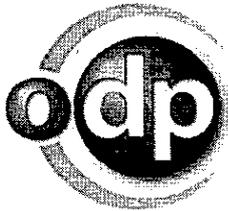


K130446



Orthodontic Design and Production, Inc.

JUN 07 2013

**510(k) Summary**

510(k) Submitter: Orthodontic Design & Production, Inc.  
1370 Decision Street, Suite D  
Vista, California 92081

Official Contact Person: Richard Merrell  
Regulatory Affairs Manager  
Telephone: (760) 734-3995 ext. 25  
Facsimile: (760) 734-1735  
E-mail: rm@odpinc.com

Date Summary was Prepared: February 8, 2013

Device Trade Name: FastBraces® Ceramic Brackets

Common Name: Orthodontic Ceramic Bracket

Classification Name: Orthodontic Ceramic Bracket, Class II  
(21 CFR 872.5470, Product Code: NJM)

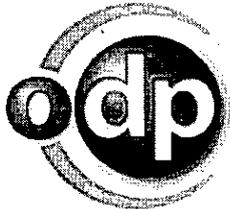
Predicate Device: K922499, Reflections Ceramic Dental Bracket

Description of Device:

Ceramic orthodontic brackets are small devices that are intended to be bonded to teeth, upon which an orthodontic wire is placed to move the teeth to desired positions. They are indicated for orthodontic treatment in patients of all ages when prescribed by an orthodontist. Ceramic orthodontic brackets are primarily offered as an aesthetic alternative to metal orthodontic brackets. They are close to natural tooth coloring, and blend in well enough that they are not as visible as metal brackets. This aesthetic look is popular with many patients, and especially older patients. Ceramic orthodontic brackets have been in use throughout the orthodontic industry for approximately thirty years.

Like its predicate, FastBraces® ceramic brackets are manufactured from polycrystalline alumina (ceramic) material, and have bases that are designed to provide maximum adhesion to the tooth while still allowing for easy and complete removal when necessary. The brackets incorporate a water soluble color placement dot as an indicator for correct selection of brackets for each tooth.

Like its predicate, FastBraces® ceramic brackets do not incorporate medicinal substances, tissues, or blood products. They do not include software or accessories, and are delivered non-



## Orthodontic Design and Production, Inc.

sterile to the end user. Ceramic brackets are intended to be used only once by a single patient. Product labels contain appropriate "do not reuse" symbols. Orthodontic ceramic brackets are used for the duration of orthodontic treatment, which can last more than 30 months. During this time, the devices remain in direct contact with the patient's oral cavity. Because the intended purpose of the device is clearly understood by licensed orthodontists, instructions for use are not provided.

With the exception of the materials from which they are constructed, the form, fit, and function of orthodontic ceramic brackets are identical to those of traditional metal orthodontic brackets. Orthodontic ceramic brackets, like metal brackets achieve their intended purpose (to move teeth into a desired position) through industry standard "prescriptions" that are pre-programmed into the design of the brackets. Specific torques, angulations, and distal offset dimensions are designed into each bracket, along with archwire slots that are designed to accommodate the correct size archwire (typically .018" or .022" thick).

Ceramic brackets are designed with tie wing undercut spaces for orthodontic ligatures. They have a molded ceramic bracket body with rounded corners and edges, and rounded hooks on the distal-gingival tie wings to accommodate ligation during orthodontic treatment. These design characteristics allow a tensioned ligating wire to move the brackets, which are securely bonded to the teeth, along a pre-determined path until the desired tooth position is reached. Elastic ligatures may be used on the tie wings and hooks to further facilitate tooth movement, and to secure the orthodontic wire into the bracket's archwire slot.

### Intended Use:

FastBraces® Ceramic Brackets are intended for orthodontic movement of natural teeth.

### Technological Characteristics:

The design, material, and intended use of FastBraces® Ceramic Brackets are similar to the predicate device.

*Regarding design*, FastBraces® ceramic brackets and their predicate both incorporate specific torques, angulations, and distal offset dimensions, along with archwire slots that are designed to accommodate the correct size archwire (typically .018" or .022" thick). They both feature tie wing undercut spaces for orthodontic ligatures, have a molded ceramic bracket bodies with rounded corners and edges for patient comfort, and rounded hooks on the distal-gingival tie wings to accommodate ligation during orthodontic treatment.

*Regarding materials*, FastBraces® ceramic brackets and its predicate are manufactured from polycrystalline alumina (ceramic) material, which is of known biocompatibility in the oral environment.

*Regarding intended use*, the design characteristics of FastBraces® ceramic brackets and its predicate allow a tensioned ligating wire to move the brackets, which are securely bonded to the teeth, along a pre-determined path until the desired tooth position is reached. Elastic ligatures may be used on the tie wings and hooks to further facilitate tooth movement, and to secure the orthodontic wire into the bracket's archwire slot.



## Orthodontic Design and Production, Inc.

### Substantial Equivalence:

FastBraces® Ceramic Brackets are safe and effective for their intended use in orthodontic treatment, and perform at least as well as the predicate device listed above. FastBraces® ceramic brackets are engineered to be substantially equivalent to the predicate with respect to intended use, technological characteristics, device design, materials, performance, safety, effectiveness, and biocompatibility. Minor design changes are the only variations as compared to the predicate. There are no changes in the intended use or the fundamental scientific technology.

### Device Material:

The FastBraces® Ceramic Bracket and its predicate are both made of ceramic tri polycrystalline alumina, which has a well-documented history of biocompatibility within the oral environment. ODP has prepared a biocompatibility summary report in accordance with ISO 10993-1:2009, which is located in Section 15 of this submission. Because the materials from which the devices are constructed are well established in the orthodontic industry, product testing in regards to biocompatibility was not performed. Instead, a literature review has been conducted in accordance with ISO 10993-1:2009, Annex C.

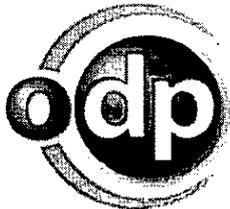
### Device Design:

FastBraces® Ceramic Brackets and its predicate both have tie wing undercut spaces for orthodontic ligatures. They each have true-twin tie wings, i.e. four tie wings, for versatile use with auxiliaries. FastBraces® Ceramic Brackets and its predicate also contain base flanges for bracket placement and adhesive flash cleanup. FastBraces® Ceramic Brackets and its predicate contain a molded ceramic bracket body with rounded corners and edges, and a round hook on the distal-gingival tie wings. Like its predicate, certain FastBraces® Ceramic brackets contain vertical slot and stress concentrators to facilitate debonding of the bracket from the tooth.

### Nonclinical Performance Testing:

The nonclinical performance testing analysis shows that FastBraces® Ceramic Brackets perform comparably to the predicate device as follows:

1. Shear Test measures shear strength required to remove a bonded bracket from a substrate when a force is applied in the occlusal direction. The test results showed that the bond strength of FastBraces® Ceramic Brackets are comparable to the predicate, and exceed the minimum bond strength required to affix the bracket to the tooth.
2. Wire Torque Test measures the torsional force required to break a bonded bracket when a rectangular wire is twisted in the wire slot. The test results showed comparable bracket strengths, with the Fast Braces® wire torque test averaging 3,473 gm Force, and the predicate device averaging 3,333 gm Force before breakage occurred.
3. Wire Drag Test measures the force required to drag a ligated stainless steel wire through the slot of a bonded bracket. The test results showed lower forces were required to drag the Fast Braces® ceramic bracket along a ligated stainless steel wire than the predicate, indicating better sliding mechanics during treatment.
4. Bracket Removal Test evaluates the visual condition of a bonded bracket after twisting it off the substrate with pliers. The Fast Braces® bracket removal test resulted in less bracket fracturing as compared to the predicate device when removing the bracket from a substrate using pliers.



## Orthodontic Design and Production, Inc.

### Clinical Performance Testing:

No clinical performance testing was conducted on FastBraces® Ceramic Brackets.

### Conclusion:

ODP's FastBraces® Ceramic Brackets are standard orthodontic appliances that are similar to those that have been legally marketed and used safely and effectively for many years in the clinical environment. FastBraces® ceramic brackets are engineered to be substantially equivalent to the predicate with respect to intended use, technological characteristics, device design, materials, performance, safety, effectiveness, and biocompatibility.

There are no major differences between the FastBraces® Ceramic Brackets and the predicate device cited. Therefore, FastBraces® Ceramic Brackets raise no new issues of safety or effectiveness.

FastBraces® Ceramic Brackets are designed and manufactured to industry-standard specifications using materials that have a well established and documented history of biocompatibility within the oral environment. As designed, FastBraces® Ceramic Brackets are as safe and effective as the predicate device, and are determined to be substantially equivalent to the referenced predicate device currently on the market. Taking these factors into account, it can be safely concluded that ODP's FastBraces® Ceramic Brackets are of low risk to the end user, are clinically safe, and perform at least as well as the predicate device referred to herein.



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

June 7, 2013

Mr. Richard Merrell  
Regulatory Affairs Manager  
Orthodontic Design and Production, Inc.  
1370 Decision Street, Suite D  
Vista, CA 92081

Re: K130446  
Trade/Device Name: FastBraces® Ceramic Brackets  
Regulation Number: 21 CFR 872.5470  
Regulation Name: Orthodontic Plastic Bracket  
Regulatory Class: II  
Product Code: NJM  
Dated: April 10, 2013  
Received: April 15, 2013

Dear Mr. Merrell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of 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>. 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,

  **Mary S.**  
**Runner-S**

Kwame Ulmer M.S.  
Acting Division Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



Orthodontic Design and Production, Inc.

