner DDS, MA 2012.12.14 10:46:55 -05'00'

M. Susan Runner, DDS
Branch Chief

Date

AMERICAN
ORTHODONTICS

510(k) Summary

Preparation Date: August 28, 2012

Company Information:

American Orthodontics
1714 Cambridge Avenue
Sheboygan, WI 53081
Phone: 920-457-5051
Fax: 920-457-5773

Contact Information:

Trang Adams / Regulatory Affairs Specialist
1536 N. 18th Street
Sheboygan, WI 53081
Phone: 920-457-5051 Ext. 4251
Fax: 920-457-5773
E-Mail: tadams@americanortho.com

Device Information:

Trade Name: Empower Clear
Common Name: Ceramic Brackets
Classification Name: Bracket, Ceramic, Orthodontic
Classification Code: NJM
Regulation Number: 872.5470

Equivalent Legally Marketed Devices Information:

510(k) #	Product Name	Device Manufacturer
K080749	Radiance	American Orthodontics
K060837	In-Ovation C	Densply

Description of the Device:

The Empower Clear line of products is single-use devices intended for use in conjunction with comprehensive orthodontics to control the movement of individual teeth. The Ceramic Bracket combines the aesthetics of a ceramic bracket with the versatility and ease of self ligation.

These brackets are comprised of several geometries that vary from bracket to bracket, corresponding to the intended tooth. These geometries contribute to the fit of the bracket to the tooth and also impart the axial control of the energy from the archwire.

Indications for Use:

Empower Clear 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. Empower Clear brackets are intended to be single use only.

AMERICAN ORTHODONTICS

Technological Characteristics Information:
The material, Alumina Oxide [Al_2O_3], is used in the manufacturing of the Radiance brackets and In-Ovation C brackets – which is the same material used for Empower Clear.

The In-Ovation C clip material is the same as the Empower Clear clip material. The Radiance bracket does not have a clip.

The function and performance of the Empower Clear brackets are substantially equivalent to the predicate devices, as outlined in the following table.

	Device Name / Manufacturer			
Product Parameter	**Radiance / American Orthodontics**	**In-Ovation / Dentsply**	**Empower / American Orthodontics**	**Substantial Equivalence Analysis**
510(k) Number	K080749	K060837	Pending	N/A
Material	Al_2O_3	Al_2O_3	Al_2O_3	Equivalent
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 Innovation C is intended for orthodontic movement of natural teeth, excluding the mandibular bicuspid 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.	Equivalent
Single Use	YES	YES	YES	Equivalent
Non-Sterile Packaging	YES	YES	YES	Equivalent

Biocompatibility Testing:
Biocompatibility testing conducted on Empower Clear brackets indicates that the bracket material is safe for use. The bracket material, Aluminum Oxide [Al2O3], was found to be free of harmful extractables. No oral mucosa irritation or skin sensitization was detected with the material.

Summary:
The function and performance of Empower Clear bracket is similar to the predicates. There are no changes in the intended use and fundamental scientific technology. All of the materials used in the device have been used in legally marketed American Orthodontics devices. Minor differences in

1714 Cambridge Avenue | P.O. Box 1048 | Sheboygan, WI 53082-1048 USA | TEL: 920-457-5051 | FAX: 920-457-5773
info@americanortho.com

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technological characteristics do not raise new types of safety and effectiveness questions.

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info@americanortho.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 26, 2012

AMERICAN ORTHODONTICS
1536 N. 18TH ST.
SHEBOYGAN, WISCONSIN 53081
ATTN: TRANG ADAMS

510k Number: K122753

Product: EMPOWER CLEAR

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Pugh, Dominique *

From: Microsoft Outlook
To: tadams@americanortho.com
Sent: Friday, October 26, 2012 11:10 AM
Subject: Relayed: K122753 AI Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

tadams@americanortho.com (tadams@americanortho.com)

Subject: K122753 AI Letter

K122753/S001

R-13

October 23, 2012

RE: Empower Clear 510(k) # K122753

Please find enclosed two copies of the additional information requested sent on 10/22/12 via e-mail.

Sincerely,

Trang Adams

Trang Adams / Regulatory Affairs Specialist

American Orthodontics
Phone: 920-457-5051 Ext. 4251
E-Mail: tadams@americanortho.com

EMPOWER CLEAR: 510(K) NUMBER K122753

ADDENDUM TO THE SUBMITTAL OF SEPTEMBER 12, 2012

CHEMICAL COMPOSITION:

(b) (4)

[redacted]

SYSTEM DESCRIPTION:

The Empower Bracket line consists of Empower Self-Ligating Stainless Steel Brackets, Empower Reconvertible Stainless Steel Buccal Tubes and Empower Clear Brackets.

The Empower Clear is different from the other two Empower bracket lines, as it is not made of Stainless Steel, but is made of aluminum oxide material. Empower Clear is available as interactive or passive self-ligating systems. The interactive self-ligating system offers less friction at the beginning of treatment and more control in the later stages. The passive self-ligating system offers the benefits of less friction and lower force mechanics throughout treatment; no wires are actively engage by the clip.

The Empower Clear bracket system consists of 20 brackets: a group of 4 identical brackets (upper bicuspids), a second group of 4 identical brackets (lower centrals and laterals) and 12 unique brackets. Slot sizes available are 0.018" and 0.022" slot. The cuspid and bicuspid brackets are available with and without hooks that are used for auxillary attachments. The attached brochure lists three axis force system [torque, rotation, angulation]; as well as describing the identification scheme used for the system.

BRACKET REMOVAL INSTRUCTIONS:

Please refer to the proposed Empower Clear bonding and debonding (removal) instructions enclosed.

BIOCOMPATIBILITY TESTING:

(b) (4)

[redacted]

COMPARISON OF RADIANCE & EMPOWER CLEAR BRACKETS:

Similarities:

(b) (4)

- [redacted]

Differences:

(b)(4)

- [redacted]

.

Empower® Clear Braces

Empower Clear combines the aesthetics of a ceramic bracket with the versatility and ease of self ligation. Strong injection molded ceramic and aesthetically plated clips blend well with teeth, giving your patients the beautiful smile they deserve.

A McLaughlin, Bennett, Trevisi* System

INTERACTIVE

Maxillary	Torq	Ang	R/L	.018 No Hook	.018 Single Hook	.018 Double Hook	.022 No Hook	.022 Single Hook	.022 Double Hook
Central	+17	+4	R L	1475-18-1117 1475-18-2117			1485-22-1117 1485-22-2117		
Lateral	+10	+8	R L	1475-18-1210 1475-18-2210			1485-22-1210 1485-22-2210		
Cuspid	0	+8	R L		1475-18-130HD 1475-18-230HD	1475-18-130HU 1475-18-230HU		1485-22-130HD 1485-22-230HD	1485-22-130HU 1485-22-230HU
	-7	+8	R L		1475-18-1307HD 1475-18-2307HD	1475-18-1307HU 1475-18-2307HU		1485-22-1307HD 1485-22-2307HD	1485-22-1307HU 1485-22-2307HU
1st and 2nd Bicuspid	-7	0	R L	1475-18-1407 1475-18-2407	1475-18-1407HD 1475-18-2407HD	1475-18-1407HU 1475-18-2407HU	1485-22-1407 1485-22-2407	1485-22-1407HD 1485-22-2407HD	1485-22-1407HU 1485-22-2407HU

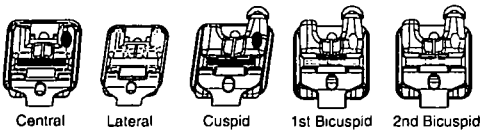
A Roth* System

INTERACTIVE

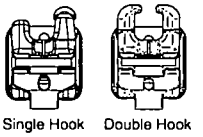
Maxillary	Torq	Ang	R/L	.018 No Hook	.018 Single Hook	.018 Double Hook	.022 No Hook	.022 Single Hook	.022 Double Hook
Central	+12	+5	R L	1475-18-1112 1475-18-2112			1485-22-1112 1485-22-2112		
Lateral	+8	+9	R L	1475-18-128 1475-18-228			1485-22-128 1485-22-228		
Cuspid	-2	+9	R L		1475-18-1302HD 1475-18-2302HD	1475-18-1302HU 1475-18-2302HU		1485-22-1302HD 1485-22-2302HD	1485-22-1302HU 1485-22-2302HU
1st and 2nd Bicuspid	-7	0	R L	1475-18-1407 1475-18-2407	1475-18-1407HD 1475-18-2407HD	1475-18-1407HU 1475-18-2407HU	1485-22-1407 1485-22-2407	1485-22-1407HD 1485-22-2407HD	1485-22-1407HU 1485-22-2407HU

Bracket identification

Individual color coding ensures easy tooth identification and bonding accuracy



Color coded elastomeric Visual Positioning Aids in arch wire slots assist with bracket alignment during bonding. VPA's contain no latex and are easily removed with a scaler.



