

K 132368

DEC 19 2013



Orthodontic Design and Production, Inc.

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: July 18, 2013

Device Trade Name: Vapor® Ceramic Brackets

Common Name: Bracket, Ceramic, Orthodontic

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

Predicate Device: K130446, FastBraces® Ceramic Brackets

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, Vapor® 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, Vapor® ceramic brackets do not incorporate medicinal substances, 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



Orthodontic Design and Production, Inc.

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. That is, 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:

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

Technological Characteristics:

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

Regarding design, Vapor® 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, Vapor® 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 Vapor® 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.

Comparison of Technological Differences between Subject and Predicate

	Subject Vapor Ceramic Bracket K132368	Predicate FastBraces Ceramic Bracket K130446
Indications for Use	Vapor Ceramic Brackets are intended for orthodontic movement of natural teeth.	FastBraces Ceramic Brackets are intended for orthodontic movement of natural teeth.
Technology	<p>Vapor® 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 brackets do not raise new types of safety or effectiveness issues. The fundamental features in the brackets are:</p> <ul style="list-style-type: none"> • 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 incorporates a rough surface to facilitate bracket bonding to the tooth. • A bracket that is comprised of pure polycrystalline aluminum oxide. <p>The Vapor® bracket is intended to be used with both .018" and .022" wire throughout the treatment, and are therefore designed with standard wire slots of .018" and .022". The bracket's tie-wings are designed to better contain the elastic ligature with less pressure against the wire.</p>	<p>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 (CDB Corporation's "Reflections" bracket K922499). Minor design differences between the brackets do not raise new types of safety or effectiveness issues. The fundamental features in the brackets are:</p> <ul style="list-style-type: none"> • 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 incorporates a rough surface to facilitate bracket bonding to the tooth. • A bracket that is comprised of pure polycrystalline aluminum oxide.
Differences	The only difference between the predicate device and the Vapor® bracket is the fact that the predicate device features a single tie-wing design on the gingival side of the archwire slot, while the Vapor® bracket features a twin tie-wing design to facilitate rotational control during the latter stages of orthodontic treatment.	Minor difference between the FastBraces ceramic brackets and the predicate device (CDB Corporation's "Reflections" bracket K922499) is that the FastBraces bracket is intended to be used with a .020" square super-elastic nickel-titanium wire exclusively throughout the treatment. The bracket is designed with a standard wire slot of .022". The bracket tie-wings are designed to better contain the elastic ligature with less pressure against the wire. This combination of the smaller resilient wire in a standard wire slot with lower ligating forces is intended to produce lower wire drag forces and less strain on the bracket.



Orthodontic Design and Production, Inc.

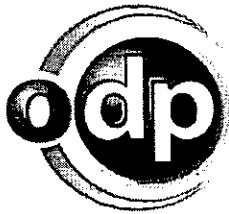
	Subject Vapor Ceramic Bracket K132368	Predicate FastBraces Ceramic Bracket K130446
Performance Testing	<ol style="list-style-type: none"> 1. The Vapor® shear strength is equivalent to the Predicate device because the Vapor® bracket exceeded the minimum test performance requirement. In the test, the average value was comparable to the predicate device. 2. The Vapor® wire torque test is equivalent to the Predicate device because the average breaking value of the Vapor® test samples exceeded the minimum test performance requirement of 2400 gm Force, as well as the breaking value of the Predicate device. 3. The Vapor® wire drag performance test is comparable to the Predicate device because the average drag force of a ligated wire on the Vapor® test samples was slightly higher than the Predicate device, but still within an acceptable range. 4. The Vapor® bracket removal performance test is equivalent or better than the Predicate device because the Vapor® bracket samples showed less fragmentation than the Predicate device upon removal from the substrates using the specified adhesive. 	<ol style="list-style-type: none"> 1. The Fast Braces® shear strength is equivalent to the Predicate device (CDB Corporation's "Reflections" bracket K922499) 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.

Substantial Equivalence:

Vapor® 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. Vapor® 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 Vapor® Ceramic Bracket and its predicate are both made of the same 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. Section 15 of this submission also includes a "Device Composition Statement" similar to the one that was requested by FDA during the review process of the predicate device's submission (K130446). This Device Composition Statement was requested in lieu of MSDS and a laboratory material analysis.



Orthodontic Design and Production, Inc.

Device Design:

Vapor® 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. Vapor® Ceramic Brackets and its predicate also contain base flanges for bracket placement and adhesive flash cleanup. Vapor® 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 Vapor® 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 Vapor® 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 Vapor® 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 Vapor® wire torque test averaging 3,806 gm Force, and the predicate device averaging 3,473 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 that slightly higher forces (but still within an acceptable range) were required to drag the Vapor® ceramic bracket along a ligated stainless steel wire than the predicate, indicating similar 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 Vapor® 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 Vapor® Ceramic Brackets.

Conclusion:

ODP's Vapor® 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. Vapor® 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 Vapor® Ceramic Brackets and the predicate device cited. Therefore, Vapor® Ceramic Brackets raise no new issues of safety or effectiveness.

Vapor® 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, Vapor® 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 Vapor® 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

December 19th, 2013

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

Re: K132368
Trade/Device Name: Vapor® Ceramic Brackets
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: November 7, 2013
Received: November 12, 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" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of 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,

Kwame O
Ulmer-S  for

Erin I. Keith, M.S.
Acting 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:

K132368

Device Name:

Vapor® Ceramic Brackets

Indications for Use:

Vapor® 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)

Mary S. Runner

Mary S. Runner **MS** 2013.12.16
10:54:43 -05'00'



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 19th, 2013

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

Re: K132368
Trade/Device Name: Vapor® Ceramic Brackets
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: November 7, 2013
Received: November 12, 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" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of 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,

Kwame O.
Ulmer-S  for

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

Enclosure

Concurrence & Template History Page

[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number:

For Office of Compliance Contact Information:

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

For Office of Surveillance and Biometrics Contact Information:

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

Digital Signature Concurrence Table	
Reviewer Sign-Off	Anita Belani
Branch Chief Sign-Off	Susan Runner
Division Sign-Off	Kwame O. Ulmer, S 2013.12.17 09:50:36 -05'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1 st 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:

K132368

Device Name:

Vapor® Ceramic Brackets

Indications for Use:

Vapor® 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)

Mary S. Runner

Susan Runner, DDS, MA
2013.12.16
10:54:43 -05'00'

K132368

FDA CDRH DMC

JUL 30 2013

Received



Orthodontic Design and Production, Inc.


eCopy Cover Letter

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

510(k) Number:

Device Name:

Vapor® Ceramic Brackets



(Signature)

Richard Merrell

(Typed Name)

July 26, 2013
(Date)

FDA CDRH DMC

AUG 10 2013

Received

FDA CDRH DMC

AUG 01 2013

Received

FDA CDRH DMC

AUG 30 2013

Received



Orthodontic Design and Production, Inc.

eCopy Cover Letter

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

510(k) Number:

Device Name:

Vapor® Ceramic Brackets



(Signature)

Richard Merrell

(Typed Name)

July 26, 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 http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFeeandModernizationAct/ucm155274.htm	Refer to Section 1		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf	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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	Refer to Section 3		
Indications for Use Statement	Device Advice "Content of a 510(k)" Section D http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080275.htm	Refer to Section 4		
510(k) Summary or 510(k) Statement	Device Advice "Content of a 510(k)" Section E http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm	Refer to Section 5		
Truthful and Accuracy Statement	Device Advice "Content of a 510(k)" Section G http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm	Refer to Section 6		
Class III Summary and Certification	Class III Summary and Certification Form http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm	Refer to Section 7		
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf Financial Disclosure by Clinical Investigators http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm	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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073752.htm</p> <p>FDA Standards program http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</p> <p>Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9</p> <p>Required Elements for Declaration of Conformity to Recognized Standard http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142706.htm</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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm</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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm</p>	Refer to Section 11		
Substantial Equivalence Discussion	<p>Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm</p>	Refer to Section 12		
Proposed Labeling	<p>Device Advice "Content of a 510(k)" Section H http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm</p>	Refer to Section 13		
Sterilization/Shelf Life	<p>Updated 510(k) Sterility Review Guidance (K90-1) http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm</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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434.htm</p>	Refer to Section 14		
Biocompatibility	<p>FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm</p>	Refer to Section 15		
Software	<p>Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm</p>	Refer to Section 16		

Title	Related Information	Present	Inadequate	N/A
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/default.htm See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)	Refer to Section 17		
Performance Testing – Bench	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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	Refer to Section 18		
Performance Testing – Animal	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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	Refer to Section 19		
Performance Testing – Clinical	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 http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf	Refer to Section 20		
FORM FDA 3654, Standards Data Report for 510(k)s - http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf	Standards Data Report Form – Form 3654 1: No standard used - No Standards Form Required 2: Declaration of Conformity – Yes Standards Form Required 3: Standard but no declaration – Yes Standards Form Required	Refer to Section 21		
Kit Certification	Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080213.htm	Refer to Section 22		

Last Updated: 9/3/08 – Brandi Stuart

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade Secret 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		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) ORTHODONTIC DESIGN AND PRODUCTION INC 1370 DECISION STREET VISTA CA 92081 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****0815	2. CONTACT NAME Richard Merrell 2.1 E-MAIL ADDRESS rm@odpinc.com 2.2 TELEPHONE NUMBER (include Area code) 760-734-3995 25 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm <u>Select an application type:</u> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice 3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)		
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> 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? <input checked="" type="checkbox"/> 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.) <input type="checkbox"/> 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/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> 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)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> 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		

17-Jul-2013

Form FDA 3601 (01/2007)

["Close Window"](#) [Print Cover sheet](#)

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

July 26, 2013

User Fee Payment ID Number

(b)(4)Trade Secret

FDA Submission Document Number (if known)

SECTION A

TYPE OF SUBMISSION

PMA

- ☐ Original Submission
☐ Premarket Report
☐ Modular Submission
☐ Amendment
☐ Report
☐ Report Amendment
☐ Licensing Agreement

PMA & HDE Supplement

- ☐ Regular (180 day)
☐ Special
☐ Panel Track (PMA Only)
☐ 30-day Supplement
☐ 30-day Notice
☐ 135-day Supplement
☐ Real-time Review
☐ Amendment to PMA & HDE Supplement
☐ Other

PDP

- ☐ Original PDP
☐ Notice of Completion
☐ Amendment to PDP

510(k)

- ☒ Original Submission:
☒ Traditional
☐ Special
☐ Abbreviated (Complete section I, Page 5)
☐ Additional Information
☐ Third Party

Meeting

- ☐ Pre-510(K) Meeting
☐ Pre-IDE Meeting
☐ Pre-PMA Meeting
☐ Pre-PDP Meeting
☐ Day 100 Meeting
☐ Agreement Meeting
☐ Determination Meeting
☐ Other (specify):

IDE

- ☐ Original Submission
☐ Amendment
☐ Supplement

Humanitarian Device Exemption (HDE)

- ☐ Original Submission
☐ Amendment
☐ Supplement
☐ Report
☐ Report Amendment

Class II Exemption Petition

- ☐ Original Submission
☐ Additional Information

Evaluation of Automatic Class III Designation (De Novo)

- ☐ Original Submission
☐ Additional Information

Other Submission

- ☐ 513(g)
☐ 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

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

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

- ☐ Other Reason (specify):

SECTION D3**REASON FOR SUBMISSION - 510(k)**

- ☒ New Device

- ☐ Additional or Expanded Indications

- ☐ Change in Technology

- ☐ Other Reason (specify):

SECTION E**ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed

1	NJM	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- ☒ 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	K130446	Fast Braces Ceramic Bracket	Orthodontic Design and Production, Inc. 1370 Decision Street, Suite D, Vista, CA 92081
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	Vapor Ceramic Bracket	N/A
2		
3		
4		
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 <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Dental		

Indications (from labeling)

Vapor 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.