Indications for Use

510(k) Number:

K130446

Device Name:

FastBraces® Ceramic Brackets

Indications for Use:

FastBraces® Ceramic Brackets are indicated for orthodontic movement of natural teeth.

Prescription Use  (Part 21 CFR 801 Subpart D)

AND/OR

Over the Counter Use \_\_\_\_\_ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen  
2013.06.07 10:48:08 -04'00'



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

510(k) Number:

K130446



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10903 New Hampshire Avenue  
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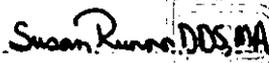
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Sincerely yours,

 Mary S.  
Runner-S

Kwame Ulmer M.S.  
Acting Division Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
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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: K130446

For Office of Compliance Contact Information:

[http://insideportlets.fda.gov:9010/portal/page?\\_pageid=197,415881&\\_dad=portal&\\_schema=PORTAL&org=318](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](http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423)

<b>Digital Signature Concurrence Table</b>	
Reviewer Sign-Off	Michael E. Adjodha -S 2013.06.06 10:46:08 -04'00'
Branch Chief Sign-Off	Andrew I. Steen 2013.06.07 10:51:59 -04'00'
Division Sign-Off	 Mary S. Runner -S

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 1 <sup>st</sup> 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".
4/2/2013	M. McCabe Janicki	Edited sentence that starts "If you desire specific advice for your device on our labeling regulation (21 CFR Part 801)..." Replaced broken Compliance link with general link to DSMICA.
4/12/2013	Margaret McCabe Janicki	Fixed a typo: Paragraph 1, final sentence, "We remind you, however; that device labeling must be truthful..." Replaced incorrect semicolon with a comma.



Orthodontic Design and Production, Inc.

**Indications for Use**

510(k) Number:

K130446

Device Name:

FastBraces® Ceramic Brackets

Indications for Use:

FastBraces® Ceramic Brackets are indicated for orthodontic movement of natural teeth.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over the Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen  
2013.06.07 10:48:08 -04'00'

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

510(k) Number: K130446

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Orthodontic Design and Production, Inc.

K130446

k 39

FDA CDRH DMC

FEB 25 2013

Received

eCopy Cover Letter

The eCopy for the below 510(k) submission is an exact duplicate of the paper copy.

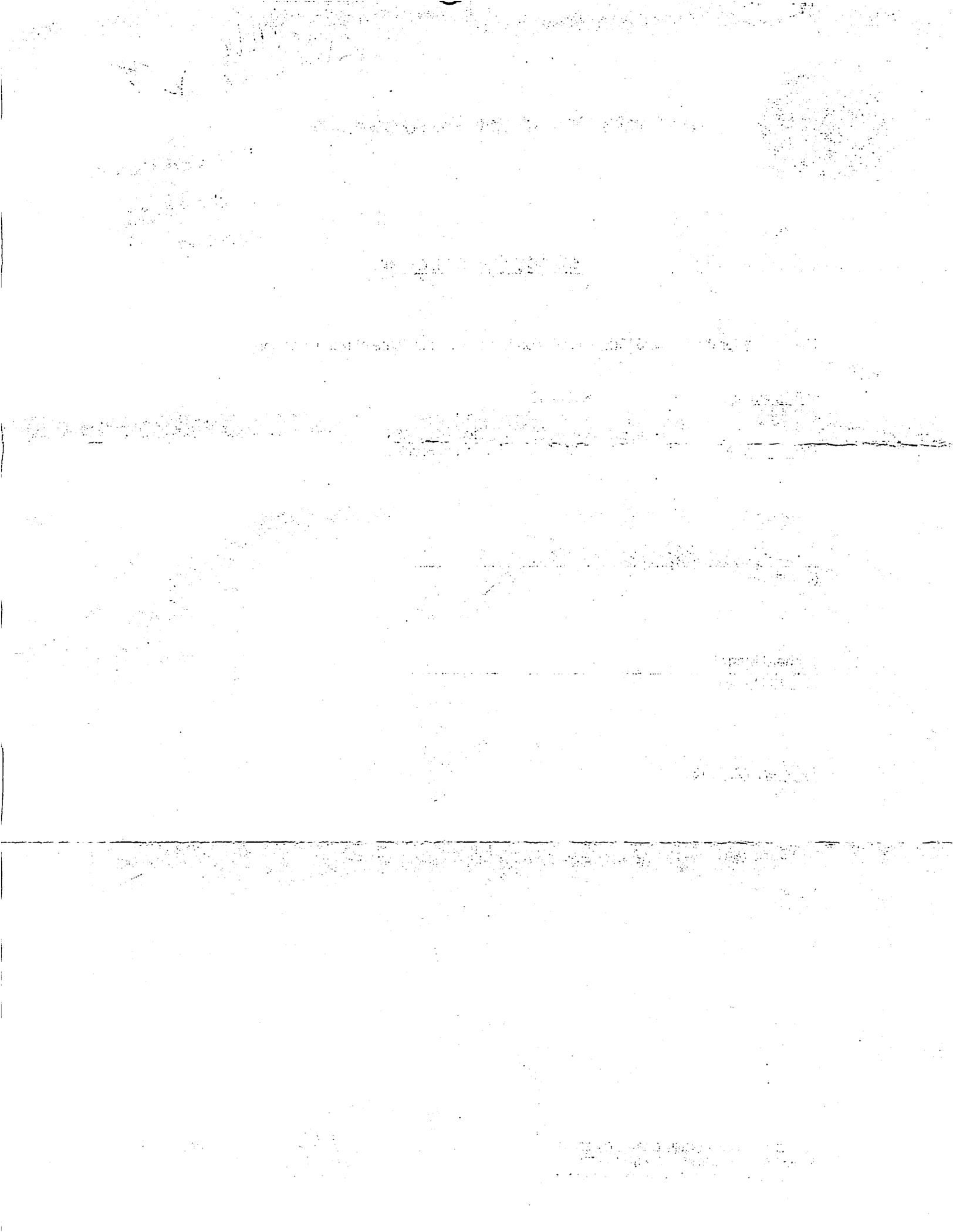
510(k) Number: K130446

Device Name: FastBraces® Ceramic Brackets

  
\_\_\_\_\_  
(Signature)

Richard Merrell  
\_\_\_\_\_  
(Typed Name)

February 22, 2013  
(Date)



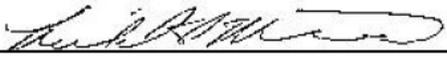


**eCopy Cover Letter**

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510(k) Number: K130446

Device Name: FastBraces® Ceramic Brackets

  
\_\_\_\_\_  
(Signature)   


Richard Merrell  
\_\_\_\_\_  
(Typed Name)

February 22, 2013  
(Date)


# Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

**Guidance for Industry and FDA Staff**

**Format for Traditional and Abbreviated 510(k)s**

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet <a href="http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFeeandModernizationAct/ucm155274.htm">http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFeeandModernizationAct/ucm155274.htm</a>	Refer to Section 1		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet <a href="http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf">http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf</a>	Refer to Section 2		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm</a>	Refer to Section 3		
Indications for Use Statement	Device Advice "Content of a 510(k)" Section D <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080275.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080275.htm</a>	Refer to Section 4		
510(k) Summary or 510(k) Statement	Device Advice "Content of a 510(k)" Section E <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm</a>	Refer to Section 5		
Truthful and Accuracy Statement	Device Advice "Content of a 510(k)" Section G <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm</a>	Refer to Section 6		
Class III Summary and Certification	Class III Summary and Certification Form <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm</a>	Refer to Section 7		
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators <a href="http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf">http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf</a> FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators <a href="http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf">http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf</a> Financial Disclosure by Clinical Investigators <a href="http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm">http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm</a>	Refer to Section 8		

Title	Related Information	Present	Inadequate	N/A
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	<p>Use of Standards in Substantial Equivalence Determinations  <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073752.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073752.htm</a></p> <p>FDA Standards program  <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</a></p> <p>Declaration of conformity  <a href="http://www.fda.gov/cdrh/devadvice/3145.html#link_9">www.fda.gov/cdrh/devadvice/3145.html#link_9</a></p> <p>Required Elements for Declaration of Conformity to Recognized Standard  <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142706.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142706.htm</a></p>	Refer to Section 9		
Executive Summary	<p>See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005  <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm</a></p>	Refer to Section 10		
Device Description	<p>See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005  <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm</a></p>	Refer to Section 11		
Substantial Equivalence Discussion	<p>Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3),  <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm</a></p>	Refer to Section 12		
Proposed Labeling	<p>Device Advice "Content of a 510(k)" Section H  <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm</a></p>	Refer to Section 13		
Sterilization/Shelf Life	<p>Updated 510(k) Sterility Review Guidance (K90-1)  <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm</a></p> <p>For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices  <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434.htm</a></p>	Refer to Section 14		
Biocompatibility	<p>FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993,  <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm</a></p>	Refer to Section 15		
Software	<p>Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices  <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm</a></p>	Refer to Section 16		