*The American Orthodontics version of the McLaughlin, Bennett, Trevisi System is not claimed to be a duplication of any other, nor does American Orthodontics imply that it is endorsed in any way by Drs. McLaughlin, Bennett, or Trevisi.

*The American Orthodontics version of the Roth System is not claimed to be a duplication of any other, nor does American Orthodontics imply that it is endorsed in any way by Dr. Roth.

LITSL-26

Empower Clear Braces

Empower Clear's patented Quad Matte™ bonding base provides a strong mechanical bond in the center of the base for reliable bond strength while delivering a weaker bond around the perimeter of the base for predictable debonding.

Empower Clear Bonding

Due to the mechanical bond, no ceramic-specific bonding technique or adhesive is needed or recommended. Follow the adhesive manufacturer's recommendations for bonding of mechanical lock bases such as metal brackets.

Direct Bonding

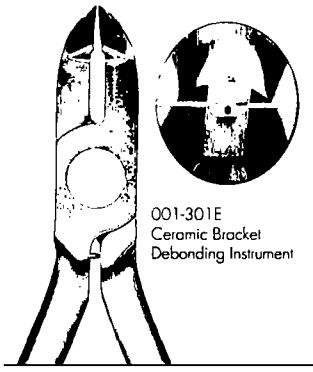
> Bond Empower Clear brackets with the clip open.
> Align the mesial and distal edges of the bracket base parallel to the long axis of the tooth.
> Use the elastomeric Visual Positioning Aid (VPA) in the slot to align the bracket parallel to the desired occlusal plane.
> If using light curable adhesive, cure Empower Clear through the face of the bracket for the amount of time recommended by the curing light manufacturer.
> Remove the VPA using a scaler or other suitable instrument.

Indirect Bonding

> Remove the VPA from the slot and position bracket on the model with the clip closed.
> Align the mesial and distal edges of the bracket base parallel to the long axis of the tooth.
> Use the closed clip as a visual reference to align the bracket parallel to the desired occlusal plane.
> To prevent impression material from entering the clip, fill the facial hole with lip balm or petroleum jelly.

Empower Clear Rebonding

Always use a new bracket if repositioning or if replacing a premature debond.



001-301E
Ceramic Bracket
Debonding Instrument

Empower Clear Debonding

> Leave arch wires in place during debonding.
> Remove adhesive flash from the mesial and distal edges of the bonding base.
> Place blades of recommended debonding instrument along the enamel/adhesive interface, occlusal/gingival for upper centrals, mesial/distal for all other brackets.
> Squeeze handles slowly until bracket releases from tooth.

AO
AMERICAN
ORTHODONTICS

3524 Washington Avenue Sheboygan, WI USA 53081 920-457-5051 USA and Canada: 1-800-558-7687
info@americanortho.com www.americanortho.com

Proudly made in the USA

UTSL-34

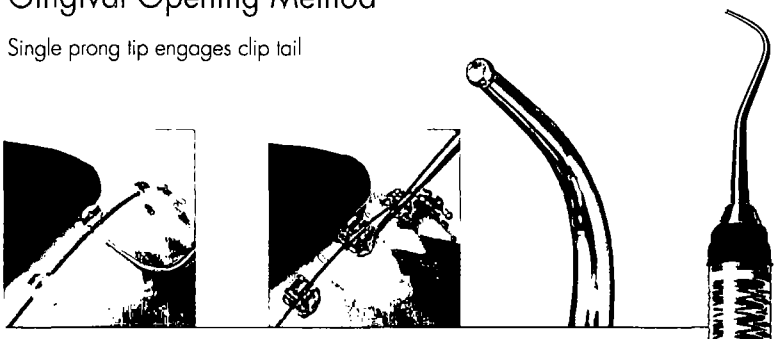
Empower Self Ligating

Easy open and close.

Double-ended opening instrument provides two opening methods and works with the entire Empower family - Clear, metal, and molars.

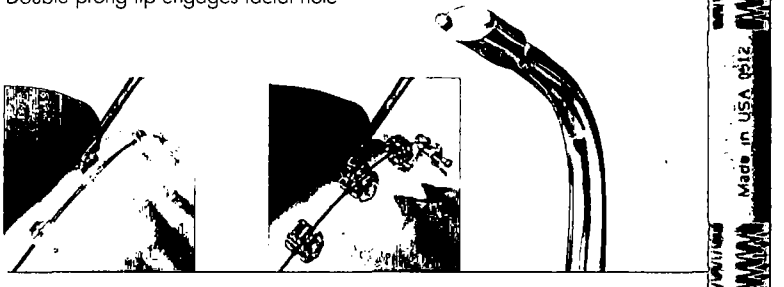
Gingival Opening Method

Single prong tip engages clip tail



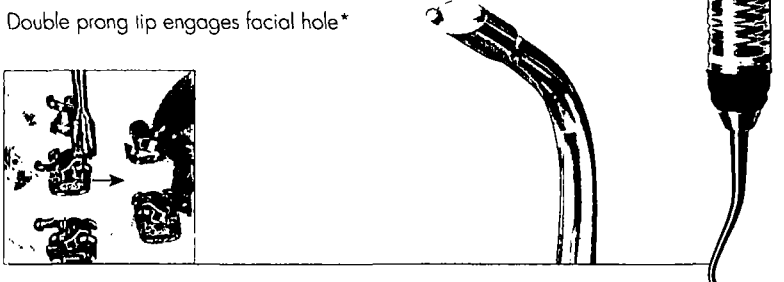
Facial Opening Method

Double prong tip engages facial hole*



Empower Tubes

Double prong tip engages facial hole*



Closing Clip

Clips close easily with just finger pressure

* Use care when using the facial hole because over-opening can deform the clip. Use a finger to support the tooth end to prevent the clip from over-opening occlusally.

Jones, Ashlee *

From: Microsoft Outlook
To: 'tadams@americanortho.com'
Sent: Monday, October 22, 2012 9:57 AM
Subject: Relayed: K122753 Hold Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

'tadams@americanortho.com' (tadams@americanortho.com) <mailto:tadams@americanortho.com>

Subject: K122753 Hold Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 22, 2012

AMERICAN ORTHODONTICS
1536 N. 18TH ST.
SHEBOYGAN, WISCONSIN 53081
ATTN: TRANG ADAMS

510k Number: K122753
Product: EMPOWER CLEAR
On Hold As of 10/19/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Myra E Brue

Subject: 510(k) Number K122753

To: The Record

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☑ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	**Class***	**Product Code**

