

K110335

MAY 19 2011

5.510(k) Summary

K110335

510k Summary

Device Name: Ceramic Brackets

Submitter's Name, address, telephone number, contact person, and date the summary was prepared:

Submitter's Name: Ortho Organizers Inc.

Submitter's Address: 1822 Aston Ave. Carlsbad, CA 92008

Submitter's Telephone: 760-448-8600

760-448-8613 fax

Submitter's Contact: Foster Boop, Director of Regulatory Affairs and Quality Assurance

Email: Foster.Boop@OrthoOrganizers.com

Ph. 760-448-8600 ext 146

Date 510(K) Summary Prepared: January 31, 2011

Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Proprietary Name: Undetermined

Common or Usual Name: Ceramic Brackets

Classification Name: Bracket, Ceramic, Orthodontic

Classification Code: NJM

Identification of Legally Marketed Device: (Device Equivalence)

Proprietary Name: Transcend Ceramic Brackets

510K Number: K861965

Common or Usual Name: Ceramic Brackets

Classification Name: Bracket, Ceramic, Orthodontic

Classification Code: DYW

Device Manufacturer: 3M-Unitek Corp.

Proprietary Name: Transcend Ceramic Brackets
510K Number: K944286
Common or Usual Name: Ceramic Brackets
Classification Name: Bracket, Ceramic, Orthodontic
Classification Code: DYW
Device Manufacturer: 3M-Unitek

Proprietary Name: Clarity Modified Ceramic Brackets
510K Number: K062305
Common or Usual Name: Ceramic Brackets
Classification Name: Bracket, Ceramic, Orthodontic
Classification Code: NJM
Device Manufacturer: 3M-Unitek

Description of the Device:

The Ceramic Bracket line of products are single-use devices intended for use in conjunction with comprehensive orthodontics to control the movement of individual teeth.

These one-piece ceramic brackets are comprised of polycrystalline aluminum oxide. The general geometric composition of these devices is made of archwire slot, tie wings, and a pad (which provides a bonding surface). The archwire slot is a channel through the bracket used to engage the archwire. The tie wings are small hook shaped protrusion use as an anchor point for the ligature; ligatures work by tying the archwire into the archwire slot. The geometry of the pad is such that the bracket has a stable footprint. The pad is coated with aluminum oxide particles to facilitate bracket bonding with orthodontic adhesives.

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

Intended Use:

These devices are intended for the correction of orthodontic malocclusions as diagnosed by a dentist or orthodontist. They are used to transmit and provide axial directional control to the kinetic energy from an orthodontic archwire, for movement of individual teeth for treatment.

Summary of the technological characteristics of the device compared to the predicate devices:

The Ortho Organizer Ceramic Bracket System is substantially equivalent to the 3M Unitek Ceramic Bracket System. Table 1 summarizes the technological characteristics of this equivalence:

Table 1.

Product Parameter	Bracket	Predicate Product: 3M Unitek Transcend and Clarity*	Ortho Organizer's ceramic brackets	Substantial Equivalence Analysis
510k Number	All	K861965, K944286, K062305	Pending	N/A
Intended use per 872.5470	All	intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter the tooth's position	intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter the tooth's position	Equivalent
Bracket Body Material	All	99.9% Polycrystalline aluminum oxide	99.9% Polycrystalline aluminum oxide	Equivalent
Pad Coating Material	All	Irregular Microcrystalline Aluminum Oxide	Irregular Microcrystalline Aluminum Oxide	Equivalent
Biocompatibility	All	Yes	Yes	Equivalent
Single Use	All	Yes	Yes	Equivalent
Non-Sterile packaging	All	Yes	Yes	Equivalent
Color coded indicator for bracket identification	All	Yes	Yes, optional	Equivalent

* A claim of Substantial Equivalence to the 3M Unitek Ceramic Bracket system is not made for the metal insert feature available in this product line. The Transcend Bracket, like the Ortho Organizer Ceramic Bracket, does not include this feature.

Conclusion:

The Ortho Organizer Ceramic Bracket System has the same intended use and similar technological characteristics as the predicate device. The minor differences in technological characteristics do not raise new types of safety and effectiveness questions. Descriptive and performance testing demonstrate substantial equivalence.



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

Mr. Foster Boop
Director of Regulatory Affairs and Quality
Ortho Organizers, Incorporated
1822 Aston Avenue
Carlsbad, California 92008-7603

MAY 19 2011

Re: K110335
Trade/Device Name: Ceramic Brackets Impression Compound
Regulation Number: 21 CFR 872.5470
Regulation Name: Plastic Orthodontic Bracket
Regulatory Class: II
Product Code: NJM
Dated: January 31, 2011
Received: February 15, 2011

Dear Mr. Boop:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110335

Device Name: Ceramic Brackets

Indications for Use:

These ceramic brackets will be used for correction of malocclusions as diagnosed and overseen by trained practitioners of orthodontics. These brackets will be directly bonded to teeth; will have interface with the archwire to direct applied forces. These devices are intended for single use only and are not delivered in a sterile state.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110335



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

Mr. Foster Boop
Director of Regulatory Affairs and Quality
Ortho Organizers, Incorporated
1822 Aston Avenue
Carlsbad, California 92008-7603

MAY 19 2011

Re: K110335
Trade/Device Name: Ceramic Brackets Impression Compound
Regulation Number: 21 CFR 872.5470
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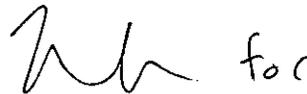
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Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
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Enclosure

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE).