Title	Related Information	Present	Inadequate	N/A
Electromagnetic Compatibility/Electrical Safety	<p>CDRH Medical Device Electromagnetic Compatibility Program  <a href="http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/default.htm">http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/default.htm</a>            See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)</p>	Refer to Section 17		
Performance Testing – Bench	<p>See section 18 in Chapter II of “Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s” updated November 17, 2005  <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm</a></p>	Refer to Section 18		
Performance Testing – Animal	<p>See section 19 in Chapter II of “Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s” updated November 17, 2005  <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm</a></p>	Refer to Section 19		
Performance Testing – Clinical	<p>See section 20 in Chapter II of “Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s” updated November 17, 2005            Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators  <a href="http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf">http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf</a>  <a href="http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf">http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf</a></p>	Refer to Section 20		
FORM FDA 3654, Standards Data Report for 510(k)s - <a href="http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf">http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf</a>	<p><b>Standards Data Report Form – Form 3654</b></p> <p>1: No standard used -  <b>No Standards Form Required</b></p> <p>2: Declaration of Conformity –  <b>Yes Standards Form Required</b></p> <p>3: Standard but no declaration –  <b>Yes Standards Form Required</b></p>	Refer to Section 21		
Kit Certification	<p>Device Advice  <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080213.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080213.htm</a></p>	Refer to Section 22		

Last Updated: 9/3/08 – Brandi Stuart

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>	<b>PAYMENT IDENTIFICATION NUMBER:</b> (b)(4) Trade Secret Process 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/cover sheet.html>

<b>1. COMPANY NAME AND ADDRESS</b> (include name, street address, city state, country, and post office code)  ORTHODONTIC DESIGN AND PRODUCTION INC 1370 DECISION STREET VISTA CA 92081 US <b>1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)</b> *****0815	<b>2. CONTACT NAME</b> Richard Merrell <b>2.1 E-MAIL ADDRESS</b> rm@odpinc.com <b>2.2 TELEPHONE NUMBER (include Area code)</b> 760-734-3995 25 <b>2.3 FACSIMILE (FAX) NUMBER (Include Area code)</b>
--	--

**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:

- 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**

CDRH

CBER

**3.2 Select one of the types below**

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

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?

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  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) Trade Secret Process

19-Feb-2013

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  
 February 19, 2013

User Fee Payment ID Number

(b)(4) Trade Secret Process

FDA Submission Document Number (if known)

SECTION A TYPE OF SUBMISSION				
<b>PMA</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<b>PMA &amp; HDE Supplement</b> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<b>PDP</b> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<b>510(k)</b> <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<b>Meeting</b> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
<b>IDE</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption (HDE)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<b>Class II Exemption Petition</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation (De Novo)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submission</b> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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 Orthodontic Design & Production, Inc.		Establishment Registration Number (if known) 2029191	
Division Name (if applicable) N/A		Phone Number (including area code) (760) 734-3995 ext. 25	
Street Address 1370 Decision Street, Suite D		FAX Number (including area code) (760) 734-1735	
City Vista	State / Province CA	ZIP/Postal Code 92081	Country USA
Contact Name Richard Merrell			
Contact Title Regulatory Affairs Manager		Contact E-mail Address rm@odpinc.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name Same as Above			
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 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

- 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

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

- 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

- 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	K922499	Reflections-Ceramic Dental Bracket	CDB Corporation
2			
3			
4			
5			
6			

**SECTION F**

**PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification name

Bracket, Ceramic, Orthodontic

Trade or Proprietary or Model Name for This Device

Model Number

1	FastBraces Ceramic Brackets	1	N/A
2		2	
3		3	
4		4	
5		5	

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

1	N/A	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

NJM

C.F.R. Section (if applicable)

21 CFR 872.5470

Device Class

- Class I
- Class II
- Class III
- Unclassified

Classification Panel

Dental

Indications (from labeling)

FastBraces Ceramic Brackets are indicated for orthodontic movement of natural teeth.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

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

Original  
 Add  Delete

Facility Establishment Identifier (FEI) Number

Manufacturer  Contract Sterilizer  
 Contract Manufacturer  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 Sterilizer  
 Contract Manufacturer  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 Sterilizer  
 Contract Manufacturer  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	ISO 10993-1:2009	ANSI/AAMI/ISO	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.	2009	10/01/2009
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.



**510(k) Notification (21 CFR 807.90(e))**  
**Cover Letter**

Submitter: Orthodontic Design & Production, Inc.  
1370 Decision Street, Suite D  
Vista, California 92081

Official Contact Person: Richard Merrell  
Regulatory Affairs Manager  
Telephone: (760) 734-3995 ext. 25  
E-mail: rm@odpinc.com

Type of 510(k) Submission: Traditional [REDACTED]

Device Common Name: Bracket, Ceramic, Orthodontic

Preference for Continued Confidentiality: In accordance with Premarket Notification Procedures regarding Confidentiality of Information (21 CFR 807.95), ODP, Inc. wishes to certify to the Food and Drug Administration that it has complied with all applicable parts of that section, and considers the content of the submission and its intention to market these devices as confidential commercial information.

Classification Regulation No.: 872.5470

Device Classification: Class II [REDACTED]

Panel: [REDACTED] Dental [REDACTED]

Product Code: NJ [REDACTED]

FDA Document Numbers Associated with Formal FDA Correspondence N/A



Basis for Submission: New Device

Design and Use of the Device: Refer to table below.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

Convenience Kits:

Upon customer request, the device(s) covered in this 510(k) submission are assembled into a convenience kit prior to being shipped to the customer. That is, each individual bracket design configuration (which are industry-standard design configurations depending upon which tooth the bracket is placed) is assembled into a convenience kit to provide the orthodontist all the brackets necessary for an orthodontic treatment. This combination of brackets is commonly referred to in the orthodontic industry as a "bracket system." A Kit Certification Statement is provided in Section 22 of this 510(k) submission. A listing of the device components included in the kit are provided on the following page, as well as on the Kit Certification Statement.

Bundling Multiple Devices:

This 510(k) submission involves bundling more than one device. The rationale for bundling is that the devices included in this submission fall under the same generic device type, do not differ significantly in purpose, design, materials, energy, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls sufficient to provide reasonable assurance of safety and effectiveness (21 CFR 860.3(i)) are employed. The only differences between the devices included in this submission are the industry standard, tooth-specific design configurations to which they are manufactured. A listing of the devices being bundled in this 510(k) submission is provided on the following page.

# INVENTORY MAINTENANCE ORTHODONTIC DESIGN & PROD

Item	Location	Description	On Hand Quantity	Units On SO	UM	Cycle Code	Bin Loc
<b>(b)(4) Trade Secret Process</b>							



**Indications for Use**

510(k) Number: \_\_\_\_\_

Device Name: FastBraces® Ceramic Brackets

Indications for Use: FastBraces® Ceramic Brackets are indicated for orthodontic movement of teeth to correct malocclusion.



Prescription Use  (Part 21 CFR 801 Subpart D)

AND/OR

Over the Counter Use \_\_\_\_\_ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)





## 510(k) Summary

510(k) Submitter: Orthodontic Design & Production, Inc.  
1370 Decision Street, Suite D  
Vista, California 92081

Official Contact Person: Richard Merrell  
Regulatory Affairs Manager  
Telephone: (760) 734-3995 ext. 25  
Facsimile: (760) 734-1735  
E-mail: rm@odpinc.com

Date Summary was Prepared: February 8, 2013

Device Trade Name: FastBr

Common Name: Orthodontic Ceramic Bracket

Classification Name: Orthodontic Ceramic Bracket, Class II  
(21 CFR 872.5470, Product Code: NJM)

Predicate Device: K922499, Reflections Ceramic Dental Bracket

### Description of Device:

Ceramic orthodontic brackets are small devices that are intended to be bonded to teeth, upon which an orthodontic wire is placed to move the teeth to desired positions. They are indicated for orthodontic treatment in patients of all ages when prescribed by an orthodontist. Ceramic orthodontic brackets are primarily offered as an aesthetic alternative to metal orthodontic brackets. They are close to natural tooth coloring, and blend in well enough that they are not as visible as metal brackets. This aesthetic look is popular with many patients, and especially older patients. Ceramic orthodontic brackets have been in use through the orthodontic industry for approximately thirty years.

Like its predicate, FastBraces® ceramic brackets are manufactured from polycrystalline alumina (ceramic) material, and have bases designed to provide maximum adhesion to the tooth while still allowing for easy and complete removal when necessary. The brackets incorporate a water soluble color placement dot as an indicator for correct selection of brackets for each tooth.

Like its predicate, FastBraces® ceramic brackets do not incorporate medicinal substances, tissues, or blood products. They do not include software or accessories, and are delivered non-



## Orthodontic Design and Production, Inc.

sterile to the end user. Ceramic brackets are intended to be used only once by a single patient. Product labels contain appropriate “do not reuse” symbols. Orthodontic ceramic brackets are used for the duration of orthodontic treatment, which can last more than 30 months. During this time, the devices remain in direct contact with the patient’s oral cavity. Because the intended purpose of the device is clearly understood by licensed orthodontists, instructions for use are not provided.

With the exception of the materials from which they are constructed, the form, fit, and function of orthodontic ceramic brackets are identical to those of traditional metal orthodontic brackets. Orthodontic ceramic brackets, like metal brackets achieve their intended purpose (to move teeth into a desired position) through industry standard “prescriptions” that are pre-programmed into the design of the brackets. Specific torques, angulations, and distal offset dimensions are designed into each bracket, along with archwire slots that are designed to accommodate the correct size archwire (typically .018” or .022” thick).