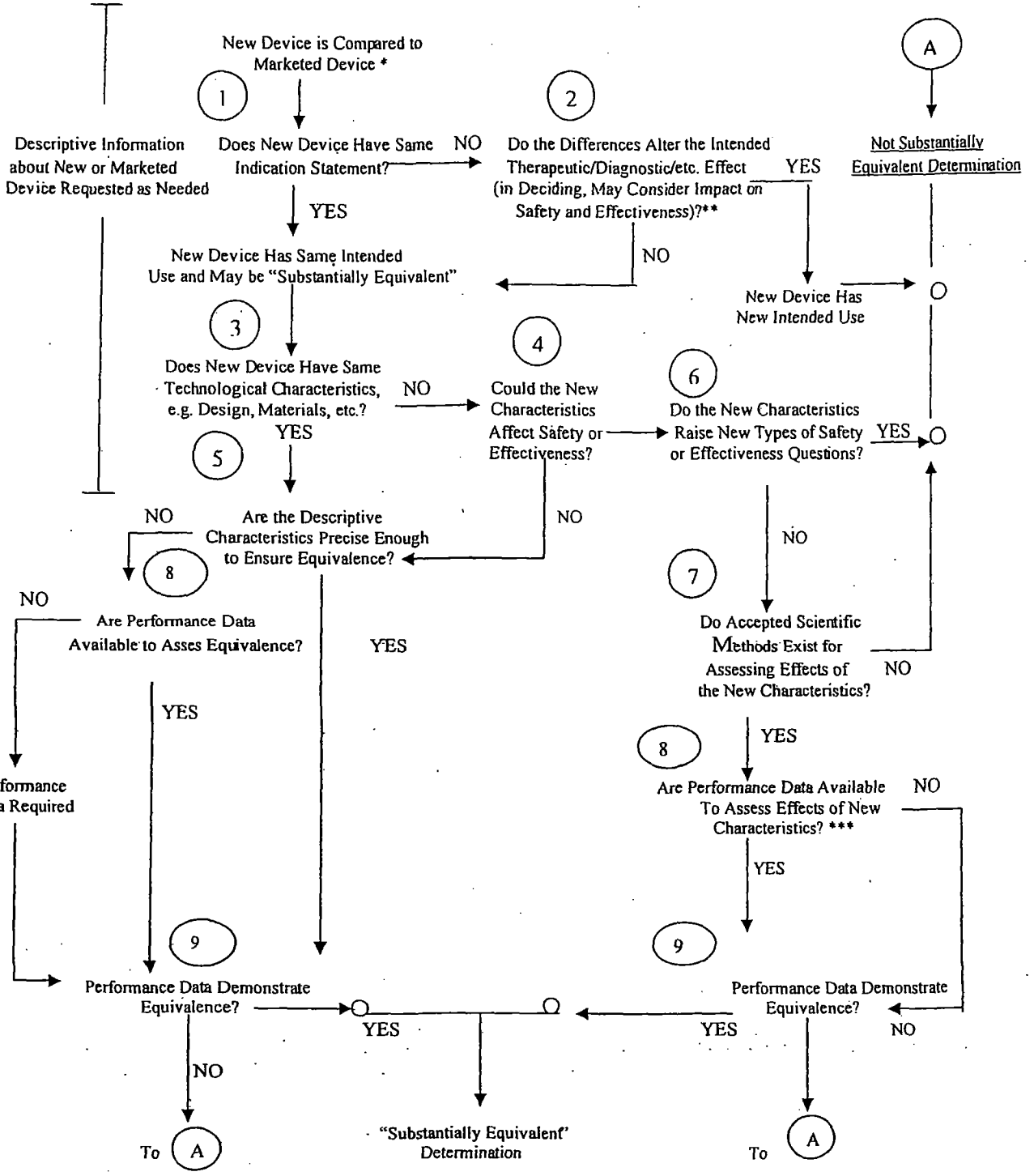
(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: Susan Runner (Branch Chief) DSDB (Branch Code) 10/19/12 (Date)

Final Review: Susan Runner (Division Director) 10/19/12 (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

To: The Record

From: Biologist, DEDB, DAGID, ODE, CDRH

Subject: K122753

Date: October 19, 2012

Background

American Orthodontics submitted a 510(k) for Empower Clear ceramic orthodontic brackets. I spoke with Ms. Trang Adams of AO today to request the following additional information:

1. the complete chemical composition of Empower Clear brackets;

2. describe the differences between the different Empower Clear brackets in the Empower line;

3. explain the recommended removal procedures for the brackets;

4. discuss the biocompatibility testing conducted for these brackets and include a summary of the testing in the 510(k) summary; and

5. discuss the differences between Empower Clear and the appropriate predicate device, and include a table with the physical properties of each device.

I explained to Ms. Adams that I will place her device on telephone hold until she submits this requested information to the Document Mail Center.

Recommendation

Place document on telephone hold.

Myra E. Browne

10/19/12

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 14, 2012

AMERICAN ORTHODONTICS
1536 N. 18TH ST.
SHEBOYGAN, WISCONSIN 53081
ATTN: TRANG ADAMS

510k Number: K122753

Received: 9/12/2012

Product: EMPOWER CLEAR

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Williams, Michael *

From: Microsoft Outlook
To: tadams@americanortho.com
Sent: Friday, September 14, 2012 8:40 AM
Subject: Relayed: Ack Letter for K122753

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

tadams@americanortho.com (tadams@americanortho.com)

Subject: Ack Letter for K122753

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 10, 2012

USER FEE HOLD LETTER - HAVE NOT RECEIVED PAYM

AMERICAN ORTHODONTICS
1536 N. 18TH ST.
SHEBOYGAN, WISCONSIN 53081
ATTN: TRANG ADAMS

510k Number: K122753
Received: 9/7/2012
User Fee ID Number: 6063568
Product: EMPOWER CLEAR

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to mail a check, please send a check to one of the addresses listed below:

By Regular Mail
Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733.

By Private Courier(e.g.,Fed Ex, UPS, etc.)
U.S. Bank
956733
1005 Convention Plaza
St. Louis, MO 63101

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301)847-8120 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/cdrh/mdufma/fy09userfee.html. In addition, the 510k Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)796-7100 or its toll-fee number (800)638-2041, or contact them at their Internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Edwena Jones at Edwena.Jones@fda.hhs.gov or directly at (301)796-7200. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Edwena Jones
Consumer Safety Technician
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Mcdonald, Lisa *

From: Microsoft Outlook
To: tadams@americanortho.com
Sent: Monday, September 10, 2012 10:24 AM
Subject: Relayed: K122753 ACK Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

tadams@americanortho.com (tadams@americanortho.com)

Subject: K122753 ACK Letter

Table of Contents

Table of Contents, Continued

SECTION 1:

MEDICAL DEVICE USER FEE

[redacted]

2

SECTION 2:

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

page 1-1

Form Approved: OMB No. 0910-511. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

AMERICAN ORTHODONTICS
1714 CAMBRIDGE AVE
SHEBOYGAN WI 53082
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****3323

2. CONTACT NAME
Trang Adams
2.1 E-MAIL ADDRESS
tadams@americanortho.com
2.2 TELEPHONE NUMBER (include Area code)
920-457-5051 4251
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) [redacted]
27-Aug-2012

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Page 1 of 2

U S Department of Health & Human Services

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

FAQ | User Fees | Draft Cover Sheet | Previous Cover Sheets | Profile | Logout

Medical Device User Fee

Confirmation

YOUR PAYMENT IDENTIFICATION NUMBER IS: MD 6063568-956733

Your Cover Sheet has been submitted electronically. You must print and sign the hard copies. Include one in each copy of your application and include a copy with your payment.

Thank you for visiting the FDA User Fee Website. As part of our efforts to improve customer service, we would like to hear from you.
Please 'click here' to submit a survey. This will only take about 2 minutes to complete.