1	Standards No. ISO 10993-1:2009	Standards Organization ANSI/AAMI/ISO	Standards Title Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.	Version 2009	Date 10/01/2009
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

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.



Orthodontic Design and Production, Inc.

510(k) Notification (21 CFR 807.90(e))

Cover Letter

Submitter:

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

Richard Merrell
Regulatory Affairs Manager
Telephone: (760) 734-3995 ext. 25
Email: rm@odpinc.com

Bracket, Ceramic, Orthodontic

In Premarket Notification Procedures regarding
Availability of Information (21 CFR 807.95), ODP, Inc. wishes
to certify to the Food and Drug Administration that it has complied
with applicable parts of that section, and considers the content
of this notification and its intention to market these devices as
confidential commercial information.

2.5470

Class II

Initial

IM

A



Orthodontic Design and Production, Inc.

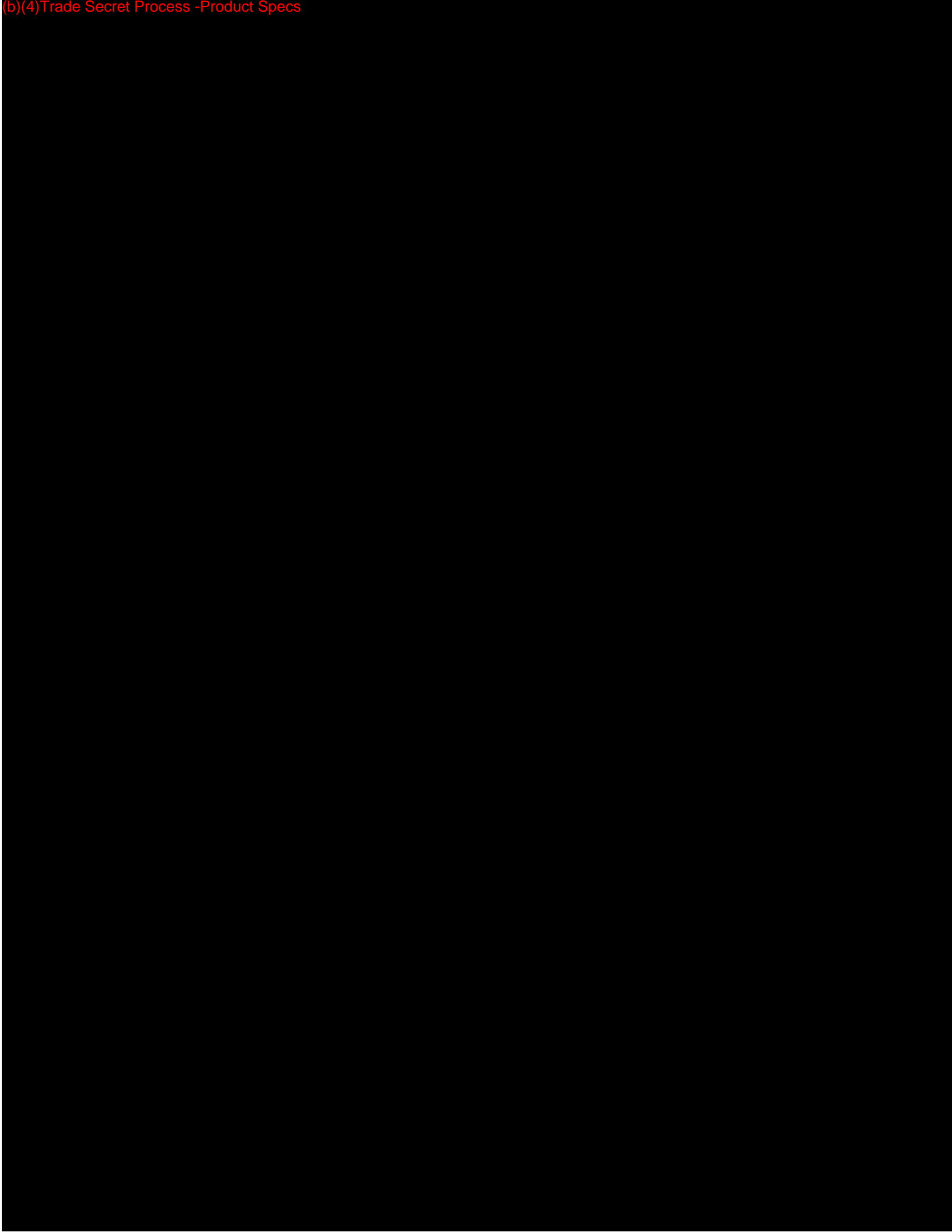
Basis for Submission: New Device

Design and Use

Question	YES	NO
...ription use (21 CFR 801 Subpart D)?	X	
...he-counter use (21 CFR 807 Subpart C)?		X
...ments derived from a tissue or other biologic		X
		X
...e?	X	
...se device?		X
		X
		X
		X
		X
		X

(s) covered in this 510(k) submission are assembled into a
...ed to the customer. That is, individual bracket designs (which
... to which tooth the bracket is placed) are
... the orthodontist all the brackets necessary for an
... of brackets is commonly referred to in the orthodontic
... Certification Statement is provided in Section 22 of this
... ience kits is provided within the Inventory Report
... where the Product Item Number prefix is either "75K"-xx-xxx or
... of the device components for each kit is included on the Kit
... 2.

...ndling ... an one device. The rationale ... ing is
... mission fall under the same generic device type, do not differ
... materials, energy source, function, or any other feature related to
... which similar regulatory controls sufficient to provide reasonable
... s (21 CFR 860.3(i)) are employed. The only differences
... submission are the industry-s ... d, tooth-specific design
... manufactured. A listing of the devices being bundled in this
... the following pages within this section (Section 3).





Indications for Use

[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]por® Ceramic Brackets

[REDACTED]por® Ceramic Brackets are indicated for orthodontic
[REDACTED]overm [REDACTED]

AND/OR

Over the Counter Use _____
(21 CFR 801 Subpart C)

THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

[REDACTED] of CDRH, Office of Device Evaluation (ODE)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



510(k) Summary

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

[REDACTED] Richard Merrell
Regulatory Affairs Manager
Telephone: (760) 734-3995 ext. 25
Facsimile: (760) 734-1735
Email: rm@odpinc.com

[REDACTED] 18, 2013

[REDACTED] por@

[REDACTED] Bracket, Ceramic, Orthodontic

[REDACTED] Ceramic Bracket, Class II
[REDACTED] 72.5470, Product Code: NJM)

[REDACTED] tBraces® Ceramic Brackets

[REDACTED] small devices that are intended to be bonded to teeth, upon
[REDACTED] to move the teeth to desired positions. They are indicated for
[REDACTED] all ages when prescribed by an orthodontist. Ceramic
[REDACTED] offered as an aesthetic alternative to metal orthodontic
[REDACTED] tooth coloring, and blend in well enough that they are not as
[REDACTED] netic look is popular with many patients, and especially older
[REDACTED] ets have been [REDACTED] throughout the orthodontic industry for

[REDACTED] c brackets are manufactured from [REDACTED] crystalline alumina
[REDACTED] s that are designed to provide maximum adhesion to the tooth
[REDACTED] complete removal when necessary. The brackets incorporate a
[REDACTED] as an indicator for correct selection of brackets for each tooth.

[REDACTED] brackets do not incorporate medicinal substances, tissues, or
[REDACTED] e software or accessories, and are delivered non-sterile to the



Orthodontic Design and Production, Inc.

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 contact with the patient's oral cavity. Because the intended purpose of the device is clear, and the device is used by trained dental professionals, 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) by following industry standard "prescriptions" that are pre-programmed into the brackets. These prescriptions, which include specific torques, angulations, and distal offset dimensions are achieved by the brackets' archwire slots that are designed to accommodate the archwire (typically .018" or .022" thick).

The brackets have tie wing undercut spaces for orthodontic ligatures. They have rounded corners and edges, and rounded hooks on the brackets to facilitate ligation during orthodontic treatment. These design features allow the brackets to hold the archwire in place, which are securely bonded to the brackets until the desired tooth position is reached. Elastic ligatures are used to secure the archwire into the brackets' archwire slot.

The brackets are designed for orthodontic movement of natural teeth.

Ceramic Brackets are identical to the predicate

ceramic brackets and their predicate both incorporate specific dimensions, along with archwire slots that are designed to accommodate the archwire (typically .018" or .022" thick). They have tie wing undercut spaces for orthodontic ligatures, have a molded ceramic body with rounded corners and edges for patient comfort, and rounded hooks on the brackets to accommodate ligation during orthodontic treatment.

Vapor® ceramic brackets and its predicate are manufactured from (ceramic) material, which is of known biocompatibility in the oral

The design characteristics of Vapor® ceramic brackets and its archwire slots are identical to the brackets, which are securely bonded to the brackets until the desired tooth position is reached. Elastic ligatures may be used on the tie wings and hooks to further facilitate the archwire into the bracket's archwire slot.