Ceramic brackets are designed with tie wing undercut spaces for orthodontic ligatures. They have a molded ceramic bracket body with rounded corners and edges, and rounded hooks on the distal-gingival tie wings to accommodate ligation during orthodontic treatment. These design characteristics allow a tensioned ligating wire to move the brackets, which are securely bonded to the teeth, along a pre-determined path until the desired position is reached. Elastic ligatures may be used on the tie wings and hooks to further facilitate tooth movement, and to secure the orthodontic wire into the bracket’s archwire slot.

### Intended Use:

FastBraces® Ceramic Brackets are intended for orthodontic movement of natural teeth.

### Technological Characteristics:

The design, material, and intended use of FastBraces® Ceramic Brackets are similar to the predicate device.

*Regarding design,* FastBraces® ceramic brackets and their predicate both incorporate specific torques, angulations, and distal offset dimensions, along with archwire slots that are designed to accommodate the correct size archwire (typically .018” or .022” thick). They both feature tie wing undercut spaces for orthodontic ligatures, have a molded ceramic bracket bodies with rounded corners and edges for patient comfort, and rounded hooks on the distal-gingival tie wings to accommodate ligation during orthodontic treatment.

*Regarding materials,* FastBraces® ceramic brackets and its predicate are made from polycrystalline alumina (ceramic) material, which is of known biocompatibility in the oral environment.

*Regarding intended use,* the design characteristics of FastBraces® ceramic brackets and its predicate allow a tensioned ligating wire to move the brackets, which are securely bonded to the teeth, along a pre-determined path until the desired position is reached. Elastic ligatures may be used on the tie wings and hooks to further facilitate tooth movement, and to secure the orthodontic wire into the bracket’s archwire slot.



Substantial Equivalence:

FastBraces® Ceramic Brackets are safe and effective for their intended use in orthodontic treatment, and perform at least as well as the predicate device listed above. FastBraces® ceramic brackets are engineered to be substantially equivalent to the predicate with respect to intended use, technological characteristics, device design, materials, performance, safety, effectiveness, and biocompatibility. Minor design changes are the only variations as compared to the predicate. There are no changes in the intended use or the fundamental scientific technology.

Device Material:

The FastBraces® Ceramic Bracket and its predicate are both made of ceramic tri polycrystalline alumina, which has a well-documented history of biocompatibility within the oral environment. ODP has prepared a biocompatibility summary report in accordance with ISO 10993-1:2009, which is located in Section 15 of this submission. Because the materials from which the devices are constructed are well established in the orthodontic industry, product testing in regards to biocompatibility was not performed. Instead, a literature review has been conducted in accordance with ISO 10993-1:2009, Annex C.

Device Design:

FastBraces® Ceramic Brackets and its [redacted] for orthodontic ligatures. They each have tr [redacted] satellite use with auxiliaries. FastBraces® Ceramic Bracket [redacted] for bracket placement and adhesive flash cleanup. [redacted] predicate contain a molded ceramic bracket body with rounded corners and edges, and a round hook on the distal-gingival tie wings. Like its predicate, certain FastBraces® Ceramic brackets contain vertical slot and stress concentrators to facilitate debonding of the bracket from the tooth.

Nonclinical Performance Testing:

The nonclinical performance testing analysis shows that FastBraces® Ceramic Brackets perform comparably to the predicate device as follows:

1. Shear Test measures shear strength required to remove a bonded bracket from a substrate when a force is applied in the occlusal direction. The test results showed that the bond strength of FastBraces® Ceramic Brackets are comparable to the predicate, and exceed the minimum bond strength required to affix the bracket to the tooth.
2. Wire Torque Test measures the torsional force required to break a bonded bracket when a rectangular wire is twisted in the wire [redacted] test results showed compa [redacted] bracket strengths, with the Fast Braces® wire torque test averaging 3,473 gm Force, and the predicate device averaging 3,333 gm Force before breakage occurred.
3. Wire Drag Test m [redacted] the force required to drag a ligated stainless steel wire through the slot of a bonded bracket. The test results showed lower forc [redacted] required to drag the Fast Braces® ceramic b [redacted] along a ligated stainless steel wire than the predicate, indicating better sliding mechanics during treatment.
4. Bracket Removal Test evaluates the visual condition of a bonded bracket after twisting it off the substrate with pliers. The Fast Braces® bracket removal test resulted in less bracket fracturing as compared to the predicate device when removing the bracket from a substrate using pliers.



Clinical Performance Testing:

No clinical performance testing was conducted on FastBraces® Ceramic Brackets.

Conclusion:

ODP's FastBraces® Ceramic Brackets are standard orthodontic appliances that are similar to those that have been legally marketed and used safely and effectively for many years in the clinical environment. FastBraces® ceramic brackets are engineered to be substantially equivalent to the predicate with respect to intended use, technological characteristics, device design, materials, performance, safety, effectiveness, and biocompatibility.

There are no major differences between the FastBraces® Ceramic Brackets and the predicate device cited. Therefore, FastBraces® Ceramic Brackets raise no new issues of safety or effectiveness.

FastBraces® Ceramic Brackets are designed and manufactured to industry-standard specifications using materials that have a well established and documented history of biocompatibility within the oral environment. As designed, FastBraces® Ceramic Brackets are as safe and effective as the predicate device, and are determined to be substantially equivalent to the referenced predicate device currently on the market. In light of the above, it can be safely concluded that ODP's FastBraces® Ceramic Brackets are safe for the end user, and perform at least as well as the predicate device herein.







Orthodontic Design and Production, Inc.

**Class III Summary and Certification**

A Class III Summary and Certification in accordance with 21 CFR 807.87(j) and 807.94 does not apply to FastBraces® Ceramic Brackets. Orthodontic Ceramic Brackets have been designated as Class II per regulation number 872.5470 (Product Code: NJM, Review Panel: Dental).

  
\_\_\_\_\_  
(Signature)

Richard Merrell  
\_\_\_\_\_  
(Typed Name)

2-19-2013  
\_\_\_\_\_  
(Date)



Orthodontic Design and Production, Inc.

**Financial Certification / Disclosure Statement**

A Financial Certification / Financial Disclosure Statement in accordance with 21 CFR 807.87(i) does not apply to FastBraces® Ceramic Brackets. Clinical studies were not conducted for this product.

  
\_\_\_\_\_  
(Signature)

Richard Merrell  
\_\_\_\_\_  
(Typed Name)

2-19-2013  
\_\_\_\_\_  
(Date)



Orthodontic Design and Production, Inc.

**Declarations of Conformity and Summary Reports**

Declarations of Conformity and Summary Reports do not apply to this 510(k) submission, as this is a "Traditional" 510(k), and not an "Abbreviated" 510(k). No recognized standards or guidance documents were relied upon for any part of the device's design or testing.

  
\_\_\_\_\_  
(Signature)

Richard Merrell  
\_\_\_\_\_  
(Typed Name)

2-19-2013  
\_\_\_\_\_  
(Date)



## Executive Summary

### Description of the Device:

Ceramic orthodontic brackets are small devices that are intended to be bonded to teeth, upon which an orthodontic wire is placed to move the teeth to desired positions. They are indicated for orthodontic treatment in patients of all ages when prescribed by an orthodontist. Ceramic orthodontic brackets are primarily offered as an aesthetic alternative to metal orthodontic brackets. They are close to natural tooth coloring, and blend in well enough that they are not as visible as metal brackets. This aesthetic look is popular with many patients, and especially older patients. Ceramic orthodontic brackets have been in use throughout the orthodontic industry for approximately thirty years.

Like its predicate, FastBraces® ceramic brackets are manufactured from polycrystalline alumina (ceramic) material, and have bases that are designed to provide maximum adhesion to the tooth while still allowing for easy and complete removal when necessary. The brackets incorporate a water soluble color placement dot as an [REDACTED] for each tooth.

Like its predicate, FastBraces® ceramic brackets are not intended for use in contact with soft tissues, or blood products. They do not [REDACTED] delivered non-sterile to the end user. Ceramic brackets are intended to be used only once by a single patient. Product labels contain appropriate “do not reuse” symbols. Orthodontic ceramic brackets are used for the duration of orthodontic treatment, which can last more than 30 months. During this time, the devices remain in direct contact with the patient’s oral cavity. Because the intended purpose of the device is clearly understood by licensed orthodontists, instructions for use are not provided.

With the exception of the materials from which they are constructed, the form, fit, and function of orthodontic ceramic brackets are identical to those of traditional metal orthodontic brackets. Orthodontic ceramic brackets, like metal brackets achieve their intended purpose (to move teeth into a desired position) through industry standard “prescriptions” that are pre-programmed into the design of the brackets. Specific torques, angulations, and distal offset dimensions are designed into each bracket, along with archwire slots that are designed to accommodate the correct size archwire (typically .018” or .022” thick).

Ceramic brackets are designed with tie wing undercut spaces for orthodontic ligatures. They have a molded ceramic bracket body with rounded [REDACTED] d edges, and rounded hook [REDACTED] distal-gingival tie wings to accommodate ligation during orthodontic treatment. These design characteristics allow a tensioned ligating wire to move the [REDACTED] brackets, which are securely bonded to the teeth, along a pre-determined path until the desired tooth position is reached. Elastic ligatures may be used on the tie wings and hooks to further facilitate tooth movement, and to secure the orthodontic wire into the bracket’s archwire slot. [REDACTED]

### Indications for Use:

FastBraces® Ceramic Brackets are indicated for orthodontic movement of natural teeth.