Coversheet		Creation Date	Last Update Date	
Medical Device User Fee and Modernization Act (Print/View Final Coversheet)	1	27-AUG-2012	27-AUG-2012	Net: $4,049.00

Total: $4,049.00

Customer Information

Customer: AMERICAN ORTHODONTICS
Trang Adams
920-457-5051 4251
tadams@americanortho.com

Applicant Contact Information

Bill To: Trang Adams
AMERICAN ORTHODONTICS
1714 CAMBRIDGE AVE
SHEBOYGAN,WI 53082
UNITED STATES

(Pay Now) (Create Another Cover Sheet)

Medical Device User Fee
User Fees | Draft Cover Sheet | Previous Cover Sheets | Profile | Logout |

FDA Home Page | Search FDA Site | FDA A-Z Index | Contact FDA | Privacy | Accessibility

FDA Website Management Staff

Trang Adams 8/27/2012

8/27/12

Page 2-1

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
09/04/2012	(b)(4)	unknown

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
American Orthodontics	2126683		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	920-457-5051		
Street Address	**FAX Number *(including area code)***		
1536 N. 18th Street	920-457-5773		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Sheboygan	Wisconsin	53081	U.S.A
Contact Name			
Trang Adams			
Contact Title	**Contact E-mail Address**		
Regulatory Affairs Specialist	tadams@americanortho.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

PSC Publishing Services (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	NJM	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K080749	1	Radiance	1	American Orthodontics
2	K060837	2	In-Ovation C	2	Detnsply
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Ceramic Bracket

	Trade or Proprietary or Model Name for This Device		Model Number
1	Empower Clear	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [ ] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
NJM	872.5470	[ ] Class I [x] Class II
Classification Panel		[ ] Class III [ ] Unclassified

Indications *(from labeling)*

Indications for Use:

Empower Clear 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. Empower Clear brackets are intended to be single use only.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)* unknown

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name American Orthodontics		Establishment Registration Number 2126683	
Division Name *(if applicable)*		Phone Number *(including area code)* 920-457-5051	
Street Address 1536 N. 18th Street		FAX Number *(including area code)* 920-457-5773	
City Sheboygan	State / Province Wisconsin	ZIP Code 53081	Country U.S.A.
Contact Name Trang Adams	Contact Title Regulatory Affairs Specialist	Contact E-mail Address tadams@americanortho.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

SECTION 3:

510(K) COVER LETTER

K122753

AMERICAN ORTHODONTICS

510(k) Cover Letter

Submission Date: September 4, 2012

To Whom It May Concern,

This 510(k) Submission Cover Letter is submitted for the following company:

Company:
American Orthodontics

Establishment Registration Number:
2126683

This 510(k) Submission is **Submitted By**:
Trang Adams / Regulatory Affairs Specialist
1536 N. 18th Street
Sheboygan, WI 53081
Phone: 920-457-5051 Ext. 4251
Fax: 920-457-5773

The **Common Name of the Device** is:
Ceramic Bracket

The **Trade Name of the Device** is:
Empower Clear

The **Classification Name of the Device** is:
Bracket, Ceramic, Orthodontic [NJM]

The **510(k) Submission Reason** is:
New Device

The following are **Legally Marketed Devices [Predicate]** that is considered Substantially Equivalent [SE]:

510(k) #	Product Name
K080749	Radiance
K060837	In-Ovation C

The **Compliance with Any Special Controls** are as follows:
No applicable mandatory performance standards or special controls exist for this device.

Sincerely,

Trang Adams

Trang Adams / Regulatory Affairs Specialist

1714 Cambridge Avenue | P.O. Box 1048 | Sheboygan, WI 53082-1048 USA | TEL: 920-457-5051 | FAX: 920-457-5773
info@americanortho.com

SECTION 4:

INDICATIONS FOR USE

K 122753

AMERICAN ORTHODONTICS

Indications for Use Statement

510(k) Number (if known):
Unknown

Device Name:
Empower Clear

Indications for Use:
Empower Clear 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. Empower Clear brackets are intended to be single use only.

Prescription Use And/Or Over-The-Counter Use:

- Prescription use by orthodontist only
- Not available Over-The-Counter [OTC]

1714 Cambridge Avenue | P.O. Box 1048 | Sheboygan, WI 53082-1048 USA | TEL: 920-457-5051 | FAX: 920-457-5773
info@americanortho.com

[redacted]

5

SECTION 5:

510(K) SUMMARY

AMERICAN
ORTHODONTICS

510(k) Summary

Preparation Date: August 28, 2012

Company Information:

American Orthodontics
1714 Cambridge Avenue
Sheboygan, WI 53081
Phone: 920-457-5051
Fax: 920-457-5773

Contact Information:

Trang Adams / Regulatory Affairs Specialist
1536 N. 18th Street
Sheboygan, WI 53081
Phone: 920-457-5051 Ext. 4251
Fax: 920-457-5773
E-Mail: tadams@americanortho.com

Device Information:

Trade Name: Empower Clear
Common Name: Ceramic Brackets
Classification Name: Bracket, Ceramic, Orthodontic
Classification Code: NJM
Regulation Number: 872.5470

Equivalent Legally Marketed Devices Information:

510(k) #	Product Name	Device Manufacturer
K080749	Radiance	American Orthodontics
K060837	In-Ovation C	Densply

Description of the Device:

The Empower Clear line of products is single-use devices intended for use in conjunction with comprehensive orthodontics to control the movement of individual teeth. The Ceramic Bracket combines the aesthetics of a ceramic bracket with the versatility and ease of self ligation.

These brackets are comprised of several geometries that vary from bracket to bracket, corresponding to the intended tooth. These geometries contribute to the fit of the bracket to the tooth and also impart the axial control of the energy from the archwire.

Indications for Use:

Empower Clear 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. Empower Clear brackets are intended to be single use only.

AMERICAN ORTHODONTICS

Technological Characteristics Information:
The material, Alumina Oxide [Al_2O_3], is used in the manufacturing of the Radiance brackets and In-Ovation C brackets – which is the same material used for Empower Clear.

The In-Ovation C clip material is the same as the Empower Clear clip material. The Radiance bracket does not have a clip.

The function and performance of the Empower Clear brackets are substantially equivalent to the predicate devices, as outlined in the following table.

	Device Name / Manufacturer			
Product Parameter	**Radiance / American Orthodontics**	**In-Ovation / Dentsply**	**Empower / American Orthodontics**	**Substantial Equivalence Analysis**
510(k) Number	K080749	K060837	Pending	N/A
Material	Al_2O_3	Al_2O_3	Al_2O_3	Equivalent
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 Innovation C is intended for orthodontic movement of natural teeth, excluding the mandibular bicuspid 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.	Equivalent
Single Use	YES	YES	YES	Equivalent
Non-Sterile Packaging	YES	YES	YES	Equivalent

Summary:
The function and performance of Empower Clear bracket is similar to the predicates. There are no changes in the intended use and fundamental scientific technology. All of the materials used in the device have been used in legally marketed American Orthodontics devices. Minor differences in technological characteristics do not raise new types of safety and effectiveness questions.

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info@americanortho.com

SECTION 6:

TRUTHFUL & ACCURACY STATEMENT

AMERICAN
ORTHODONTICS

Truthful & Accuracy Statement

510(k) Number: Unknown

Premarket Notification Truthful & Accurate Statement [As required by 21 CFR 807.87(k)]

I certify that, in my capacity as Regulatory Affairs Specialist of American Orthodontics, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Trang Adams 8/28/2012

Trang Adams / Regulatory Affairs Specialist

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SECTION 7:

CLASS III SUMMARY & CERTIFICATION

AMERICAN
ORTHODONTICS

Class III Summary & Certification

**This section is not applicable. **

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info@americanortho.com

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SECTION 8:

FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

AMERICAN
ORTHODONTICS

Financial Certification or Disclosure Statement

**This section is not applicable. **

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[redacted]

9

SECTION 9:

DECLARATIONS OF CONFORMITY & SUMMARY REPORTS

AMERICAN
ORTHODONTICS

Declaration of Conformity & Summary Reports

**This section is not applicable. **

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SECTION 10:

EXECUTIVE SUMMARY

AMERICAN
ORTHODONTICS

Executive Summary

Device Information:

Trade Name: Empower Clear
Common Name: Ceramic Brackets
Classification Name: Bracket, Ceramic, Orthodontic
Classification Code: NJM
Regulation Number: 872.5470

Description of the Device:

The Empower Clear line of products is single-use devices intended for use in conjunction with comprehensive orthodontics to control the movement of individual teeth. The Empower Clear combines the aesthetics of a ceramic bracket with the versatility and ease of self ligation.

These brackets are comprised of several geometries that vary from bracket to bracket, corresponding to the intended tooth. These geometries contribute to the fit of the bracket to the tooth and also impart the axial control of the energy from the archwire.

Indications for Use:

Empower Clear 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. Empower Clear brackets are intended to be single use only.

Summary:

The function and performance of Empower Clear bracket is similar to the predicates, as outlined below in "**Technological Characteristics Information**". There are no changes in the intended use and fundamental scientific technology. All of the materials used in the device have been used in legally marketed American Orthodontics devices. Minor differences in technological characteristics do not raise new types of safety and effectiveness questions.