Substantial Equivalence:

Vapor® 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. Vapor® ceramic brackets are engineered to be [REDACTED] equivalent to the predicate with respect to intended use, technological characteristics, [REDACTED]s, 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.

[REDACTED] and its predicate are both made of the same ceramic tri [REDACTED] as a well-documented history of biocompatibility within the oral [REDACTED] a biocompatibility summary report in accordance with ISO [REDACTED] in Section 15 of this submission. Because the materials from [REDACTED] are well established in the orthodontic industry, product testing [REDACTED] not performed. Instead, a literature review has been conducted [REDACTED] 9, Annex C. Section 15 of this submission also includes a [REDACTED] similar to the one that was requested by FDA during the review [REDACTED] submission (K130446). This Device Composition Statement [REDACTED] a la [REDACTED]

[REDACTED] predicate [REDACTED] orthodontic [REDACTED] tie wings, not [REDACTED] auxiliaries. [REDACTED] predicate also contain base flanges for bracket placement and [REDACTED] Vapor® Ceramic Brackets and its predicate contain a molded ceramic [REDACTED] and edges, and a round hook on the distal-gingival tie wings. [REDACTED]s contain vertical slot and stress concentrators [REDACTED] tooth.

[REDACTED] shows that Vapor® Ceramic Brackets perform [REDACTED]

[REDACTED] strength required to remove a bonded bracket from a [REDACTED] applied in the occlusal direction. The test results showed that [REDACTED] Vapor® Ceramic Brackets are comparable to the predicate, and [REDACTED] strength required to affix the bracket to the tooth.

[REDACTED]s the torsional force required to break a bonded bracket when [REDACTED] in the [REDACTED]. The test results showed [REDACTED] bracket [REDACTED] wire torque test averaging 3,806 gm Force, and the predicate [REDACTED] Force before [REDACTED] occurred.

[REDACTED] force required to drag a ligated stainless steel wire through [REDACTED]. The test results showed that [REDACTED] higher forces (but still [REDACTED]) were required to drag the Vapor® ceramic bracket along a [REDACTED] than the predicate, indicating similar sliding mechanics during [REDACTED]

[REDACTED] evaluates the visual condition of a bonded bracket after twisting it [REDACTED]. The Vapor® bracket removal test resulted in less bracket [REDACTED] the predicate device when removing the bracket from a [REDACTED]



Clinical Performance Testing:

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

Conclusion:

ODP's Vapor® 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. Vapor® ceramic brackets are engineered to be substantially equivalent to the [redacted] use, technological characteristics, device design, materials, [redacted] process, and biocompatibility.

[redacted] between the Vapor® Ceramic Brackets and the predicate device [redacted] Brackets raise no new issues of safety or effectiveness.


[redacted] designed and manufactured to industry-standard specifications [redacted] established and documented history of biocompatibility within the [redacted] Vapor® Ceramic Brackets are as safe and effective as the [redacted] to be substantially equivalent to the referenced predicate [redacted] taking these factors into account, it can be safely concluded that [redacted] and perform [redacted]



Orthodontic Design and Production, Inc.

Truthful and Accurate Statement

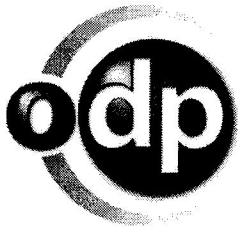
I certify that, in my capacity as the regulatory affairs manager for Orthodontic Design & Production, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.


(Signature)

Richard Merrell
(Typed Name)

7-26-13
(Date)

(Premarket Notification [510(k)] Number)



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 Vapor® 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)


7-26-13
(Date)



Orthodontic Design and Production, Inc.

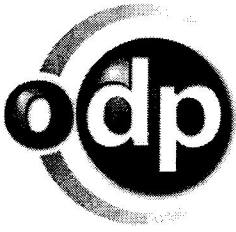
Financial Certification / Disclosure Statement

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


(Signature)

Richard Merrell
(Typed Name)

7-26-13
(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)

7-26-13
(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 patients of all ages when prescribed by an orthodontist. Ceramic brackets are typically offered as an aesthetic alternative to metal orthodontic brackets. Natural tooth coloring, and blend in well enough that they are not as noticeable. The aesthetic look is popular with many patients, and especially older patients. Ceramic brackets have been in use throughout the orthodontic industry for many years.

Ceramic orthodontic brackets are manufactured from polycrystalline alumina. They are designed to provide maximum adhesion to the tooth surface, and are intended to be removed upon complete removal when necessary. The brackets incorporate a slot for the archwire for each tooth.

Ceramic orthodontic brackets are used on teeth, tissues, or soft tissue. They are intended to be used only once by a single patient. Product labels include instructions for use, and symbols. Orthodontic ceramic brackets are used for the treatment of orthodontic conditions which can last more than 30 months. During this time, the brackets are bonded to the teeth with the patient's oral cavity. Because the intended purpose of the brackets is to move teeth, instructions for use are not provided.

The brackets are constructed from the form, fit, and function of traditional metal orthodontic brackets.

The brackets achieve their intended purpose (to move teeth) by using industry standard "prescriptions" that are pre-programmed into the brackets. The brackets have archwire slots that are designed to accommodate the archwire (.022" thick).

The brackets have tie wing undercut spaces for orthodontic ligatures. They have rounded corners and edges, and rounded hooks on the brackets for use during orthodontic treatment. The brackets are designed to hold the archwire in place, which are securely bonded to the teeth until the desired tooth position is reached. Elastic ligatures are used to further facilitate tooth movement, and to secure the archwire slot.

The brackets are indicated for orthodontic movement of natural teeth.



Technology:

Ceramic orthodontic brackets such as Vapor® and its predicate (ODP's "FastBraces® ceramic bracket K130446") are cemented to the front surface of the tooth where they direct the mechanical forces that urge the tooth to move. 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 the orientation of the bracket slot, it is possible to apply forces, pulling or pushing teeth in any desired direction.

	Vapor® Ceramic Bracket vs. FastBraces® Ceramic Bracket (K130446)		
	Vapor® Ceramic Bracket	FastBraces® Ceramic Bracket	Equivalence Result
	(b)(4) Trade Secret Process -Product Specs		Equivalent
			Equivalent
	Test		Equivalent

The shear strength required to remove the bonded bracket from the tooth in the occlusal direction.

The lateral force required to break a bonded bracket from the tooth in the slot.

Measures the force required to drag a ligated stainless steel wire through the slot.

Test: Evaluates the visual condition of a bonded bracket after removal from the tooth.

The average force was (b)(4) T d, compared to a strength of (b)(4) T d for the predicate device.

The average force was (b)(4) T d Force, while the Predicate device averaged (b)(4) T d Force.

The test resulted in an average force of (b)(4) T d, while the Predicate device resulted in an average force of (b)(4) T d.

The lateral test resulted in similar fracturing characteristics as the predicate device upon removal of the brackets from the substrate using the predicate device.



Substantial Equivalence:

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

1. The Vapor® shear strength is equivalent to the Predicate device because the Vapor® bracket exceeded the minimum test requirement. In the test, the average value was

predicate device.

The test is equivalent to the Predicate device because the average Vapor® test samples exceeded the minimum test requirement of as the breaking value of the Predicate device.

is equivalent to the Predicate device because the average on the Vapor® test samples was only slightly higher than the within an acceptable range.

test is equivalent or better than the Predicate device et samples showed less fragmentation than the Predicate



Device Description

Description of the Device:

are small devices that are intended to be bonded to teeth, upon
ced to move the teeth to desired positions. They are indicated for
of all ages when prescribed by an orthodontist. Ceramic
ny offered as an aesthetic alternative to metal orthodontic
ral tooth coloring, and blend in well enough that they are not as
hetic look is popular with many patients, and especially older
kets have been in use throughout the orthodontic industry for

brackets are manufactured from polycrystalline alumina
s that [redacted] in to the tooth
corporate a
s and [redacted] for each tooth.
brack [redacted] es, tissues, or
e software or accessories, and are delivered non-sterile to the
ended to be used only once by a single patient. Product labels
symbols. Orthodontic ceramic brackets are used for the
[redacted] more than 30 months. During this time, the
[redacted] ent's oral cavity. Because the intended purpose of
[redacted] licensed orthodontists, instructions for use are not provided.

h they are constructed, the form, fit, and function of
[redacted] ose of traditional metal orthodontic brackets.
e metal brackets achieve their intended purpose (to move teeth
[redacted] industry standard "prescriptions" that are pre-programmed into
[redacted] c torques, angulations, and distal offset dimensions are
[redacted] with archwire slots that are designed to accommodate the
[redacted] " or .022" thick).

h tie wing undercut spaces for orthodontic ligatures. They have
h rounded corners and edges, and rounded hooks on the
[redacted] odate ligation during orthodontic treatment. These design
[redacted] ing wire to [redacted] e brackets, which are securely bonded to
[redacted] th until the desired tooth position is reached. Elastic ligatures
[redacted] ocks to further facilitate tooth movement, and to secure the
[redacted] archwire slot.



Performance Specifications:

The goal for the m [REDACTED] performance requirement for the Vapor® bracket line is to be used with comprehensive orthodontics to control the movement of individual teeth. During normal treatment, the b [REDACTED] is intended to move individual teeth without failure to the bracket at normal tooth movement forces.

- 1 The Vapor® shear strength performance goal is to have a minimum shear strength of 5 [REDACTED] sufficient for the bracket to stay on the individual teeth and facilitate flexible archwire.

[REDACTED] The test performance goal was to achieve 2400 gm Force calculated [REDACTED] of the wire slot. This equates to a minimum of four times the tooth [REDACTED] Force without breakage.

[REDACTED] performance requirement goal was to attain a constant wire [REDACTED] The average drag force of the Predicate device was used as [REDACTED]

[REDACTED] oval [REDACTED] the bracket with [REDACTED] ve. A visual [REDACTED] the dev [REDACTED]

[REDACTED] single-use devices intended to be used with comprehensive [REDACTED] movement of Individual teeth. The general design [REDACTED] brackets are:

[REDACTED] crystalline aluminum oxide.

[REDACTED] al and occlusal ends of the bracket used as an anchor point [REDACTED] the archwires in the archwire slots.

[REDACTED] extends mesially and distally through the bracket and engages [REDACTED]

[REDACTED] with irregular surface to facilitate bracket bonding with [REDACTED] ves.