Technology:

Ceramic Orthodontic Brackets such as FastBraces® and its predicate (CDB Corporation’s “Reflections” ceramic bracket K922499) are cemented to the front surface of the tooth where they direct the mechanical forces that urge teeth into the correct alignment. A curved arch wire that is bent or twisted into a particular prescription is secured into a slot that is engineered into each bracket. The resulting torque or restoring force causes teeth to shift into the desired alignment. Depending on the shape and twist of the arch wire and the orientation of the bracket slot, it is possible to apply forces, which can shift, rotate, or tip the teeth in any desired direction.

Device Comparison Table:

ODP’s FastBraces® Ceramic Bracket vs.  
Predicate: CDB Corporation’s “Reflections” Ceramic Bracket (K922499)

	Fast Braces® Ceramic Bracket	Predicate Ceramic Bracket	Equivalence Result
Test # 1*: Shear Test Result	(b)(4) Trade Secret Process - Testing		Equivalent
Test # 2**: Wire Torque Test			Equivalent
Test # 3***: Wire Drag Test			Equivalent
Test # 4****: Bracket Removal Test			Equivalent

Test # 1\*: Shear Test: Measures the shear strength required to remove the bonded bracket from a substrate when a force is applied in the occlusal direction.

Test # 2\*\*: Wire Torque Test: Measures the torsional force required to break a bonded bracket when a rectangular wire is twisted in the wire slot.

Test # 3\*\*\*: Wire Drag Test: Measures the force required to drag a ligated stainless steel wire through the wire slot of a bonded bracket.

Test # 4\*\*\*\*: Bracket Removal Test: Evaluates the visual condition of a bonded bracket after twisting it off the substrate with pliers.

Test Summary:

The test results show that:

1. The Fast Braces® shear strength was (b) [redacted], compared to a strength of (b) [redacted] for the Predicate device. (4)T d
2. The Fast Braces® wire torque torque test averaged (b) [redacted] Force, while the Predicate device averaged (b) [redacted] Force. (4)T d
3. The Fast Braces® wire drag test resulted in an average force of (b) [redacted] while the Predicate device averaged (b) [redacted] Force. (4)T d
4. The Fast Braces® bracket removal test resulted in less fracturing of the bracket compared to the Predicate device upon removal of the brackets from the substrate using pliers. (4)T d



Substantial Equivalence:

The device comparison table shown above confirms substantial equivalence in regards to device performance.

1. The Fast Braces® shear strength is equivalent to the Predicate device because the Fast braces bracket exceeded the minimum test requirement. In the test, the average value was greater the predicate device.
2. The Fast Braces® wire torque test is equivalent to the Predicate device because the average breaking value of the Fast Braces® test samples exceeded the minimum test requirement of 2400 gm Force.
3. The Fast Braces® wire drag test is equal or better than the Predicate device because the average drag force of a ligated wire on the Fast Braces® test samples was less than the Predicate device.
4. The Fast Braces® bracket removal test is equivalent or better than the Predicate device because the Fast Braces® bracket samples showed less fragmentation than the Predicate device upon removal [REDACTED]hesive.





## Device Description

### Description of the Device:

Ceramic orthodontic brackets are small devices that are intended to be bonded to teeth, upon which an orthodontic wire is placed to move the teeth to desired positions. They are indicated for orthodontic treatment in patients of all ages when prescribed by an orthodontist. Ceramic orthodontic brackets are primarily offered as an aesthetic alternative to metal orthodontic brackets. They are close to natural tooth coloring, and blend in well enough that they are not as visible as metal brackets. This aesthetic look is popular with many patients, and especially older patients. Ceramic orthodontic brackets have been in use throughout the orthodontic industry for approximately thirty years.

Like its predicate, FastBraces® ceramic brackets are manufactured from polycrystalline alumina (ceramic) material, and have bases that bond to the tooth while still allowing for easy and complete removal. They incorporate a water soluble color placement dot as an aesthetic feature for each tooth.

Like its predicate, FastBraces® ceramic brackets are not intended for use in contact with soft tissues, or blood products. They do not include software or accessories, and are delivered non-sterile to the end user. Ceramic brackets are intended to be used only once by a single patient. Product labels contain appropriate “do not reuse” symbols. Orthodontic ceramic brackets are used for the duration of orthodontic treatment, which can last more than 30 months. During this time, the devices remain in direct contact with the patient’s oral cavity. Because the intended purpose of the device is clearly understood by licensed orthodontists, instructions for use are not provided.

With the exception of the materials from which they are constructed, the form, fit, and function of orthodontic ceramic brackets are identical to those of traditional metal orthodontic brackets. Orthodontic ceramic brackets, like metal brackets achieve their intended purpose (to move teeth into a desired position) through industry standard “prescriptions” that are pre-programmed into the design of the brackets. Specific torques, angulations, and distal offset dimensions are designed into each bracket, along with archwire slots that are designed to accommodate the correct size archwire (typically .018” or .022” thick).

Ceramic brackets are designed with tie wing undercut spaces for orthodontic ligatures. They have a molded ceramic bracket body with rounded corners and edges, and rounded hooks on the distal-gingival tie wings to accommodate ligation during orthodontic treatment. These design characteristics allow a thermoplastic ligating wire to move the brackets, which are securely bonded to the teeth, along a pre-determined path until the desired tooth position is reached. Elastic ligatures may be used on the tie wings and hooks to further facilitate tooth movement, and to secure the orthodontic wire into the bracket’s archwire slot.

















**Substantial Equivalence Discussion**

Predicate:

- 1. Reflections Ceramic Dental Bracket  
CDB Corporation  
K922499

Below is a detailed comparison between FastBraces® Ceramic Brackets and the predicate listed above. Substantial equivalence with the predicate is discussed in terms of Indications for Use, Technology, and Performance.

Indications for Use:

FastBraces™ Orthodontic Ceramic Brackets are intended for orthodontic movement of natural teeth. [Redacted] intended for

Technology:

Fast Braces® ceramic brackets are single-use devices intended for use in conjunction with comprehensive orthodontics to control the movement of individual teeth. This bracket line is designed to have the same intended use and similar technological characteristics as the predicate device. Minor design differences between the bracket do not raise new types of safety or effectiveness issues. The fundamental features in the brackets are:

- Wire slots that run mesial and distally through the bracket to hold the archwire
- Tiewings on the gingival and occlusal end of the brackets that facilitate the anchoring of elastic ligatures to hold the wire in place.
- A base pad surface that incorporate a rough surface to facilitate bracket bonding to the tooth.
- A bracket that is comprised of 99.9% polycrystalline aluminum oxide. [Redacted]

Minor differences in the brackets is that the bracket is intended to be used with a .020" square super-elastic nickel-titanium wire exclusively throughout the [Redacted] arch. The bracket is designed with a standard wire slot [Redacted]. The bracket tie-wings are designed to better contain the elastic ligature with less pressure against the wire. This combination of the [Redacted] resilient wire in a standard wire slot with lower ligating [Redacted] is intended to produce lower wire drag forces and less strain on the bracket.



Performance Testing

1. The Fast Braces® shear strength is equivalent to the Predicate device because the Fast braces bracket exceeded the minimum test performance requirement. In the test the average value was greater the predicate device.
2. The Fast Braces® wire torque test is equivalent to the Predicate device because the average breaking value of the Fast Braces® test samples exceeded the minimum test performance requirement of 2400 gm Force.
3. The Fast Braces® wire drag performance test is equal or better than the Predicate device because the average drag force of a ligated wire on the Fast Braces® test samples was less than the Predicate device.
4. The Fast Braces® bracket removal performance test is equivalent or better than the Predicate device because the Fast Braces® bracket samples showed less fragmentation than the Predicate device upon removal from the substrates using the specified adhesive.





# Orthodontic Design and Production, Inc.

## Proposed Labeling

Below is the proposed labeling for each of the devices listed in Section 3 of this 510(k) submission. Instructions for use are not provided with the product.

.022 LO ANT CERAMIC

-5 T, 0 A

REF 99-L1-2U

LOT XXXXX

QTY: 1

Made in USA

**FASTBRACES®**

www.fastbraces.com • ORTHOWORLD®  
2301 Colt Rd., Ste. A-1 • Plano, Texas 75075, USA  
972-867-9473 Office • 972-867-2210 Fax

CE MDSS GmbH  
0086 Schiffgraben 41 30175 Hannover, Germany  
Phone +49 511 6262 8630



.022 UL2 CERAMIC

+10°T +10°A

REF 99-U2-2L

LOT XXXXX

QTY: 1

Made in USA

**FASTBRACES®**

www.fastbraces.com • ORTHOWORLD®  
2301 Colt Rd., Ste. A-1 • Plano, Texas 75075, USA  
972-867-9473 Office • 972-867-2210 Fax

CE MDSS GmbH  
0086 Schiffgraben 41 30175 Hannover, Germany  
Phone +49 511 6262 8630



.022 LL3 HK CERAMIC

-5°T +5°A

REF 99-L3-2LK

LOT XXXXX

QTY: 1

Made in USA

**FASTBRACES®**

www.fastbraces.com • ORTHOWORLD®  
2301 Colt Rd., Ste. A-1 • Plano, Texas 75075, USA  
972-867-9473 Office • 972-867-2210 Fax

CE MDSS GmbH  
0086 Schiffgraben 41 30175 Hannover, Germany  
Phone +49 511 6262 8630