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info@americanortho.com

AMERICAN ORTHODONTICS

Technological Characteristics Information:
The material, Alumina Oxide [Al_2O_3], is used in the manufacturing of the Radiance brackets and In-Ovation C brackets – which is the same material used for Empower Clear.

The In-Ovation C clip material is the same as the Empower Clear clip material. The Radiance bracket does not have a clip.

The function and performance of the Empower Clear brackets are substantially equivalent to the predicate devices, as outlined in the following table.

	Device Name / Manufacturer			
Product Parameter	**Radiance / American Orthodontics**	**In-Ovation / Dentsply**	**Empower / American Orthodontics**	**Substantial Equivalence Analysis**
510(k) Number	K080749	K060837	Pending	N/A
Material	Al_2O_3	Al_2O_3	Al_2O_3	Equivalent
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 Innovation C is intended for orthodontic movement of natural teeth, excluding the mandibular bicuspid 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.	Equivalent
Single Use	YES	YES	YES	Equivalent
Non-Sterile Packaging	YES	YES	YES	Equivalent

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SECTION 11:

DEVICE DESCRIPTION

AMERICAN ORTHODONTICS

Device Description

Device Information:

Trade Name: Empower Clear
Common Name: Ceramic Brackets
Classification Name: Bracket, Ceramic, Orthodontic
Classification Code: NJM
Regulation Number: 872.5470

Description of the Device:

The Empower Clear bracket line of products is single-use devices intended for use in conjunction with comprehensive orthodontics to control the movement of individual teeth. The Ceramic Bracket combines the aesthetics of a ceramic bracket with the versatility and ease of self ligation.

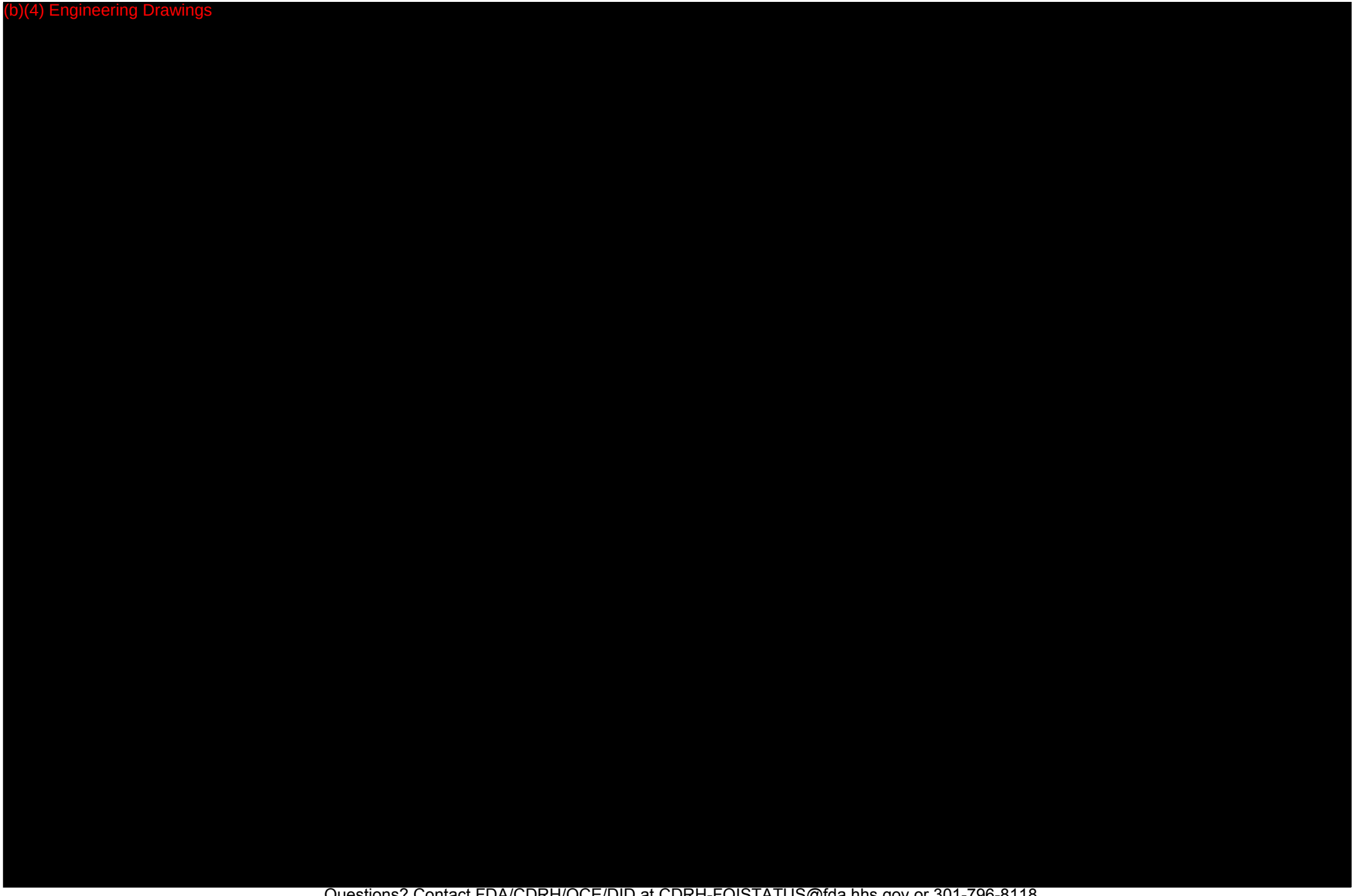
These brackets are comprised of several geometries that vary from bracket to bracket, corresponding to the intended tooth. These geometries contribute to the fit of the bracket to the tooth and also impart the axial control of the energy from the archwire.

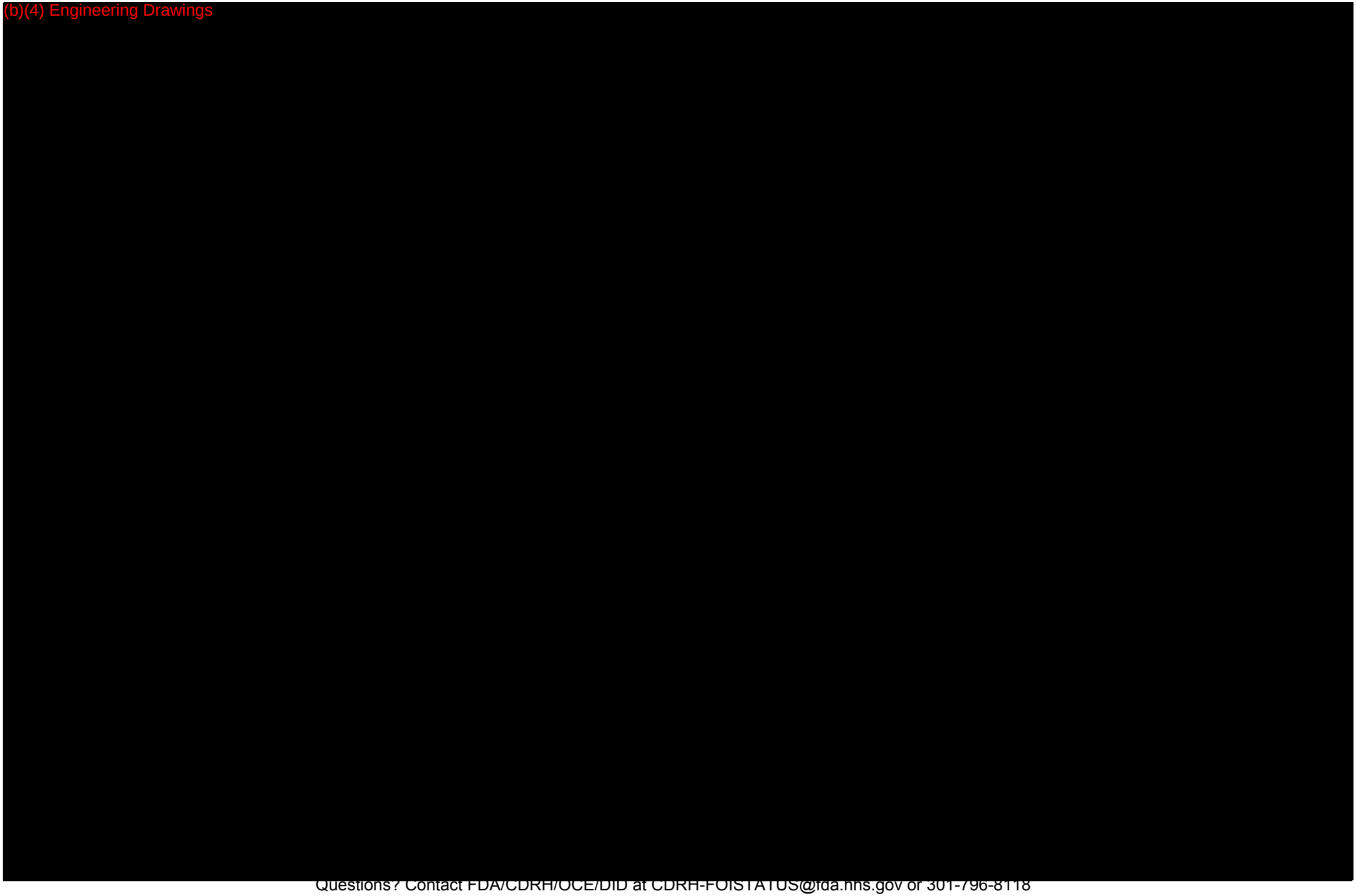
(b) (4)