[REDACTED] -code [REDACTED] charts for the Vapor® Ceramic Brackets [REDACTED] w. The product drawings include dimensions, tolerances, and [REDACTED] conformity to [REDACTED] requirements.

[REDACTED] Ceramic Brackets come into direct contact [REDACTED] with the patients' oral [REDACTED] 93-1:2009, Annex A, Table A.1, ceramic orthodontic brackets [REDACTED] t, permanent (>30 days) contact with the mucosal membrane [REDACTED] treatment. The material from which these devices are [REDACTED] vice Composition Statement provided in Section 15 of this [REDACTED] DS provided in the Performance Evaluation located in Section



Substantial Equivalence Discussion

[REDACTED]
[REDACTED]

Predicate:

1. FastProcess® Ceramic Bracket
Orthodontic Design and Production, Inc.

[REDACTED]

between Vapor® Ceramic Brackets and the predicate listed
the predicate is discussed in terms of Indications for Use,

[REDACTED]
[REDACTED]
[REDACTED] kets, [REDACTED] ded for
[REDACTED] eth.

single-use devices intended for use in conjunction with
[REDACTED] ment of individual teeth. This bracket line is
[REDACTED] se and similar technological characteristics as the
[REDACTED] ferences between the bracket do not raise new types of safety
[REDACTED] tures in the brackets are:

and distally through the bracket to hold the archwire
[REDACTED] nd occlusal end of the brackets that facilitate the anchoring of
[REDACTED] wire in place.

incorporate a rough surface to facilitate bracket bonding to the

of pure polycrystalline aluminum oxide. [REDACTED]

to be used with both .018" and .022" wire throughout the
[REDACTED] ed with sta [REDACTED] e slots of .018" and .022". The bracket's
[REDACTED] ain the elastic ligature with less pressure against the wire. .

[REDACTED]



Performance Testing

1. The Vapor® shear strength is equivalent to the Predicate device because the Vapor® bracket [REDACTED] performance requirement. In the test, the average value was comparable to the predicate device.

2. The Vapor® wire torque test is equivalent to the Predicate device because the average Vapor® test samples exceeded the minimum test performance [REDACTED] Force, as well as the breaking value of the Predicate device.

[REDACTED] performance test is comparable to the Predicate device because [REDACTED] of a ligated wire on the Vapor® test samples was slightly higher [REDACTED] but still within an acceptable range.

[REDACTED] performance test is equivalent or better than the Predicate [REDACTED] bracket samples showed less fragmentation than the [REDACTED] removal from the substrates using the specified adhesive.



Orthodontic Design and Production, Inc.

Proposed Labeling

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



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U1-8L

VAPOR™ .018 UL1
+12°T +5°A

Brackets

QTY: _____ UM: EA

LOT _____
Made in USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U3-8LK

VAPOR™ .018 UL3 HK
0°T +11°A 4°R

Brackets

QTY: _____ UM: EA

LOT _____
Made in USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U1-8R

VAPOR™ .018 UR1
+12°T +5°A

Brackets

QTY: _____ UM: EA

LOT _____
Made in USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U3-8RK

VAPOR™ .018 UR3 HK
0°T +11°A 4°R

Brackets

QTY: _____ UM: EA

LOT _____
Made in USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U2-8L

VAPOR™ .018 UL2
+8°T +9°A

Brackets

QTY: _____ UM: EA

LOT _____
Made in USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U4-8U

VAPOR™ .018 UP45
-7°T 0°A

Brackets

QTY: _____ UM: EA

LOT _____
Made in USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U2-8R

VAPOR™ .018 UR2
+8°T +9°A

Brackets

QTY: _____ UM: EA

LOT _____
Made in USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U4-8LK

VAPOR™ .018 UL45 HK
-7°T 0°A

Brackets

QTY: _____ UM: EA

LOT _____
Made in USA



L604-01



Orthodontic Design and Production, Inc.

Proposed Labeling

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



1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U4-8RK

VAPOR™ .018 UR45 HK
-7°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made in USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L4-8U

VAPOR™ .018 L04
-17°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made in USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L1-8U

VAPOR™ .018 L01/2
0°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made in USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L5-8LK

VAPOR™ .018 LL5 HK
-22°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made in USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L3-8LK

VAPOR™ .018 LL3 HK
-11°T +5°A 2°R

Brackets

QTY: _____ UM: EA

LOT

Made in USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L5-8RK

VAPOR™ .018 LR5 HK
-22°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made in USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L3-8RK

VAPOR™ .018 LR3 HK
-11°T +5°A 2°R

Brackets

QTY: _____ UM: EA

LOT

Made in USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L5-8U

VAPOR™ .018 L05
-22°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made in USA



L604-01



Orthodontic Design and Production, Inc.

Proposed Labeling

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



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U1-2L

VAPOR™ .022 UL1
+12°T +5°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U3-2LK

VAPOR™ .022 UL3 HK
0°T +11°A 4°R

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U1-2R

VAPOR™ .022 UR1
+12°T +5°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U3-2RK

0°T +11°A 4°R

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U2-2L

VAPOR™ .022 UL2
+8°T +9°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U4-2U

VAPOR™ .022 UP45
-7°T 0°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U2-2R

VAPOR™ .022 UR2
+8°T +9°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L1-2U

VAPOR™ .022 LO1/2
0°T 0°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design and Production, Inc.

Proposed Labeling

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



1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE [EC REP] Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L3-2LK

VAPOR™ .022 LL3 HK
-11°T +5°A 2°R

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE [EC REP] Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L4-2RK

VAPOR™ .022 LR4 HK
-17°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE [EC REP] Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L3-2RK

VAPOR™ .022 LR3 HK
-11°T +5°A 2°R

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE [EC REP] Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L5-2U

VAPOR™ .022 L05
-22°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE [EC REP] Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L4-2U

VAPOR™ .022 L04
-17°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE [EC REP] Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L5-2LK

VAPOR™ .022 LL5 HK
-22°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE [EC REP] Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L4-2LK

VAPOR™ .022 LL4 HK
-17°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE [EC REP] Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L5-2RK

VAPOR™ .022 LR5 HK
-22°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design and Production, Inc.

Proposed Labeling

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



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U1-8L

VAPOR™ .018 UL1
+17°T +4°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U3-8LK

VAPOR™ .018 UL3 HK
-7°T +8°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U1-8R

VAPOR™ .018 UR1
+17°T +4°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U3-8LK0

VAPOR™ .018 UL3 HK
0°T +8°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U2-8L

VAPOR™ .018 UL2
+10°T +8°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U3-8RK

VAPOR™ .018 UR3 HK
-7°T +8°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U2-8R

VAPOR™ .018 UR2
+10°T +8°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U3-8RK0

VAPOR™ .018 UR3 HK
0°T +8°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design and Production, Inc.

Proposed Labeling

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



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U4-8U

VAPOR™ .018 UP4/5
-7°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L3-8LK

VAPOR™ .018 LL3 HK
-5°T +3°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U4-8LK

VAPOR™ .018 UL45 HK
-7°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L3-8LK0

VAPOR™ .018 LL3 HK
0°T +3°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U4-8RK

VAPOR™ .018 UR45 HK
-7°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L3-8RK

VAPOR™ .018 LR3 HK
-6°T +3°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L1-8U

VAPOR™ .018 L1/2
-6°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L3-8RK0

VAPOR™ .018 LR3 HK
0°T +3°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA



L604-01



Orthodontic Design and Production, Inc.

Proposed Labeling

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



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L4-8U

VAPOR™ .018 L04
-12°T 0°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L5-8LK

VAPOR™ .018 LL5 HK
-17°T 0°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L4-8LK

VAPOR™ .018 LL4 HK
-12°T 0°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L5-8RK

VAPOR™ .018 LR5 HK
-17°T 0°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L4-8RK

VAPOR™ .018 LR4 HK
-12°T 0°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L5-8U

VAPOR™ .018 L05
-17°T 0°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design and Production, Inc.

Proposed Labeling

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



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U1-2L

VAPOR™ .022 UL1
+17°T +4°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U3-2LK

76-u3-2lk
-7°T +8°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U1-2R

VAPOR™ .022 UR1
+17°T +4°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U3-2LK0

VAPOR™ .022 UL3 HK
0°T +8°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U2-2L

VAPOR™ .022 UL2
+10°T +8°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U3-2RK

VAPOR™ .022 UR3 HK
-7°T +8°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U2-2R

VAPOR™ .022 UR2
+10°T +8°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U3-2RK0

VAPOR™ .022 UR3 HK
0°T +8°A

Brackets

QTY: _____ UM: EA

LOT
Made In USA



L604-01



Orthodontic Design and Production, Inc.

Proposed Labeling

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



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U4-2U

VAPOR™ .022 UP4/5
-7°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA

2



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L3-2LK

VAPOR™ .022 LL3 HK
-6°T +3°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA

2



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U4-2LK

VAPOR™ .022 UL45 HK
-7°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA

2



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L3-2LK0

VAPOR™ .022 LL3 HK
0°T +3°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA

2



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U4-2RK

VAPOR™ .022 UR45 HK
-7°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA

2



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L3-2RK

VAPOR™ .022 LR3 HK
-6°T +3°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA

2



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L1-2U

VAPOR™ .022 L1/2
-6°T 0°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA

2



L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L3-2RK0

VAPOR™ .022 LR3 HK
0°T +3°A

Brackets

QTY: _____ UM: EA

LOT

Made In USA

2



L604-01



Orthodontic Design and Production, Inc.

Proposed Labeling

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



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L4-2U

VAPOR™ .022 L04
-12°T 0°A

Brackets

QTY: _____ UM: EA

LOT _____ **2**
Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L5-2LK

VAPOR™ .022 LL5 HK
-17°T 0°A

Brackets

QTY: _____ UM: EA

LOT _____ **2**
Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L4-2LK

VAPOR™ .022 LL4 HK
-12°T 0°A

Brackets

QTY: _____ UM: EA

LOT _____ **2**
Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L5-2RK

VAPOR™ .022 LR5 HK
-17°T 0°A

Brackets

QTY: _____ UM: EA

LOT _____ **2**
Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L4-2RK

VAPOR™ .022 LR4 HK
-12°T 0°A

Brackets

QTY: _____ UM: EA

LOT _____ **2**
Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L5-2U

VAPOR™ .022 L05
-17°T 0°A

Brackets

QTY: _____ UM: EA

LOT _____ **2**
Made in USA

L604-01



Orthodontic Design and Production, Inc.