.022 UR2 CERAMIC

+10°T +10°A

REF 99-U2-2R

LOT XXXXX

QTY: 1

Made in USA

**FASTBRACES®**

www.fastbraces.com • ORTHOWORLD®  
2301 Colt Rd., Ste. A-1 • Plano, Texas 75075, USA  
972-867-9473 Office • 972-867-2210 Fax

CE MDSS GmbH  
0086 Schiffgraben 41 30175 Hannover, Germany  
Phone +49 511 6262 8630



.022 LR3 HK CERAMIC

-5°T +5°A

REF 99-L3-2RK

LOT XXXXX

QTY: 1

Made in USA

**FASTBRACES®**

www.fastbraces.com • ORTHOWORLD®  
2301 Colt Rd., Ste. A-1 • Plano, Texas 75075, USA  
972-867-9473 Office • 972-867-2210 Fax

CE MDSS GmbH  
0086 Schiffgraben 41 30175 Hannover, Germany  
Phone +49 511 6262 8630



.022 UL3 HK CERAMIC

+5°T +5°A

REF 99-U3-2LK

LOT XXXXX

QTY: 1

Made in USA

**FASTBRACES®**

www.fastbraces.com • ORTHOWORLD®  
2301 Colt Rd., Ste. A-1 • Plano, Texas 75075, USA  
972-867-9473 Office • 972-867-2210 Fax

CE MDSS GmbH  
0086 Schiffgraben 41 30175 Hannover, Germany  
Phone +49 511 6262 8630



.022 UL1 CERAMIC

+20°T +5°A

REF 99-U1-2L

LOT XXXXX

QTY: 1

Made in USA

**FASTBRACES®**

www.fastbraces.com • ORTHOWORLD®  
2301 Colt Rd., Ste. A-1 • Plano, Texas 75075, USA  
972-867-9473 Office • 972-867-2210 Fax

CE MDSS GmbH  
0086 Schiffgraben 41 30175 Hannover, Germany  
Phone +49 511 6262 8630



.022 UR3 HK CERAMIC

+5°T +5°A

REF 99-U3-2RK

LOT XXXXX

QTY: 1

Made in USA

**FASTBRACES®**

www.fastbraces.com • ORTHOWORLD®  
2301 Colt Rd., Ste. A-1 • Plano, Texas 75075, USA  
972-867-9473 Office • 972-867-2210 Fax

CE MDSS GmbH  
0086 Schiffgraben 41 30175 Hannover, Germany  
Phone +49 511 6262 8630



.022 UR1 CERAMIC

+20°T +5°A

REF 99-U1-2R

LOT XXXXX

QTY: 1

Made in USA

**FASTBRACES®**

www.fastbraces.com • ORTHOWORLD®  
2301 Colt Rd., Ste. A-1 • Plano, Texas 75075, USA  
972-867-9473 Office • 972-867-2210 Fax

CE MDSS GmbH  
0086 Schiffgraben 41 30175 Hannover, Germany  
Phone +49 511 6262 8630



.022 U4/5 HK CERAMIC

-5°T 0°A

REF 99-U4-2UK

LOT XXXXX

QTY: 1

Made in USA

**FASTBRACES®**

www.fastbraces.com • ORTHOWORLD®  
2301 Colt Rd., Ste. A-1 • Plano, Texas 75075, USA  
972-867-9473 Office • 972-867-2210 Fax

CE MDSS GmbH  
0086 Schiffgraben 41 30175 Hannover, Germany  
Phone +49 511 6262 8630





Orthodontic Design and Production, Inc.

Proposed Labeling

Below is the proposed labeling for the convenience kits as described on page 2 of the 510(k) cover letter that is provided in Section 3 of this 510(k) submission, and as listed on the inventory listing also provided in Section 3.

**99K-345-22-01**

**FASTBRACES®**  
022 FULL CASE HOOKS ON 3,4,6  
(20 BRACKETS / 4 LOW PROFILE TUBES)

**FASTBRACES®** • [www.fastbraces.com](http://www.fastbraces.com)  
**ORTHOWORLD®**  
2301 Colt Rd., Ste. A-1 • Plano, Texas 75075, USA  
972-867-9473 Office • 972-867-2210 Fax

**REF 99K-345-22-01**

**LOT XXXXX**

Made in  
**USA**

**CE** Victor Cerrpa S.L. • Plaza Mayor 40-2o-2a  
48100 Alzira Spain • Phone 00-3490-241-5847

**CAUTION:** Federal law restricts this device to sale by or on the order of a licensed health professional. For Single Patient Use Only





## Sterilization and Shelf Life

Sterilization:

FastBraces® Ceramic Brackets are sold non-sterile to the end user.

Shelf Life:

FastBraces® Ceramic Brackets have no defined shelf life, as the materials from which they are constructed do not deteriorate or expire.





Orthodontic Design and Production, Inc.

## Biocompatibility

### Predicate:

1. Reflections Ceramic Dental Bracket  
CDB Corporation  
K922499

FastBraces® Ceramic Brackets and its predicate are constructed of identical materials that come into contact with the patient's mucosal membrane during the duration of orthodontic treatment, which can last more than 30 months.

The FastBraces® Ceramic Bracket and its predicate are both made of ceramic tri polycrystalline alumina, which has a well documented history of biocompatibility within the oral environment. Because the materials from which the devices are constructed are well established in the orthodontic industry, product testing in regards to biocompatibility was not performed. Instead, ODP has conducted a literature review in accordance with ISO 10993-1:2009, Annex C. This literature review (Titled "Biocompatibility Summary Report") is provided in the pages that follow in this section (section 15).

Included in section 21 of this 510(k) submission is a Standards Data Report for 510(k)s (Form FDA 3654) that covers the use of ISO 10993-1:2009 in conducting the biological evaluation of the devices described herein.

















































**Software**

Predicate:

1. Reflections Ceramic Dental Bracket  
CDB Corporation  
K922499

Neither FastBraces® Ceramic Brackets nor its predicate are dependent upon the use of computer software for their intended use.





**Electromagnetic Compatibility and Electrical Safety**

Predicate:

1. Reflections Ceramic Dental Bracket  
CDB Corporation  
K922499

Neither FastBraces® Ceramic Brackets nor its predicate include an electronic component.





Orthodontic Design and Production, Inc.

## Performance Testing – Bench

Predicate:

1. Reflections Ceramic Dental Bracket  
CDB Corporation  
K922499

For details on the bench testing that was performed using ODP's FastBraces® ceramic bracket with the predicate defined above, please refer to the "Performance Evaluation of FastBraces™ bracket (test report # TR-001.2013) that is provided in this section (section 18) of this 510(k) submission.













## ATTACHMENTS

1. IMAGES and Figures (Page 8)
2. TEST RESULTS / DATA SHEETS (Page 15)
3. SUPPORTING DOCUMENTS (Page 22)

**ATTACHMENT 1**

**IMAGES AND FIGURES**













**ATTACHMENT 2**

**TEST RESULTS / DATA SHEETS**













**ATTACHMENT 3**

**Supporting Documents**







































**Performance Testing – Animal**

Animal testing to support the substantial equivalence of FastBraces® Ceramic Brackets with its predicates was not performed.





**Performance Testing – Clinical**

Clinical studies to support the substantial equivalence of FastBraces® Ceramic Brackets with its predicates was not performed.



Department of Health and Human Services  
 Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
 (To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing...

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #2-156

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....       
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....       
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
 If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: Guidance for Industry Pyrogen and Endotoxins Testing: Questions and Answers

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing...

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.1, Annex C	Suggested procedure for literature review	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>  
The option selected for the biocompatibility statement was "Literature Review"

DESCRIPTION  
The option selected for the biocompatibility statement was "Literature Review"

JUSTIFICATION  
Results are available from relevant, previously published studies.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

<sup>♦</sup> Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 1 hour 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:

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.*



**Kit Certification**

I certify that the following components of my kit have been found to be substantially equivalent through the premarket notification process for the use(s) for which the kit is to be intended (i.e., I am not claiming or causing a new use for the component(s)).

I further certify that these components are not purchased in "bulk", but are purchased in finished form, i.e., they are packaged, labeled, etc., consistent with their pre-Amendments, exemption, or premarket notification criteria and status.

Kit Part Number: 99K-345-22-01

Kit Description: FastBraces™ .022 Hk/345 W/Case

Kit Components:

- P/N 99-L1-2U; FastBraces™ - Ceramic .022; -5°T, 0°A
- P/N 99-L3-2LK; FastBraces™ - Ceramic .022; -5°T, +5°A
- P/N 99-L3-22RK; FastBraces™ - Ceramic .022; -5°T, +5°A
- P/N 99-U1-2L; FastBraces™ - Ceramic .022; +20°T, +5°A
- P/N 99-U1-2R; FastBraces™ - Ceramic .022; +20°T, +5°A
- P/N 99-U2-2L; FastBraces™ - Ceramic .022; +10°T, +10°A
- P/N 99-U2-2R; FastBraces™ - Ceramic .022; +10°T, +10°A
- P/N 99-U3-2LK; FastBraces™ - Ceramic .022; +5°T, +5°A
- P/N 99-U3-2RK; FastBraces™ - Ceramic .022; +5°T, +5°A
- P/N 99-UL45-2UK; FastBraces™ - Ceramic .022; +5°T, 0°A

  
\_\_\_\_\_  
(Signature)

Richard Merrell  
\_\_\_\_\_  
(Typed Name)

2-19-2013  
\_\_\_\_\_  
(Date)

\* \* \* COMMUNICATION RESULT REPORT ( JUN. 12. 2013 12:12PM ) \* \* \*

FAX HEADER 1:  
FAX HEADER 2:TRANSMITTED/STORED : JUN. 12. 2013 12:06PM  
FILE MODE                      OPTION

ADDRESS

RESULT

PAGE

5479 MEMORY TX

917607341735

OK

3/3

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

DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

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

June 7, 2013

Mr. Richard Merrell  
Regulatory Affairs Manager  
Orthodontic Design and Production, Inc.  
1370 Decision Street, Suite D  
Vista, CA 92081

Re: K130446  
Trade/Device Name: FastBraces® Ceramic Brackets  
Regulation Number: 21 CFR 872.5470  
Regulation Name: Orthodontic Plastic Bracket  
Regulatory Class: II  
Product Code: NJM  
Dated: April 10, 2013  
Received: April 15, 2013

Dear Mr. Merrell:

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.