[redacted]

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings





(b)(4) Engineering Drawings

[redacted]

12

SECTION 12:

SUBSTANTIAL EQUIVALENCE DISCUSSION

AMERICAN ORTHODONTICS

Substantial Equivalence Discussion

Device Information:

Trade Name: Empower Clear
Common Name: Ceramic Brackets
Classification Name: Bracket, Ceramic, Orthodontic
Classification Code: NJM
Regulation Number: 872.5470

Indications for Use:

Empower Clear 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. Empower Clear brackets are intended to be single use only.

Equivalent Legally Marketed Devices Information:

510(k) #	Product Name	Device Manufacturer
K080749	Radiance	American Orthodontics
K060837	In-Ovation C	Densply

Technological Characteristics Information:

The material, Alumina Oxide [Al_2O_3], is used in the manufacturing of the Radiance brackets and In-Ovation C brackets – which is the same material used for Empower Clear.

The In-Ovation C clip material is the same as the Empower Clear clip material. The Radiance bracket does not have a clip.

The function and performance of the Empower Clear brackets are substantially equivalent to the predicate devices, as outlined in the following table.

Summary:

The function and performance of Empower Clear bracket is similar to the predicates. There are no changes in the intended use and fundamental scientific technology. All of the materials used in the device have been used in legally marketed American Orthodontics devices. Minor differences in technological characteristics do not raise new types of safety and effectiveness questions.

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AMERICAN ORTHODONTICS

Technological characteristic comparisons are outlined below:

	Device Name / Manufacturer			
Product Parameter	**Radiance / American Orthodontics**	**In-Ovation / Dentsply**	**Empower / American Orthodontics**	**Substantial Equivalence Analysis**
510(k) Number	K080749	K060837	Pending	N/A
Material	Al_2O_3	Al_2O_3	Al_2O_3	Equivalent
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 Innovation C is intended for orthodontic movement of natural teeth, excluding the mandibular bicuspid 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.	Equivalent
Single Use	YES	YES	YES	Equivalent
Non-Sterile Packaging	YES	YES	YES	Equivalent

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SECTION 13:

PROPOSED LABELING

AO AMERICAN ORTHODONTICS

Empower® Self Ligating System

CE 0408 ⓩ Cr Ni Contains Nickel and/or Chromium

Patents #5,630,715
#5,722,826
#4,659,309

EC REP EC Certification Service GmbH • Sandgasse39a, A-9300 St. Veit/Glan. Austria

Made in USA

☐ .018 ☐ .022
☐ Interactive
☐ Passive

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AO AMERICAN ORTHODONTICS

Empower Clear Braces®

Rx/Patient _____

☐ .018 ☐ .022

☐ Interactive

☐ Passive

CE 0408

EC REP EC Certification Service GmbH · Sandgasse39a, A-9300 · St. Veit/Glan, Austria

Made in USA

Cr Ni Contains Nickel and/or Chromium

Patents #5,630,715 #5,722,826 #4,659,309

L-000424 REV0

Empower® Clear Braces

Empower Clear combines the aesthetics of a ceramic bracket with the versatility and ease of self ligation. Strong injection molded ceramic and aesthetically plated clips blend well with teeth, giving your patients the beautiful smile they deserve.

A McLaughlin, Bennett, Trevisi* System

INTERACTIVE

Maxillary	Torq	Ang	R/L	.018 No Hook	.018 Single Hook	.018 Double Hook	.022 No Hook	.022 Single Hook	.022 Double Hook
Central	+17	+4	R L	1475-18-1117 1475-18-2117			1485-22-1117 1485-22-2117		
Lateral	+10	+8	R L	1475-18-1210 1475-18-2210			1485-22-1210 1485-22-2210		
Cuspid	0	+8	R L		1475-18-130HD 1475-18-230HD	1475-18-130HU 1475-18-230HU		1485-22-130HD 1485-22-230HD	1485-22-130HU 1485-22-230HU
	-7	+8	R L		1475-18-1307HD 1475-18-2307HD	1475-18-1307HU 1475-18-2307HU		1485-22-1307HD 1485-22-2307HD	1485-22-1307HU 1485-22-2307HU
1st and 2nd Bicuspid	-7	0	R L	1475-18-1407 1475-18-2407	1475-18-1407HD 1475-18-2407HD	1475-18-1407HU 1475-18-2407HU	1485-22-1407 1485-22-2407	1485-22-1407HD 1485-22-2407HD	1485-22-1407HU 1485-22-2407HU

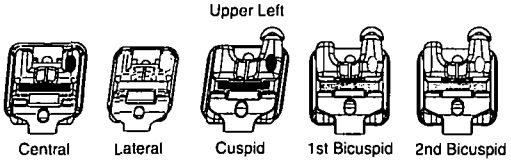
A Roth* System

INTERACTIVE

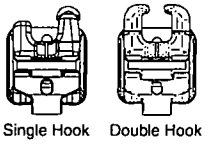
Maxillary	Torq	Ang	R/L	.018 No Hook	.018 Single Hook	.018 Double Hook	.022 No Hook	.022 Single Hook	.022 Double Hook
Central	+12	+5	R L	1475-18-1112 1475-18-2112			1485-22-1112 1485-22-2112		
Lateral	+8	+9	R L	1475-18-128 1475-18-228			1485-22-128 1485-22-228		
Cuspid	-2	+9	R L		1475-18-1302HD 1475-18-2302HD	1475-18-1302HU 1475-18-2302HU		1485-22-1302HD 1485-22-2302HD	1485-22-1302HU 1485-22-2302HU
1st and 2nd Bicuspid	-7	0	R L	1475-18-1407 1475-18-2407	1475-18-1407HD 1475-18-2407HD	1475-18-1407HU 1475-18-2407HU	1485-22-1407 1485-22-2407	1485-22-1407HD 1485-22-2407HD	1485-22-1407HU 1485-22-2407HU

Bracket Identification

Individual color coding ensures easy tooth identification and bonding accuracy

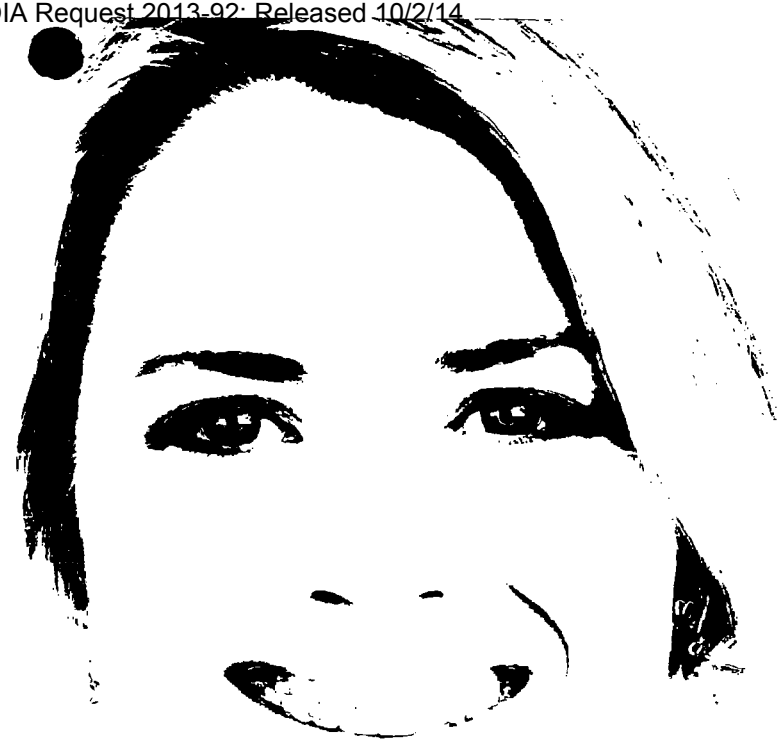


Color coded elastomeric Visual Positioning Aids in arch wire slots assist with bracket alignment during bonding. VPA's contain no latex and are easily removed with a scaler.