Proposed Labeling

Below is an example of 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. Please note that the labeling remains the same for all convenience kits, with the exception of the product part number, description, and lot number.

75K-3-22-6

Vapor™

CERAMIC BRACKET SYSTEM

ROTH™ PRESCRIPTION 022 UP 3x3 CASE

HOOKS ON 3 (6 BRACKETS)

*ODP Inc. prescriptions do not imply endorsement by the Doctor

REF **75K-3-22-6**

LOT

MADE IN
USA



Orthodontic Design and Production, Inc.

1370 Decision Street Suite D • Vista, California USA 92081

Telephone: (760) 734-3995 • USA Toll Free: (800) 383-5301

Fax: (760) 734-1735 • www.odpinc.com • info@odpinc.com

© 2009 Orthodontic Design and Production, Inc.

CE **0086** Victor Campe S.L. • Plaza Mayor 40-2o-2a
46600 Alzira Spain • Phone 00-3496-241-5647

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

PC 510 K 1002-01





Sterilization and Shelf Life

[Redacted]

Sterilization:

[Redacted]

old non-sterile to the end user.

defined shelf life, as the materials from which they are
pire.

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]



Biocompatibility

Predicate:

FastBrace™ Ceramic Bracket
Orthodontic Design and Production, Inc.

Predicate are constructed of identical materials that come into contact with oral tissue during the duration of orthodontic treatment, which

its predicate is constructed of identical materials that come into contact with oral tissue during the duration of orthodontic treatment, which
the device is constructed of identical materials that come into contact with oral tissue during the duration of orthodontic treatment, which
view in accordance with ISO 10993-1:2009, Annex C. This
Biocompatibility Summary Report") is provided in the pages that follow in

a Standards Data Report for 510(k)s (Form
3-1:2009 in conducting the biological evaluation of the



Orthodontic Design and Production, Inc.

Device Composition Statement

Name of Device:

Vapor® Ceramic Bracket

Predicate:

FastBraces® Ceramic Bracket (K130446)
Orthodontic Design and Production, Inc.

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

Name of Material

Aluminium Oxide

% of Composition

100.00%

CAS#

CAS-Nr.: 1344-28-1



(Signature)

Richard Merrell

(Typed Name)

7-26-13

(Date)




Orthodontic Design and Production, Inc.

Note to 510(k) Reviewer

(b)(4)Trade Secret Process

A large black rectangular redaction box covers the majority of the page content below the 'Note to 510(k) Reviewer' section header.


(Signature)

Richard Merrell
(Typed Name)

7-26-13
(Date)



Orthodontic Design and Production, Inc.

Software

[REDACTED]

[REDACTED]

Predicate:

1. FastProcess® Ceramic Bracket
Production, Inc.

[REDACTED]

or its predicate are dependent upon the use of computer

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



Electromagnetic Compatibility and Electrical Safety

[REDACTED]

[REDACTED]

Predicate:

1. FastProcess® Ceramic Bracket
Orthodontic Design and Production, Inc.

[REDACTED]

or its predicate include an electronic component.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



Performance Testing – Bench

[Redacted]

Predicate:

1. FastPress® Ceramic Bracket
[Redacted] Production, Inc.

[Redacted]

It was performed using ODP's Vapor® ceramic bracket and refer to the test report entitled "Performance Evaluation of report # TR-002.2013) that is provided in this section (section

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

ATTACHMENTS

1. FIGURES and IMAGES
2. TEST RESULT AND DATA SHEETS
3. RELATED DOCUMENTATION

ATTACHMENT 1

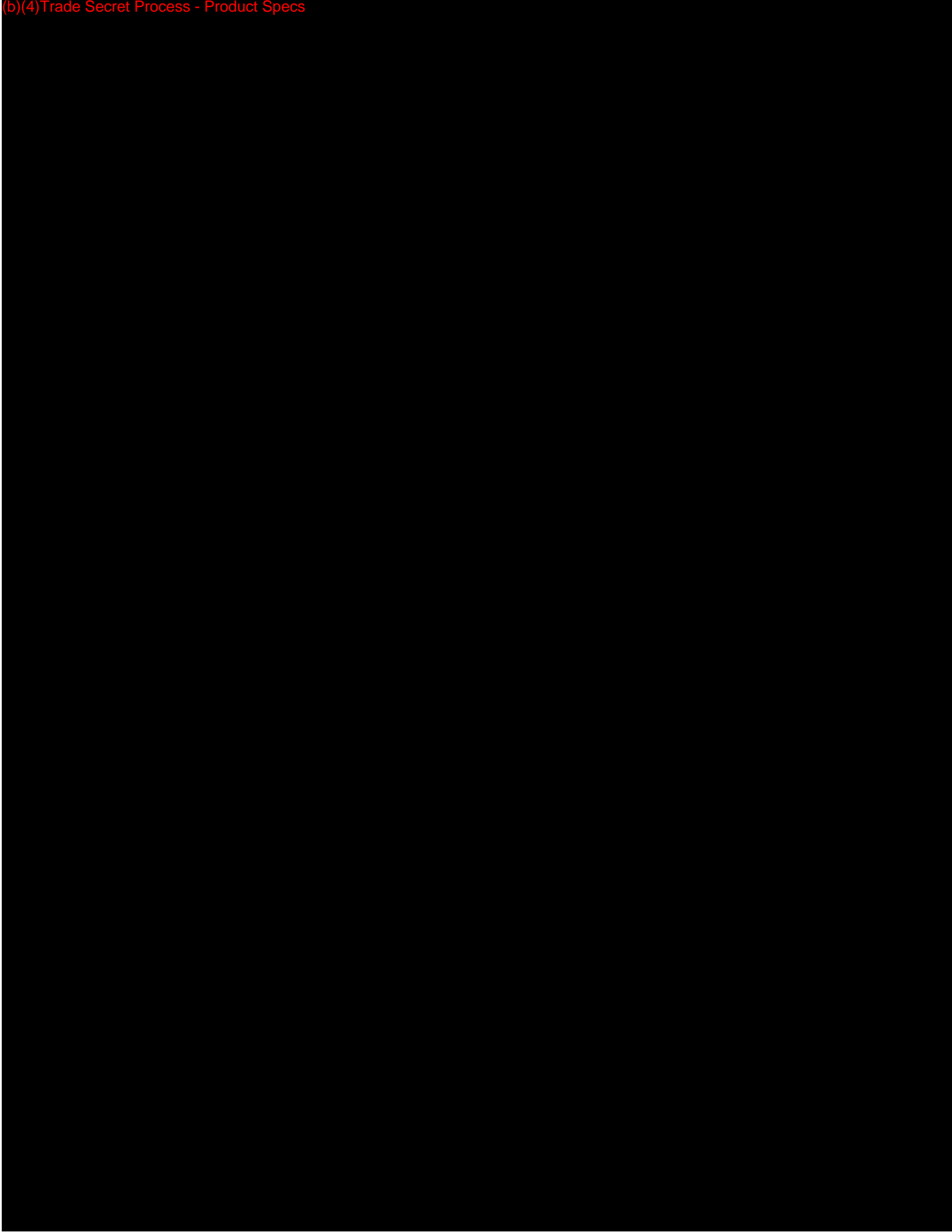
IMAGES AND FIGURES

ATTACHMENT 2

TEST RESULT DATA SHEETS

ATTACHMENT 3

Related Documentation





Performance Testing – Animal

[Redacted]

Animal testing to support the substantial equivalence of Vapor® Ceramic Brackets with its

[Redacted]



Performance Testing – Clinical

[REDACTED]

Clinical studies to support the substantial equivalence of Vapor® Ceramic Brackets with its

[REDACTED]

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 ¹

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 ²? ☒ ☐

FDA Recognition number ³ #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 ⁴ 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) ⁵? ☐ ☒

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 ⁶ 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

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

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

⁴ 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.

⁵ 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>

⁶ The online search for CDRH Guidance Documents can be found at 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 *

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 *

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 *

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.

* 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.



Orthodontic Design and Production, Inc.

Kit Certification

I certify that the following components of my kits 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.



(Signature)

Richard Merrell

(Typed Name)

7-26-13

(Date)



Kit Certification (Continued)

Kit Part Number: (b) [REDACTED]

Kit Description: (b)(4)Trade Secret Process

Kit Components:

(b)
(4) Trade
Secret
Process
- Product
Specs

(b)(4)Trade Secret
P d t S

(b)(4)Trade Secret Process -
Product Specs



Kit Certification (Continued)

Kit Part Number: (b) [redacted]

Kit Description: (b)(4)Trade Secret Process [redacted]
P d t S

Kit Components:

(b)(4)Trade Secret Process -
Product Specs

[redacted]

[redacted]

(b)(4)Trade
S
(b)(4)Trade Secret Process
P d t S

(b)(4)Trade Secret Process -
Product Specs

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]



Kit Certification (Continued)

Kit Part Number: (b) [REDACTED]

Kit Description: (b)(4)Trade Secret Process - [REDACTED]

Kit Components: P d t S

(b)(4)Trade Secret Process -
Product Specs

[REDACTED]

(b) [REDACTED]
(b)(4)Trade Secret Process - [REDACTED]
P d t S

(b)(4)Trade Secret Process -
Product Specs

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



Kit Certification (Continued)

Kit Part Number: (b)(4)Trade

Kit Description: (b)(4)Trade Secret Process -

Kit Components: P d t S

(b)(4)Trade Secret Process -
Product Specs

[Redacted text block]

[Redacted text block]

[Redacted text block]

(b)(4)Trade
(b)(4)Trade Secret Process -
P d t S

(b)(4)Trade Secret Process -
Product Specs

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]



Kit Certification (Continued)

Kit Part Number: (b)(4)Trade

Kit Description: (b)(4)Trade Secret Process -

Kit Components:

(b)(4)Trade Secret Process -
Product Specs

(b)(4)Trade

(b)(4)Trade Secret Process -
Product Specs

(b)(4)Trade Secret Process -
Product Specs



Kit Certification (Continued)

Kit Part Number: (b) [REDACTED]

Kit Description: (b)(4) Trade Secret

Kit Components:

(b)
(4) Trade
Secret
Process
- Product
Specs

(b)(4)Trade Secret
P P d t S

(b)(4)Trade Secret Process -
Product Specs



Kit Certification (Continued)

Kit Part Number: (b) [REDACTED]

Kit Description: (b)(4)Trade Secret Process - [REDACTED]