5



# COVER SHEET MEMORANDUM

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

**From:** Reviewer Name Michael E. Adjodha  
**Subject:** 510(k) Number K130446  
**To:** The Record

**Please list CTS decision code:** SE - Substantially Equivalent

- Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)
- Hold (Additional Information or Telephone Hold)
- Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e. SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page ( <i>Attach IFU</i> )	X	
510(k) Summary or 510(k) Statement ( <i>Attach Summary or Statement</i> )	X	
Truthful and Accurate Statement ( <i>Must be present for a Final Decision</i> )	X	
Is the device Class III?		X
Does firm reference standards? (If yes, please attach <u>Form 3654</u> .)	X	
Is this a combination product?		X
Is this a reprocessed single use device? (See <u>Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices</u> .)		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
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 was incomplete, then applicant must be contacted to obtain completed form.)		X
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21	X	
Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)		X
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		

Nanotechnology		X
Is this device subject to the Tracking Regulation? ( <a href="#">Medical Device Tracking Guidance</a> )		X

<b>Regulation Number:</b>	21 CFR 872.5470
<b>Class:</b>	II
<b>Product Code:</b>	NJM
<b>Additional Product Codes:</b>	

<b>Digital Signature Concurrence Table</b> (Not all signatures may be required)	
Branch Chief Sign-Off	<p><b>Andrew I. Steen</b> 2013.06.07 10:47:48 -04'00'</p>
Division Sign-Off	<p><i>Susan Runner DDS, MA</i> <b>Mary S. Runner -S</b></p>



**COVER SHEET MEMORANDUM**

From: Reviewer Name  
Subject: 510(k) Number  
To: The Record

*Michael F. Adjo dha*  
K130446

Please list CTS decision code RTA1

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%202%2007.doc](http://eroom.fda.gov/eRoomReq/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 <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )			
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			
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, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			
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
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(\*if unclassified, see 510(k) Staff)

Additional Product Codes: \_\_\_\_\_

Review: \_\_\_\_\_  
(Branch Chief) (Branch Code) (Date)

Final Review: \_\_\_\_\_  
(Division Director) (Date)



Contains Nonbinding Recommendations

Print Form

# Acceptance Checklist for Traditional 510(k)s

**(Should be completed within 15 days of DCC receipt)**

The following information is not intended to serve as a comprehensive review.

510(k) #: K130446

Date Received by DCC: 02/25/2013

Lead Reviewer: Michael E. Adjodha

Branch: DEDB

Division: DAGRID

Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

<b>Preliminary Questions</b>		
Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
<p><b>1) Is the product a device (per section 201(h) of the FD&amp;C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?</b></p> <p>If it appears not to be a device (per section 201(h) of the FD&amp;C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If the product does not appear to be a device or such a combination product, mark "No."</p>	X	
Comments?		
<p><b>the application with the appropriate Center?</b></p> <p>If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If application should not be reviewed by your Center mark "No."</p>	X	
Comments?		
<p><b>3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:</b></p> <p>a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?</p> <p>b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ?</p> <p>If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide summary of Jurisdictional Officer's/Liaison's determination.</i></p> <p>If the answer to either question is no, mark "No." If there was no RFD, skip this question.</p>		X
Comments?		
<p><b>4) Is this device type eligible for a 510(k) submission?</b></p> <p>If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."</p>	X	
Comments?		

<b>5) Is there a pending PMA for the same device with the same indications for use?</b> If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
<b>clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?</b> If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at <a href="http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm">http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm</a>		X
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.  
 If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.  
 If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.  
 If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.  
 If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

12

## Organizational Elements

*Failure to include these items alone generally should not result in an RTA designation.*

	Yes	No
Submission contains a Table of Contents	X	
Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

## Elements of a Complete Submission (RTA Items)

### (21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

Any "No" answer will result in a "Refuse to Accept" decision.

- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

	Yes	No	N/A	Comment
<b>A. Administrative</b>				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 (See also 510(k) Summary Checklist)	X			
b) Statement contains all elements per 21 CFR 807.93			X	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) See recommended format.	X			
6) Submission contains Class III Summary and Certification. See recommended content.			X	
7) Submission contains clinical data			X	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X			
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X			
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.				
<b>B. Device Description</b>				

## Elements of a Complete Submission (RTA Items)

**(21 CFR 807.87 unless otherwise indicated)**

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

<p>Any "No" answer will result in a "Refuse to Accept" decision.                      Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.</p>	Yes	No	N/A	Comment
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
<b>11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:</b>				
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			
<b>13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system</b>				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.			X	
<b>C. Substantial Equivalence Discussion</b>				
<b>14) Submitter has identified a predicate device.</b>				
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is available online.</i>	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
<b>15) Submission includes a comparison of the following for the predicate(s) and subject device</b>				
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			

## Elements of a Complete Submission (RTA Items)

### (21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and <u>21 CFR 807.87(f)</u> )	X			

### D. Proposed Labeling (see also 21 CFR part 801)

If *in vitro* diagnostic (IVD) device, criteria 17, 18, & 19 may be omitted.

17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see <u>21 CFR 801.5</u> ) OR submission states that device qualifies for exemption per <u>21 CFR 801 Subpart D</u>	X			
18) If indicated for prescription use, labeling includes the prescription use statement (see <u>21 CFR 801.109(b)(1)</u> ) or "Rx only" symbol (See also <u>Alternative to Certain Prescription Device Labeling Requirements</u> )	X			
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor ( <u>21 CFR 801.1</u> ).	X			
b) Labeling includes device common or usual name. ( <u>21 CFR 801.61</u> )	X			
20)				
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
21) If the device is an <i>in vitro</i> diagnostic device, provided labeling includes all applicable information required per <u>21 CFR 809.10</u> .			X	

## Elements of a Complete Submission (RTA Items)

**(21 CFR 807.87 unless otherwise indicated)**

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

Any "No" answer will result in a "Refuse to Accept" decision.

- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes

No

N/A

Comment

### E. Sterilization

If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.

X

### F. Shelf Life

26) Proposed shelf life/expiration date stated

X

27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.

X

28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.

X

### G. Biocompatibility

If IVD device, select "N/A" and the below criteria will be omitted from checklist.

Submission states that there: (one of the below must be checked)

are direct or indirect (e.g., through fluid infusion) patient-contacting components.

are not direct or indirect (e.g., through fluid infusion) patient-contacting components.

Information regarding the sterility status of the device is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present

X

X

Comments? Complete chemical composition of the brackets, including the chemical identity of any additives, including color additives, has not been provided.

30) Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration, etc.)

X

31) Biocompatibility assessment of patient-contacting components

Submission includes:

Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR

a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).

X

### H. Software

Submission states that the device: (one of the below must be checked)

does contain software/firmware.

does not contain software/firmware.

**Elements of a Complete Submission (RTA Items)**

**(21 CFR 807.87 unless otherwise indicated)**

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
---	-----	----	-----	---------

Information regarding whether the device contains software is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

**I. EMC and Electrical Safety**

Submission states that the device: (one of the below must be checked)

does require EMC and Electrical Safety evaluation.

does not require EMC and Electrical Safety evaluation.

Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

**J. Performance Data - General**

If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.

Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.

37)

a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.

b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.

c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.

38) If literature is referenced in the submission, submission includes:

39) For each completed nonclinical (i.e., animal) study conducted

**Performance Characteristics - In Vitro Diagnostic Devices Only**

see 21 CFR 809.10(b)(12))

Submission states that the device: (one of the below must be checked)

**Elements of a Complete Submission (RTA Items)**  
**(21 CFR 807.87 unless otherwise indicated)**

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

Any "No" answer will result in a "Refuse to Accept" decision.

- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes

No

N/A

Comment

is an in vitro diagnostic device.

✗

is not an in vitro diagnostic device.

**Decision:**     Accept     Refuse to Accept

If Accept, notify applicant.