*The American Orthodontics version of the McLaughlin, Bennett, Trevisi System is not claimed to be a duplication of any other, nor does American Orthodontics imply that it is endorsed in any way by Drs. McLaughlin, Bennett, or Trevisi.

*The American Orthodontics version of the Roth System is not claimed to be a duplication of any other, nor does American Orthodontics imply that it is endorsed in any way by Dr. Roth.



Empower®
Self Ligating

AO
AMERICAN
ORTHODONTICS

It's all about choice.

Empower is the industry's most complete self ligating bracket system, bringing you choice like you've never had before. Empower's unique design options not only adapt to your treatment philosophies, they allow treatment to be tailored to your patients' needs. This unprecedented array of possibilities inspires you to treat patients your way. Empower puts control back in your hands.

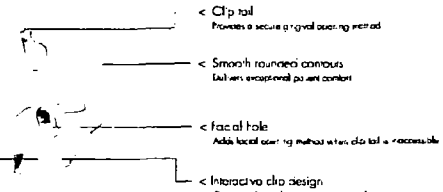
- Clear bracket combines performance with patient-pleasing aesthetics
- Metal brackets offer fully interactive, fully passive, or combination Dual Activation™ options
- Reconvertible molar tubes provide versatility without compromise

Quality Features

Empower's complete line of brackets - clear, metal, and molar tubes - gives you the tools you need to give your patients the smile they deserve.

Empower Clear Braces

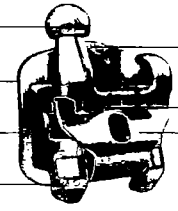
- Low profile, patient-friendly hooks (top and) >
- Compound contoured Quad-Mate™ base >
- Chamfered slot entrances >
- Durable, aesthetically plated clip >
- Individual color coding and Visual Positioning Aids >



- < Clip tail
- < Smooth rounded contours
- < Facial hole
- < Interactive clip design
- < Ceramic Injection Molded bracket body

Empower Self Ligating

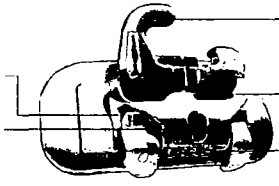
- Low profile, patient-friendly hooks (top and) >
- Compound contoured Maximum Retention™ pads >
- Rounded slot entrances >
- Extended tie wings >



- < Center line
- < Keeper notch
- < Precision heat treated chromium cobalt clip
- < Individual color coding

Empower Reconvertible SL Molars

- Multiple design choices >
- Funneled tube entrances >
- Easy access facial hole >



- < Low profile, patient-friendly hooks
- < Full slot-width clip
- < Reconvertible passive clip design

Page 13-6

Treatment Versatility

Empower is the first in the industry to offer you the versatility of both interactive and passive bracket designs in one unified system with coordinated in/outs.

Empower's Interactive and Passive bracket designs allow unprecedented treatment options.

Interactive Bracket

> Lower friction sliding mechanics early in treatment exceptional torque and rotation control during working and finishing phases

> Available in metal upper and lower S - S and in ceramic upper S - S

Initial Leveling and Alignment

- Selective Engagement™ clip does not actively engage smaller round and rectangular wires
- Allows smaller wires to unravel destroy for a more comfortable experience and with less clip friction during early treatment

Wires not actively engaged by clip:
018 slot: 018 and .016 x .016 and smaller
022 slot: 018 and .016 x .022 and smaller

Working Stage and Finishing

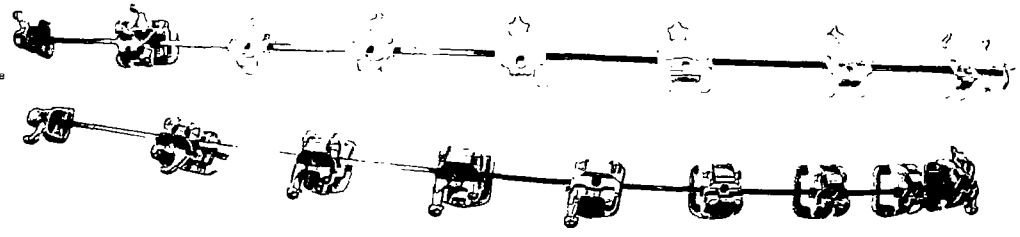
- Selective Engagement clip actively engages larger wires for precise tooth control during mid-treatment and finishing phases

Wires actively engaged by clip
.018 slot: 016 x .022 and larger
022 slot: 017 x .025 and larger

Passive Bracket

> Lower friction sliding mechanics throughout treatment

> Available in metal upper and lower S - S



Empower's interactive self ligating system offers the benefits of less friction at the beginning of treatment and more control in the later stages to assist with final torques and rotations.

Empower's passive self ligating system offers the benefits of less friction and lower force mechanics throughout treatment. No wires are actively engaged by the clip.

™

> Anterior teeth - interactive brackets
low friction, low force during initial leveling and alignment stages, increased torque and rotation control during finishing

> Posterior teeth - passive brackets
lower friction mechanics throughout treatment

Matching in/outs between interactive and passive designs means no 1st order wire bending compensations

Page 13-7

Bond with confidence.

Empower's pads and bases give you the bonding strength you demand and help reduce the risk of emergency appointments due to debonding.

Empower

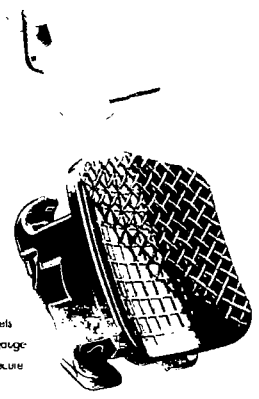
Quad-Matte™ Base

The patented mechanical lock base of Empower Clear incorporates alumina particles only on the center of the base. This allows for a strong bond in the center of the pad and weaker bond on the edges for easy and predictable debonding.

Empower Self Ligating

Maximum Retention[64]

The Maximum Retention pad on Empower metal brackets and tubes features photoetched pockets beneath 80 gauge mesh to increase pad surface area and ensure safe, secure bonds (see cutaway view).



Empower metal brackets offer multiple biaxial pad options to meet every need.

Standard, nonoffset pad

Slightly larger pad than a twin bracket. Extends gingivally, positioned to tool for easier engagement.

True offset pad

Bracket positioned toward the gingival allows easier bonding on shorter clinical crowns and also works well when retraction is not possible.

Extended offset pad

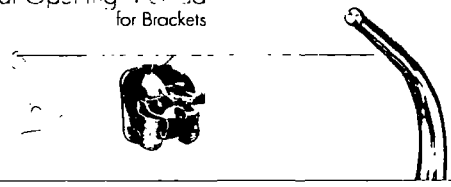
Slightly larger pad surface area for greater bond strength.

Patent 5,639,309
5,730,715
5,759,826

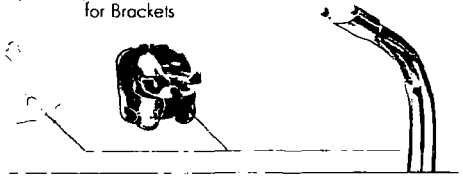
Easy open. Easy close.