Kit Components:

(b)(4)Trade Secret Process -
Product Specs

[REDACTED]

(b)
(4)T-d
(b)(4)Trade Secret
P d tS

[REDACTED]

(b)(4)Trade Secret Process -
Product Specs

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



Kit Certification (Continued)

Kit Part Number: (b)(4)Trade

Kit Description: (b)(4)Trade Secret

Kit Components: P d t S

(b)(4)Trade Secret Process -
Product Specs

[Redacted content]

(b)
(4)T - d
(b)(4)Trade Secret Process -
P d t S

(b)(4)Trade Secret Process -
Product Specs

[Redacted content]



Kit Certification (Continued)

Kit Part Number: (b)(4)Trade

Kit Description: (b)(4)Trade Secret Process -

Kit Components: P d t S

(b)(4)Trade Secret Process -
Product Specs

[Redacted text block]

[Redacted text block]

(b)(4)Trade
(b)(4)Trade Secret Process -
P d t S

(b)(4)Trade Secret Process -
Product Specs

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]



Kit Certification (Continued)

Kit Part Number: (b)(4)Trade

Kit Description: (b)(4)Trade Secret Process -

Kit Components: P d t S

(b)(4)Trade Secret Process -
Product Specs

[Redacted text block]

[Redacted text block]

(b)(4)Trade
(b)(4)Trade Secret Process -
P d t S

(b)(4)Trade Secret Process -
Product Specs

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]



COVER SHEET MEMORANDUM

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

From: Reviewer Name Anita Belani
Subject: 510(k) Number K132368
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>)	×	
510(k) Summary or 510(k) Statement (<i>Attach Summary or Statement</i>)	×	
Truthful and Accurate Statement (<i>Must be present for a Final Decision</i>)	×	
Is the device Class III?		×
Does firm reference standards? (If yes, please attach Form 3654 .)	×	
Is this a combination product?		×
Is this a reprocessed single use device? (See Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices .)		×
Is this device intended for pediatric use only?		×
Is this a prescription device? (If both prescription & OTC, check both boxes.)	×	
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 was 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 to < 2 years)		×
Child (2 years to <12 years)		×
Adolescent (12 years to <18 years)		×
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.)		×
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)	×	




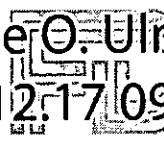
Nanotechnology		×
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		×

Regulation Number: 21CFR 872.5470

Class: II

Product Code: NJM

Additional Product Codes:

Digital Signature Concurrence Table	
(Not all signatures may be required)	
Branch Chief Sign-Off	  Mary S. Runner -S 2013.12.16 10:27:29 -05'00'
Division Sign-Off	  Kwame O. Ulmer -S 2013.12.17 09:47:44 -05'00'



Orthodontic Design and Production, Inc.

K132368/S001

eCopy Cover Letter

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

510(k) Number

K132368


Device Name:

Vapor® Ceramic Brackets

FDA CDRH DMC

AUG 21 2013

Received


(Signature)

Richard Merrel

(Typed Name)

August 19, 2013

(Date)



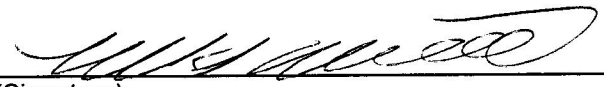
Orthodontic Design and Production, Inc.

eCopy Cover Letter

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

510(k) Number: K132368

Device Name: Vapor® Ceramic Brackets


(Signature)

Richard Merrell
(Typed Name)

August 19, 2013
(Date)



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

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

Richard Merrell
Regulatory Affairs Manager
Telephone: (760) 734-3995 ext. 25
Email: rm@odpinc.com

Additional

Bracket

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

2.5470

Class II

ental

1

N/A

There are no prior FDA submissions for the devices listed in this
510(k) submission (Vapor® Ceramic Brackets).



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

Question	YES	NO
...description use (21 CFR 801 Subpart D)?	X	
...the-counter use (21 CFR 807 Subpart C)?		X
...components derived from a tissue or other biologic		X
...		X
...?	X	
...se device?		X
...		X
...		X
...		X
...l info		X
...		X

[illegible]

handling more than one device. The rationale for bundling is that all devices in the submission fall under the same generic device type, do not differ in materials, energy source, function, or any other feature related to safety or effectiveness. Such similar regulatory controls sufficient to provide reasonable assurance that the devices (21 CFR 860.3(ii)) are employed. The only differences between the devices in this submission are the industry-standard, tooth-specific design features. The devices are manufactured. A listing of the devices being bundled in this submission is provided on the following pages within this section (Section 3).



Substantial Equivalence Discussion

Predicate:

1. FastBrazee® Ceramic Bracket
Orthodontic Design and Production, Inc.

Between Vapor® Ceramic Brackets and the predicate listed above, the predicate is discussed in terms of Indications for Use,

Brackets, [redacted] for
eth. [redacted]

single-use devices intended for use in conjunction with [redacted] movement of individual teeth. This bracket line is [redacted] and similar technological characteristics as the [redacted] differences between the brackets do not raise new types of safety [redacted] features in the brackets are:

[redacted] and distally through the bracket to hold the archwire

[redacted] and occlusal end of the brackets that facilitate the anchoring of [redacted] wire in place.

[redacted] incorporate a rough surface to facilitate bracket bonding to the

[redacted] of pure polycrystalline aluminum oxide. [redacted]

[redacted] to be used with both .018" and .022" wire throughout the [redacted] with standard [redacted] slots of .018" and .022". The bracket's [redacted] the elastic ligature with less pressure against the wire. [redacted]

[redacted] predicate device and the Vapor® bracket is the fact that the [redacted] tie-wing design on the gingival side of the archwire slot, while [redacted] tie-wing design to facilitate rotational control during the latter [redacted] please refer to the attached document titled "Predicate Device/[redacted]" for a visual representation of the design differences.



Performance Testing

1. The Vapor® shear strength is equivalent to the Predicate device because the Vapor® bracket [REDACTED] performance requirement. In the test, the average value was comparable to the predicate device.

2. The Vapor® wire torque test is equivalent to the Predicate device because the average Vapor® test samples exceeded the minimum test performance [REDACTED] Force, as well as the breaking value of the Predicate device.

[REDACTED] performance test is comparable to the Predicate device because [REDACTED] of a ligated wire on the Vapor® test samples was slightly higher [REDACTED] but still within an acceptable range.

[REDACTED] performance test is equivalent or better than the Predicate [REDACTED] bracket samples showed less fragmentation than the [REDACTED] removal from the substrates using the specified adhesive.



Instructions For Use

Name of Device:

Vapor® Ceramic Bracket

made of the alumina (ceramic) material, Vapor® ceramic brackets are small and are bonded to teeth, upon which an orthodontic wire is placed to move teeth into positions. Vapor® ceramic brackets achieve their intended purpose (to move teeth) through the specific torques, angulations, and distal offset of the bracket, along with archwire slots that are designed to hold the archwire (typically .018" or .022" thick).

The bracket is designed with tie wing undercut spaces to accommodate orthodontic archwires. The ceramic body with rounded corners and edges for patient comfort. The bracket is designed to be removed when needed. The bracket has a water soluble color placement dot as an indicator for placement on each tooth.

Orthodontic movement of natural teeth.



for single patient use.



Use for prescription use only, under the order of a licensed



Do not sell this device to sale by or on the order of a licensed



Products are delivered non-sterile to the customer.



Orthodontic Design and Production, Inc.

K132368/S002

FDA CDRH DMC

NOV 12 2013

Received

eCopy Cover Letter

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

510(k) Number: K132368

Device Name: Vapor® Ceramic Brackets

(Signature)

A handwritten signature in blue ink, appearing to read 'Richard Merrell', is written over a horizontal line.

Richard Merrell

(Typed Name)

November 7, 2013

(Date)

25



Orthodontic Design and Production, Inc.

eCopy Cover Letter

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

K132368

por® Ceramic Brackets

A handwritten signature in black ink, appearing to read 'L. J. M...', is written over a white rectangular background.

Error - Couldn't merge file with following reason - PdfReader not opened with owner password
09002621815f256b.pdf

System attempted to attach the file. Please look at attachments to open this file manually.



510(k) Summary

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

[REDACTED] Richard Merrell
Regulatory Affairs Manager
Telephone: (760) 734-3995 ext. 25
Facsimile: (760) 734-1735
Email: rm@odpinc.com

[REDACTED] 18, 2013

[REDACTED] por@

[REDACTED] Bracket, Ceramic, Orthodontic

[REDACTED] Ceramic Bracket, Class II
[REDACTED] 72.5470, Product Code: NJM)

[REDACTED] etBraces® Ceramic Brackets

[REDACTED] Small devices that are intended to be bonded to teeth, upon
[REDACTED] to move the teeth to desired positions. They are indicated for
[REDACTED] all ages when prescribed by an orthodontist. Ceramic
[REDACTED] offered as an aesthetic alternative to metal orthodontic
[REDACTED] tooth coloring, and blend in well enough that they are not as
[REDACTED] netic look is popular with many patients, and especially older
[REDACTED] ets have been [REDACTED] throughout the orthodontic industry for

[REDACTED] s brackets are manufactured from [REDACTED] crystalline alumina
[REDACTED] s that are designed to provide maximum adhesion to the tooth
[REDACTED] complete removal when necessary. The brackets incorporate a
[REDACTED] s an indicator for correct selection of brackets for each tooth.

[REDACTED] brackets do not incorporate medicinal substances, tissues, or
[REDACTED] e software or accessories, and are delivered non-sterile to the
[REDACTED] ended to be used only once by a single patient. Product labels
[REDACTED] 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 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 brackets. That is, specific torques, angulations, and distal offset dimensions are programmed into the brackets with archwire slots that are designed to accommodate the archwire (typically .018" or .022" thick).

The brackets have tie wing undercut spaces for orthodontic ligatures. They have rounded corners and edges, and rounded hooks on the sides to facilitate ligation during orthodontic treatment. These design features allow the orthodontist to attach a ligating wire to move the brackets, which are securely bonded to the teeth until the desired tooth position is reached. Elastic ligatures are used to further facilitate tooth movement, and to secure the archwire in the slot.

ended

The use of Vapor® Ceramic Brackets are identical to the predicate

Vapor® brackets and their predicate both incorporate specific design features, including set dimensions, along with archwire slots that are designed to accommodate the correct size archwire (typically .018" or .022" thick). They also have tie wing undercut spaces for orthodontic ligatures, have a molded ceramic body with rounded corners and edges for patient comfort, and rounded hooks on the sides to accommodate ligation during orthodontic treatment.