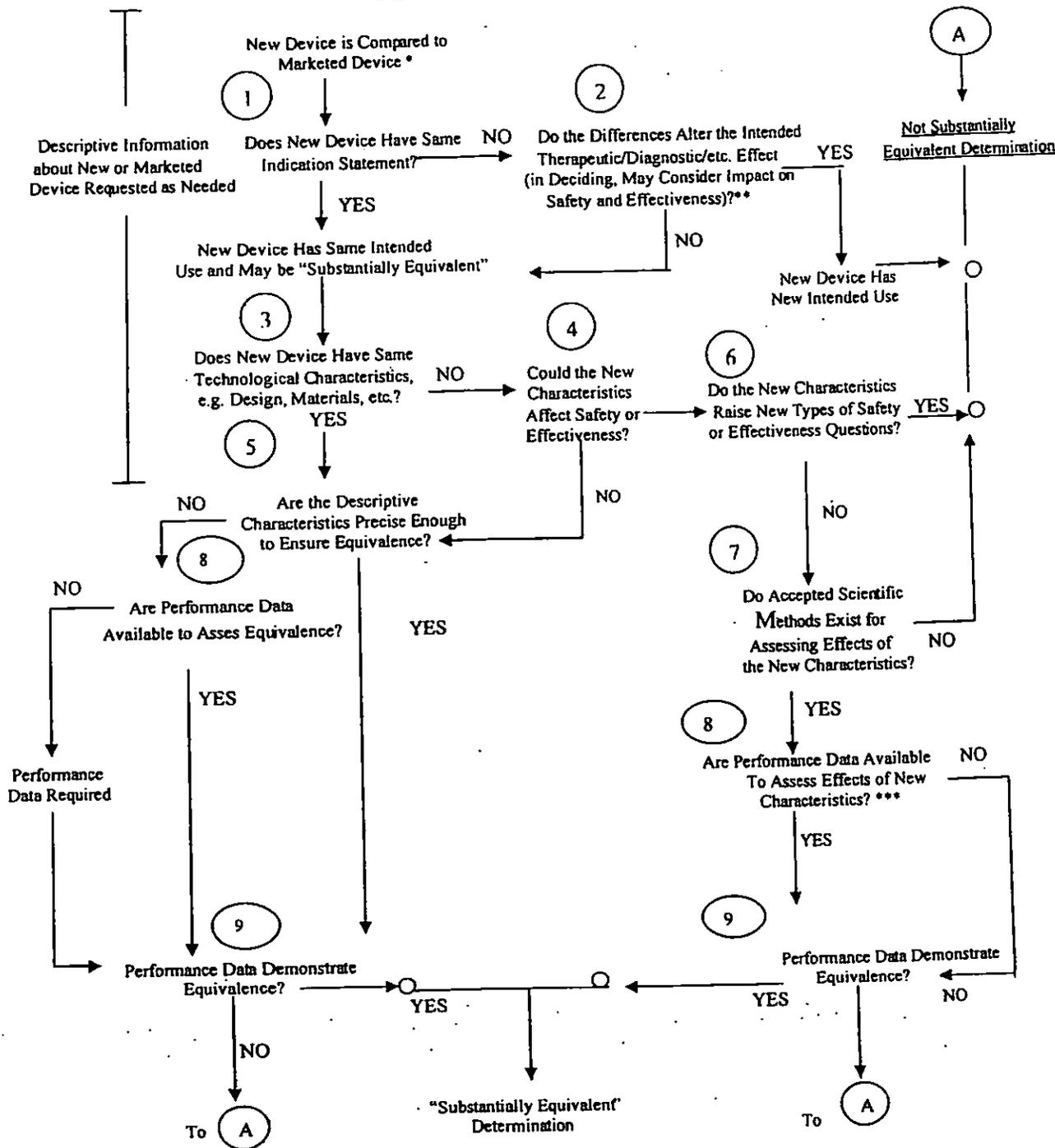
If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

**Digital Signature Concurrence Table**

Reviewer Sign-Off	Michael E. Adjodha -S 2013.02.28 08:42:27 -05'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

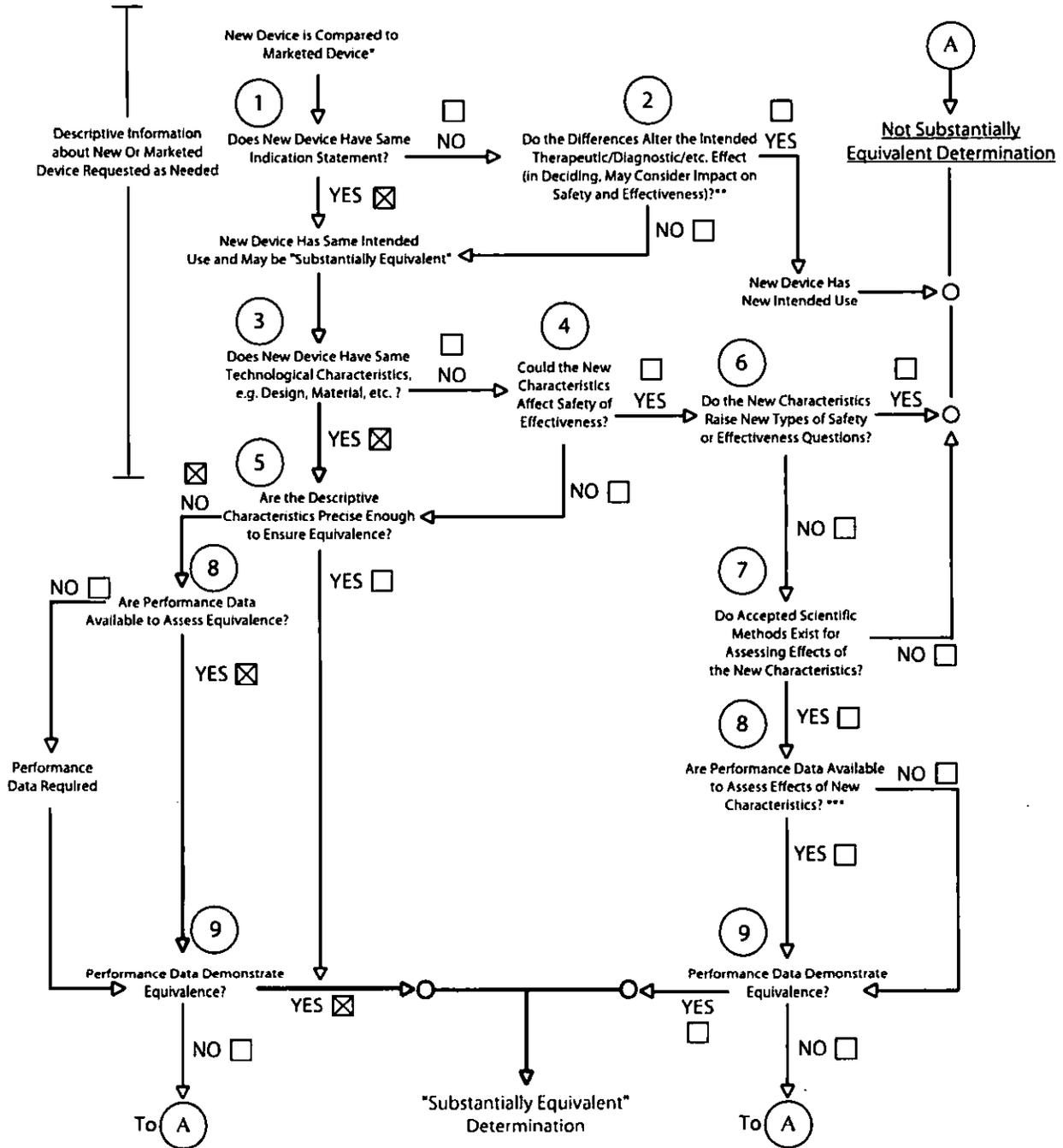
\* Branch and Division review of checklist and concurrence with decision required.  
Branch and Division digital signature optional.

## 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.

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



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



Orthodontic Design and Production, Inc.

K130446/S001

FDA CDRH DMC

APR 15 2013

Received

eCopy Cover Letter

The eCopy for the below 510(k) submission is an exact duplicate of the paper copy.

This eCopy addresses the eCopy Hold Letter dated April 11, 2013 regarding invalid naming conventions, which originated from the RTA dated February 28, 2013 regarding Item #29 of the "Acceptance Checklist for Traditional 510(k)s," where "Complete chemical composition of the brackets... has not been provided."

510(k) Number: K130446/S001

Device Name: Fast Braces® Ceramic Brackets

  
\_\_\_\_\_  
(Signature)

Richard Merrell  
\_\_\_\_\_  
(Typed Name)

April 12, 2013  
(Date)

23



Orthodontic Design and Production, Inc.

K130446/S001

FDA CDRH DMC  
APR 11 2013  
Received

eCopy Cover Letter

The eCopy for the below 510(k) submission is an exact duplicate of the paper copy. This eCopy addresses the RTA regarding Item #29 in the Acceptance Checklist for Traditional 510(k)s, where "Complete chemical composition of the brackets... has not been provided."

510(k) Number: K130446

Device Name: FastBraces® Ceramic Brackets

  
\_\_\_\_\_  
(Signature)

Richard Merrell  
\_\_\_\_\_  
(Typed Name)

April 10, 2013  
(Date)

sl



**Device Composition Statement**

Name of Device:

Fast Braces Ceramic Bracket  
K130446

Predicate:

Reflections Ceramic Dental Bracket  
CDB Corporation  
K922499

I certify that the FastBraces® Ceramic Brackets and its predicate are constructed solely of the following biocompatible material, and that no other materials are included in the finished device:

<u>Name of Material</u>	<u>% of Composition</u>	<u>CAS#</u>
<b>(b)(4) Trade Secret Process - Product Specs</b>		

  
\_\_\_\_\_  
(Signature)

Richard Merrell  
\_\_\_\_\_  
(Typed Name)

April 12, 2013  
(Date)