Significantly faster wire changes than traditionally ligated brackets.[1] The entire Empower family utilizes one double-ended opening instrument providing two opening methods.

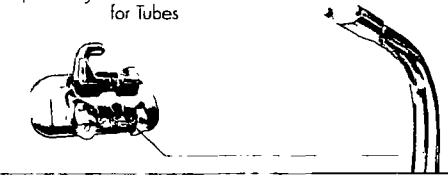
Original Opening Method for Brackets



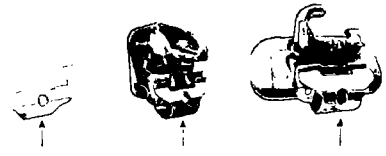
Facial Opening Method* for Brackets



Facial Opening Method* for Tubes



Closing Clip



Close clips easily with simple finger pressure.

*Use care when using the facial hook because overopening can deform the clip. Use a tweezer in conjunction with hook to prevent the clip from overopening accidentally.

[1] Chen SSH, Greenlee GM, Kim JE, Smith CL, Huang GJ. Systematic review of self-ligating brackets. *Am J Orthod Dentofacial Orthop* 2010 137/726.e1-726.e18.

Page 13-8

The power to choose.

Empower's breadth of line is unequaled. You get the most features, prescription choices, and treatment possibilities all in one quality, unified system.

More choices. Trusted power.

	Empower™	Empower™	Empower™
Interactive design	•	•	
Passive design		•	•
Maximum Retention™ banding pads		•	•
Quad-Vate™ banding pads	•		
Standard nonoffset bicuspid pads	•	•	
True offset bicuspid pads		•	
Extended offset bicuspid pads		•	
Optional hooks available	•	•	
Individual color coding	•	•	
Visual Positioning Aids (VPA)	•		
McLaughlin, Bennett, Trevisi system	•	•	•
Roth[2] system	•	•	•
Modified Damon[3] system		•	•
Ronconi[4] system		•	•
Gianelly Bimetric oval vertical slot system		•	•
Additional torque options		•	•

The American Orthodontics version of the McLaughlin, Bennett, Trevisi System is not claimed to be a duplication of any other nor does American Orthodontics imply that it is endorsed in any way by Drs. McLaughlin, Bennett, or Trevisi.

[2] The American Orthodontics version of the Roth System is not claimed to be a duplication of any other, nor does American Orthodontics imply that it is endorsed in any way by Dr. Roth.

[3] The American Orthodontics version of the Damon System is not claimed to be a duplication of any other, nor does American Orthodontics imply that it is endorsed in any way by Dr. Damon.

[4] The American Orthodontics version of the Ronconi System is not claimed to be a duplication of any other, nor does American Orthodontics imply that it is endorsed in any way by Dr. Ronconi.

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CORPORATE PARTNER
DIAMOND CORPORATE PARTNER
$1,000,000 LEVEL DONOR

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LITSI-37 REV 1

CLEAR, BEAUTIFUL BRACES. CLEAR, BEAUTIFUL SMILE.

Presenting Empower Clear Braces – a technologically advanced, ceramic bracket system that will bring you the confidence of a beautiful smile both during and after treatment.

Empower Clear Braces combine two of the orthodontic industry's leading trends - clear cosmetic appliances and self ligation. They are an integral part of Empower, the most complete self ligating bracket system in the world.

The self ligating technology of the Empower system uses integrated clips to hold your arch wire in place, instead of traditional rubber bands (ligatures) that tend to stain and wear down over time. These clips allow your orthodontist to make quicker wire adjustments and deliver the rewarding experience you deserve on the path to your ideal smile.

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CLEAR.
COMFORTABLE.
PERFORMANCE.

There's no compromise when it comes to how Empower Clear Braces are built. Each bracket is manufactured with leading edge Ceramic Injection Molding technology and aesthetically treated, high performance clips. Empower Clear combines beauty and finesse with performance and precision.

○ Blends beautifully with teeth

Empower Clear Braces are made of strong ceramic material that looks great on your teeth. You'll be noticed, your braces won't.

○ Quicker, easier wire adjustments

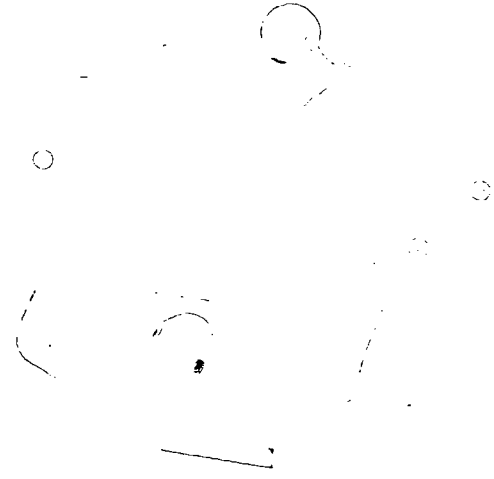
State of the art self ligating clips eliminate rubber bands (ligatures) to hold your arch wire in place, allowing your orthodontist to make quicker wire adjustments. This could mean shorter appointments, and may even reduce the total number of visits required during your treatment.

○ Comfortable inside your mouth

Empower Clear's contoured edges and sculpted, low profile design mean a smoother surface against your cheeks and lips.

○ No staining

Self ligating clips eliminate plastic ligatures, which are prone to discoloration and fatigue over time. This, combined with the extremely stable ceramic bracket body material, reduces any risk of staining. Your Empower Clear Braces will stay beautiful throughout treatment



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THE PROMISE OF A BETTER SMILE

Your orthodontist is committed to providing you with the brilliant, healthy smile you desire. Empower Clear Braces provide the right tools to make it happen. Leading edge design, aesthetics, and functionality, combined with your orthodontist's clinical expertise help you achieve a smile that will last a lifetime.

Empower Clear Braces

For more information scan this code
with your mobile phone's QR reader.

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empowerbraces.com/clear

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SECTION 14:

STERILIZATION / SHELF LIFE

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Sterilization / Shelf Life

**This section is not applicable. **

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SECTION 15:

BIOCOMPATIBILITY

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Biocompatibility

Device Information:

Trade Name: Empower Clear
Common Name: Ceramic Brackets
Classification Name: Bracket, Ceramic, Orthodontic
Classification Code: NJM
Regulation Number: 872.5470

Equivalent Legally Marketed Devices Information:

Trade Name: Radiance
Common Name: Ceramic Brackets
Classification Name: Bracket, Ceramic, Orthodontic
Classification Code: NJM
Regulation Number: 872.5470
510(k) Number: K080749

Trade Name: In-Ovation C
Common Name: Ceramic Brackets
Classification Name: Bracket, Ceramic, Orthodontic
Classification Code: NJM
Regulation Number: 872.5470
510(k) Number: K060837

Summary:
The material, Alumina Oxide [Al_2O_3], is used in the manufacturing of the Radiance brackets and In-Ovation C brackets – which is the same material used for Empower Clear. The material was chosen due to the historical use and shown biocompatibility and resistance to corrosion in the oral/human body environment.

Since the Alumina Oxide [Al_2O_3] material is chemically inert, is not a metal and is non-conductive, there is no corrosion concerns associated with the bracket relative to the clip or archwire material. Based on these facts, there are no undue risks to patients, users or other persons arising from incompatibilities among the materials used in the manufacture of Empower Clear brackets or among the materials into which the Empower Clear brackets would come into contact with during normal use.

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SECTION 16:

SOFTWARE

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Software

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SECTION 17:

ELECTROMAGNETIC COMPATIBILITY / ELECTRICAL SAFETY

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Sterilization / Shelf Life

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SECTION 18:

PERFORMANCE TESTING – BENCH

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Performance Testing – Bench

**This section is not applicable. **

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SECTION 19:

PERFORMANCE TESTING – ANIMAL

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Performance Testing – Animal

**This section is not applicable. **

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SECTION 20:

PERFORMANCE TESTING – CLINICAL

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Performance Testing – Clinical

**This section is not applicable. **

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