Vapor® ceramic brackets and its predicate are manufactured from a ceramic (zirconia) material, which is of known biocompatibility in the oral

The design characteristics of Vapor® ceramic brackets and its predicate allow the orthodontist to move the brackets, which are attached to the teeth along a pre-determined path until the desired tooth position is reached. Elastic ligatures may be used with the tie wings and hooks to further facilitate tooth movement and to secure the orthodontic wire into the bracket's archwire slot.



Comparison of Technological Differences between Subject and Predicate

	Subject Vapor Ceramic Bracket K122268	Predicate FastBraces Ceramic Bracket K130446
Indications for Use	Vapor Ceramic Brackets are intended for orthodontic movement of natural teeth.	FastBraces Ceramic Brackets are intended for orthodontic movement of natural teeth.
Technological Differences	<p>[REDACTED]</p> <p>[REDACTED] 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 brackets do not raise new types of safety or effectiveness issues. The fundamental features in the brackets are:</p> <p>[REDACTED] and [REDACTED] mesial and distally through the archwire slot and [REDACTED] mesial and distal end of the brackets that facilitate the anchoring of elastic ligatures to hold the wire in place.</p> <p>[REDACTED] incorporates a rough base pad surface to facilitate bracket bonding to the tooth.</p> <p>[REDACTED] is designed to be used with both standard and super-elastic archwires, and standard wire slots of .020" and .022". The bracket's tie-wings are designed to better contain the elastic ligature with less pressure against the wire.</p>	<p>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 (CDB Corporation's "Reflections" bracket K922499). Minor design differences between the brackets do not raise new types of safety or effectiveness issues. The fundamental features in the brackets are:</p> <p>[REDACTED] mesial and distally through the archwire slot and [REDACTED] mesial and distal end of the brackets that facilitate the anchoring of elastic ligatures to hold the wire in place.</p> <ul style="list-style-type: none">• A base pad surface that incorporates a rough surface to facilitate bracket bonding to the tooth.• A bracket that is comprised of pure polycrystalline aluminum oxide.
Differences	<p>[REDACTED] the predicate device is the fact that the predicate device has a .022" square super-elastic nickel-titanium wire slot, while the Vapor® bracket has a .020" square super-elastic nickel-titanium wire slot. This design difference is intended to facilitate the use of the Vapor® bracket in later stages of treatment.</p>	<p>Minor difference between the FastBraces ceramic brackets and the predicate device (CDB Corporation's "Reflections" bracket K922499) is that the FastBraces bracket is intended to be used with a .020" square super-elastic nickel-titanium wire exclusively throughout the treatment. The bracket is designed with a standard wire slot of .022". The bracket tie wings are designed to better contain the elastic ligature with less pressure against the wire. This combination of the smaller resilient wire in a standard wire slot with lower ligating forces is intended to produce lower wire drag forces and less strain on the bracket.</p>



	Subject Vapor Ceramic Bracket K132368	Predicate FastBraces Ceramic Bracket K130446
Performance Testing	<p>1. The [redacted] device is equivalent to the Predicate device because the Vapor® bracket exceeded the minimum test performance requirement. In the test, the average value was [redacted] the predicate device.</p> <p>[redacted] torque test is equivalent to the [redacted] because the average breaking [redacted] test samples exceeded the [redacted] performance requirement of 2400 [redacted] breaking value of the [redacted]</p> <p>[redacted] performance test is [redacted] the Predicate device because the [redacted] ligated wire on the [redacted] as slid [redacted]</p> <p>[redacted] bracket removal performance [redacted] better than the Predicate [redacted] device because the Fast Braces® bracket samples showed less fragmentation than the Predicate device upon removal from the substrates using the [redacted]</p>	<p>1. The Fast Braces® shear strength is equivalent to the Predicate device (CDB Corporation's "Reflections" bracket K922499) because the Fast braces bracket exceeded the minimum test performance requirement. In the test the average value was greater the predicate device.</p> <p>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.</p> <p>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 test samples was less than [redacted]</p> <p>[redacted] bracket removal performance [redacted] better than the Predicate [redacted] device because the Fast Braces® bracket samples showed less fragmentation than the Predicate device upon removal from the substrates using the specified adhesive.</p>

[redacted] for their intended use in orthodontic treatment, [redacted] a predicate device listed above. Vapor® ceramic brackets are [redacted] equivalent to the predicate with respect to intended use, [redacted] design, materials, performance, safety, effectiveness, and [redacted] changes are the only variations as compared to the predicate. [redacted] use or the fundamental scientific technology.

[redacted] its predicate are both made of the same ceramic [redacted] [redacted] well-documented history of biocompatibility within the oral [redacted] biocompatibility [redacted] report in accordance with ISO [redacted] Section 15 of this submission. Because the materials from [redacted] are well established in the orthodontic industry, product testing [redacted] not performed. Instead, a literature review has been conducted [redacted] 2009, Annex C. Section 15 of this submission also includes a [redacted] similar to the one that was requested by FDA during the review [redacted] submission (K130446). This Device Composition Statement [redacted] a laboratory material analysis.



Device Design:

Vapor® 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. Vapor® Ceramic Brackets and its predicate also contain base flanges for bracket placement and adhesive flash clearance. Vapor® 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 Vapor® Ceramic brackets contain vertical slot and stress concentrators to facilitate debonding of the bracket from the tooth.

[REDACTED] g:
[REDACTED] testing analysis shows that Vapor® Ceramic Brackets perform
[REDACTED] vice as follows:
[REDACTED] r strength required to remove a bonded bracket from a
[REDACTED] applied in the occlusal direction. The test results showed that
[REDACTED] Ceramic Brackets are comparable to the predicate, and
[REDACTED] strength required to affix the bracket to the tooth.
[REDACTED] s the torsional force required to break a bonded bracket when
[REDACTED] d in t [REDACTED] arable bracket
[REDACTED] the predicate
[REDACTED] Force [REDACTED]
[REDACTED] the fo [REDACTED] l wire through
[REDACTED] t. The test results showed that slightly higher forces (but still
[REDACTED]) were required to drag the Vapor® ceramic bracket along a
[REDACTED] than the predicate, indicating similar sliding mechanics during
[REDACTED]
[REDACTED] visual condition of a bonded bracket after twisting it
[REDACTED] The vapor® bracket removal test resulted in less bracket
[REDACTED] he predicate device when removing the bracket from a

[REDACTED] conducted on Vapor® Ceramic Brackets.
[REDACTED]
[REDACTED] re standard orthodontic appliances that are similar to those
[REDACTED] d use [REDACTED] nd effectively for many years [REDACTED] nical
[REDACTED] kets are engineered to be substantially equivalent to the
[REDACTED] se, technological characteristics, device design, materials,
[REDACTED] and biocompatibility. There are no major differences between
[REDACTED] e predicate device cited. Therefore, Vapor® Ceramic
[REDACTED] ty or effectiveness.
[REDACTED]
[REDACTED] gned and manufactured to industry-standard specifications
[REDACTED] blished and documented history of biocompatibility within the
[REDACTED] or® Ceramic Brackets are as safe and effective as the
[REDACTED] ed to be substantially equivalent to the referenced predicate
[REDACTED] ing these factors into account, it can be safely concluded that
[REDACTED] re of low risk to the end user, are clinically safe, and perform
[REDACTED] vice referred to herein.



Orthodontic Design and Production, Inc.

Proposed Labeling

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



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



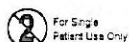
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U1-8L

VAPOR™ .018 UL1
+12°T +5°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



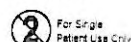
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U3-8LK

VAPOR™ .018 UL3 HK
0°T +11°A 4°R
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



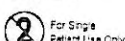
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U1-8R

VAPOR™ .018 UR1
+12°T +5°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



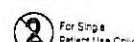
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U3-8RK

VAPOR™ .018 UR3 HK
0°T +11°A 4°R
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



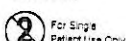
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U2-8L

VAPOR™ .018 UL2
+8°T +8°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



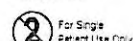
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U4-8U

VAPOR™ .018 UP45
-7°T 0°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



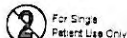
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U2-8R

VAPOR™ .018 UR2
+8°T +8°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U4-8LK

VAPOR™ .018 UL45 HK
-7°T 0°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design and Production, Inc.

Proposed Labeling

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



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U4-8RK

VAPOR™ .018 UR45 HK

-7°T 0°A

Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L4-8U

VAPOR™ .018 LO4

-17°T 0°A

Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L1-8U

VAPOR™ .018 LO1/2

0°T 0°A

Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L5-8LK

VAPOR™ .018 LL5 HK

-22°T 0°A

Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L3-8LK

VAPOR™ .018 LL3 HK

-11°T +5°A 2°R

Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L5-8RK

VAPOR™ .018 LR5 HK

-22°T 0°A

Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L3-8RK

VAPOR™ .018 LR3 HK

-11°T +5°A 2°R

Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L5-8U

VAPOR™ .018 LOS

-22°T 0°A

Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design and Production, Inc.


Proposed Labeling

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



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE  Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U1-2L

VAPOR™ .022 UL1
+12°T +5°A
Brackets

Qty: _ UM: EA

LOT -  For Single
Patient Use Only


Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE  Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U3-2LK

VAPOR™ .022 UL3 HK
0°T +11°A 4°R
Brackets

Qty: _ UM: EA

LOT -  For Single
Patient Use Only


Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE  Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U1-2R

VAPOR™ .022 UR1
+12°T +5°A
Brackets

Qty: _ UM: EA

LOT -  For Single
Patient Use Only


Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE  Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U3-2RK

VAPOR™ .022 UR3 HK
0°T +11°A 4°R
Brackets

Qty: _ UM: EA

LOT -  For Single
Patient Use Only


Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE  Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U2-2L

VAPOR™ .022 UL2
+8°T +9°A
Brackets

Qty: _ UM: EA

LOT -  For Single
Patient Use Only


Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE  Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U4-2U

VAPOR™ .022 UP45
-7°T 0°A
Brackets

Qty: _ UM: EA

LOT -  For Single
Patient Use Only


Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE  Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-U2-2R

VAPOR™ .022 UR2
+8°T +9°A
Brackets

Qty: _ UM: EA

LOT -  For Single
Patient Use Only


Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE  Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 75-L1-2U

VAPOR™ .022 LO1/2
0°T 0°A
Brackets

Qty: _ UM: EA

LOT -  For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design and Production, Inc.

Proposed Labeling

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



1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE **EC** **REF** Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647
0086

REF 75-L3-2LK

VAPOR™ .022 LL3 HK
-11°T +5°A 2°R
Brackets

Qty: _ UM: EA

LOT - For Single Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE **EC** **REF** Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647
0086

REF 75-L4-2RK

VAPOR™ .022 LR4 HK
-17°T 0°A
Brackets

Qty: _ UM: EA

LOT - For Single Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE **EC** **REF** Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647
0086

REF 75-L3-2RK

VAPOR™ .022 LR3 HK
-11°T +5°A 2°R
Brackets

Qty: _ UM: EA

LOT - For Single Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE **EC** **REF** Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647
0086

REF 75-L5-2U

VAPOR™ .022 LO5
-22°T 0°A
Brackets

Qty: _ UM: EA

LOT - For Single Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE **EC** **REF** Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647
0086

REF 75-L4-2U

VAPOR™ .022 LO4
-17°T 0°A
Brackets

Qty: _ UM: EA

LOT - For Single Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE **EC** **REF** Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647
0086

REF 75-L5-2LK

VAPOR™ .022 LL5 HK
-22°T 0°A
Brackets

Qty: _ UM: EA

LOT - For Single Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE **EC** **REF** Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647
0086

REF 75-L4-2LK

VAPOR™ .022 LL4 HK
-17°T 0°A
Brackets

Qty: _ UM: EA

LOT - For Single Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE **EC** **REF** Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647
0086

REF 75-L5-2RK

VAPOR™ .022 LR5 HK
-22°T 0°A
Brackets

Qty: _ UM: EA

LOT - For Single Patient Use Only

Made in USA

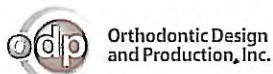
L604-01



Orthodontic Design and Production, Inc.

Proposed Labeling

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



1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE **EC REP** Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647
0086

REF 76-U1-8L

VAPOR™ .018 UL1
+17°T +4°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE **EC REP** Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647
0086

REF 76-U3-8LK

VAPOR™ .018 UL3 HK
-7°T +8°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE **EC REP** Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647
0086

REF 76-U1-8R

VAPOR™ .018 UR1
+17°T +4°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE **EC REP** Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647
0086

REF 76-U3-8LK0

VAPOR™ .018 UL3 HK
0°T +8°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE **EC REP** Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647
0086

REF 76-U2-8L

VAPOR™ .018 UL2
+10°T +8°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE **EC REP** Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647
0086

REF 76-U3-8RK

VAPOR™ .018 UR3 HK
-7°T +8°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE **EC REP** Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647
0086

REF 76-U2-8R

VAPOR™ .018 UR2
+10°T +8°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE **EC REP** Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647
0086

REF 76-U3-8RK0

VAPOR™ .018 UR3 HK
0°T +8°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design and Production, Inc.

Proposed Labeling

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



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



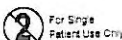
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U4-8U

VAPOR™ .018 UP4/5
-7°T 0°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



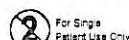
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L3-BLK

VAPOR™ .018 LL3 HK
-6°T +3°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



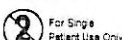
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U4-8LK

VAPOR™ .018 UL45 HK
-7°T 0°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



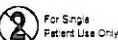
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L3-8LK0

VAPOR™ .018 LL3 HK
0°T +3°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



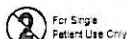
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U4-8RK

VAPOR™ .018 UR45 HK
-7°T 0°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



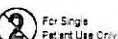
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L3-8RK

VAPOR™ .018 LR3 HK
-6°T +3°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



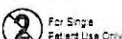
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L1-8U

VAPOR™ .018 L1/2
-6°T 0°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



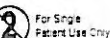
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L3-8RK0

VAPOR™ .018 LR3 HK
0°T +3°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design and Production, Inc.

Proposed Labeling

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



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



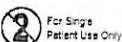
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L4-8U

VAPOR™ .018 L04
-12°T 0°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L5-8LK

VAPOR™ .018 LL5 HK
-17°T 0°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



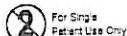
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L4-8LK

VAPOR™ .018 LL4 HK
-12°T 0°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



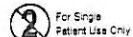
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L5-8RK

VAPOR™ .018 LR5 HK
-17°T 0°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



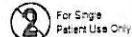
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L4-8RK

VAPOR™ .018 LR4 HK
-12°T 0°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



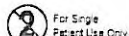
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L5-8U

VAPOR™ .018 L05
-17°T 0°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design and Production, Inc.

Proposed Labeling

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



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U1-2L

VAPOR™ .022 UL1
+17°T +4°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U3-2LK

VAPOR™ .022 UL3 HK
-7°T +8°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U1-2R

VAPOR™ .022 UR1
+17°T +4°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U3-2LK0

VAPOR™ .022 UL3 HK
0°T +8°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U2-2L

VAPOR™ .022 UL2
+10°T +8°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U3-2RK

VAPOR™ .022 UR3 HK
-7°T +8°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U2-2R

VAPOR™ .022 UR2
+10°T +8°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com

CE Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U3-2RK0

VAPOR™ .022 UR3 HK
0°T +8°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design and Production, Inc.

Proposed Labeling

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



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



0086

Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U4-2U

VAPOR™ .022 UP4/5
-7°T 0°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



0086

Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L3-2LK

VAPOR™ .022 LL3 HK
-6°T +3°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



0086

Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U4-2LK

VAPOR™ .022 UL45 HK
-7°T 0°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



0086

Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L3-2LK0

VAPOR™ .022 LL3 HK
0°T +3°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



0086

Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-U4-2RK

VAPOR™ .022 UR45 HK
-7°T 0°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



0086

Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L3-2RK

VAPOR™ .022 LR3 HK
-6°T +3°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



0086

Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L1-2U

VAPOR™ .022 L1/2
-6°T 0°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



0086

Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L3-2RK0

VAPOR™ .022 LR3 HK
0°T +3°A
Brackets

Qty: _ UM: EA

LOT - For Single
Patient Use Only

Made in USA

L604-01



Orthodontic Design and Production, Inc.

Proposed Labeling

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



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



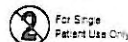
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L4-2U

VAPOR™ .022 LO4
-12°T 0°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



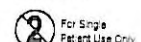
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L5-2LK

VAPOR™ .022 LL5 HK
-17°T 0°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L4-2LK

VAPOR™ .022 LL4 HK
-12°T 0°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



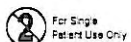
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L5-2RK

VAPOR™ .022 LR5 HK
-17°T 0°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



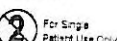
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L4-2RK

VAPOR™ .022 LR4 HK
-12°T 0°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design
and Production, Inc.

1370 Decision Street Ste D
Vista, California 92081 USA
800.383.5301 Outside USA 760.734.3995
www.odpinc.com • info@odpinc.com



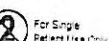
Victor Camps S.L. Plaza Mayor
40-2o-2a • 46600 Alzira Spain
Ph 00.3496.241.5647

REF 76-L5-2U

VAPOR™ .022 L05
-17°T 0°A
Brackets

Qty: _ UM: EA

LOT -



Made in USA

L604-01



Orthodontic Design and Production, Inc.

Proposed Labeling

Below is an example of 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. Please note that the labeling remains the same for all convenience kits, with the exception of the product part number, description, and lot number.

75K-3-22-6

Vapor™
CERAMIC BRACKET SYSTEM
 ROTH® PRESCRIPTION .022 UP 3x3 CASE
 HOOKS ON 3 (6 BRACKETS)
*ODP Inc. prescriptions do not imply endorsement by the Doctor

REF 75K-3-22-6
LOT

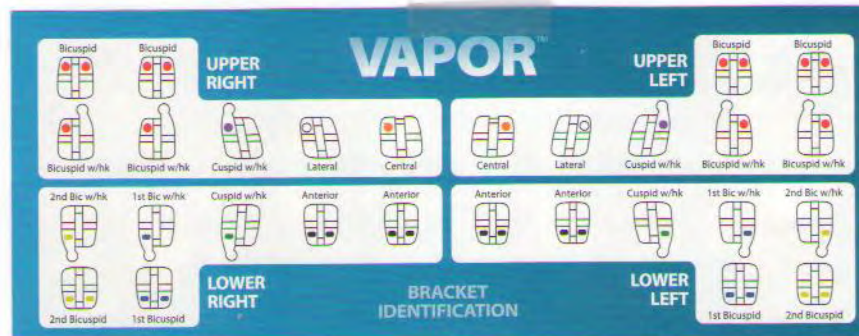
MADE IN USA

Orthodontic Design and Production, Inc.
 1370 Decision Street Suite D • Vista, California USA 92081
 Telephone: (760) 734-3995 • USA Toll Free: (800) 383-5301
 Fax: (760) 734-1735 • www.odpinc.com • info@odpinc.com
© 2009 Orthodontic Design and Production, Inc.

CE 0086 Victor Camps S.L. • Plaza Mayor 40-20-2a
 46600 Alzira Spain • Phone 00-3496-241-5647

CAUTION: Federal law restricts this device to sale by or on the order of a licensed health care professional.

10201
 PC SKU # 10201



1370 Decision Street, Suite D Vista, CA 92081
 Phone (760) 734-3995 Fax (760) 734-1735
 USA Toll Free 1-800-383-5301 www.odpinc.com



Biocompatibility

Predicate:

FastBrace™ Ceramic Bracket
Production, Inc.

predicate are constructed of identical materials, using identical
processes, and are manufactured in the same physical
environment. There is no introduction of contaminants into or on the surface
of the devices differing manufacturing process and facilities. The only
difference is the production of the device (FastBrace™) characteristics.

The devices are pre-sterilized in a dry heat (stalline)
environment. The devices are not in contact with the patient's mucosal membrane during the duration
of use, last more than 30 months.

The devices are constructed are well established in the
market. Biocompatibility was not performed. As per ISO
10993-1:2009, "An evaluation may include both a study of relevant
data and actual testing. Such an evaluation might result in the
conclusion that the material has a demonstrable safe history of use in a
similar environment to the device under design."

A literature review in accordance with ISO 10993-1:2009, Annex C.
(Compatibility Summary Report") is provided in the pages that

The submission is a Standards Data Report for 510(k)s (Form
FDA 10993-1:2009 in conducting the biological evaluation of the