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

510(k) Number: K110335



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

April 19, 2011

ORTHO ORGANIZERS, INC.
1822 ASTON AVENUE
CARLSBAD, CALIFORNIA 92008-7603
ATTN: FOSTER BOOP

510k Number: K110335

Product: CERAMIC BRACKETS

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

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

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

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

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

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health



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

February 16, 2011

ORTHO ORGANIZERS, INC.
1822 ASTON AVENUE
CARLSBAD, CALIFORNIA 92008-7603
ATTN: FOSTER BOOP

510k Number: K110335

Received: 2/15/2011

Product: CERAMIC BRACKETS

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

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

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

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

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007"

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

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

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

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

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

Sincerely,

510(k) Staff

30



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center 4 WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 04, 2011

ORTHO ORGANIZERS, INC.
1822 ASTON AVENUE
CARLSBAD, CALIFORNIA 92008-7603
UNITED STATES
ATTN: FOSTER BOOP

510k Number: K110335
Received: 2/4/2011
User Fee ID Number: 6053806
Product: CERAMIC BRACKETS

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

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

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

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

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

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

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm>.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)796-7100 or its toll-free number (800)638-2041, or contact them at their Internet address

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Diane Garcia at Diane.Garcia@fda.hhs.gov or directly at (301)796-7200. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Diane Garcia
Public Affairs Specialist
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

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4-35.

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1. Medical Device User Fee Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade Secret Process Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover-sheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) ORTHO ORGANIZERS INC 1822 Aston Avenue Carlsbad CA 92008 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****1977	2. CONTACT NAME Foster Boop 2.1 E-MAIL ADDRESS foster.boop@orthoorganizers.com 2.2 TELEPHONE NUMBER (include Area code) 760-448-8600 2.3 FACSIMILE (FAX) NUMBER (include Area code)	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) <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"/> Annual Fee for Periodic Reporting (APR) <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/cdrh/mdufma for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <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

19-Jan-2011

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

2. CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 FOOD AND DRUG ADMINISTRATION
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
 OMB No. 0910-0120
 Expiration Date: August 31, 2010.
 See OMB Statement on page 5.

Date of Submission 1/31/2011	User Fee Payment ID Number (b)(4)Trade	FDA Submission Document Number (if known)
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SECTION A TYPE OF SUBMISSION

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Ortho Organizers, Inc.		Establishment Registration Number (if known) 2081322	
Division Name (if applicable)		Phone Number (including area code) 760-448-8600	
Street Address 1822 Aston Ave.		FAX Number (including area code) 760-448-8613	
City Carlsbad	State / Province CA	ZIP/Postal Code 92008	Country USA
Contact Name Foster Boop			
Contact Title Director of Regulatory Affairs and Quality Assurance		Contact E-mail Address Foster.Boop@orthoorganizers.com	

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

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

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SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR HDE

<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (specify):		

SECTION D2

REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		
<input type="checkbox"/> Other Reason (specify):		

SECTION D3

REASON FOR SUBMISSION - 510(k)

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (specify):		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	DYW	2	DYW	
3	NJM	4		
5		6		
7		8		

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

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K861965	Transcend Ceramic Brackets	3M Unitek Corp.
2	K944286	Transcend Ceramic Brackets	3M Unitek Corp.
3	K062305	Clarity Modified Ceramic Brackets	3M Unitek Corp.
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	TBD	VARIOUS
2		
3		
4		
5		

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

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

Data Included in Submission
 Laboratory Testing
 Animal Trials
 Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code NJM	C.F.R. Section (if applicable) 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)

 These ceramic brackets will be used for correction of malocclusions as diagnosed and overseen by trained practitioners of orthodontics. These brackets will be directly bonded to teeth; will have interface with the archwire to direct applied forces. These devices are intended for single use only and are not delivered in a sterile state.

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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 2081322	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Ortho Organizers Inc.		Establishment Registration Number 2081322		
Division Name (if applicable)		Phone Number (including area code)		
Street Address 1822 Aston Ave.		FAX Number (including area code)		
City Carlsbad		State / Province CA	ZIP Code 92008	Country USA
Contact Name Foster Boop		Contact Title Director of Regulatory Affairs and Quality Assurance		Contact E-mail Address Foster.Boop@orthoorganizers.com

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 1054415	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input checked="" type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name (b)(4)Trade		Establishment Registration Number (b)		
Division Name (if applicable)		Phone Number (including area code) (b)		
Street Address (b)(4)Trade		FAX Number (including area code) (b)		
City (b)		State / Province ■	ZIP Code (b)	Country (b)
Contact Name (b)		Contact Title (b)(4)Trade		Contact E-mail Address (b)(4)Trade

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> 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

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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 2081322	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Ortho Organizers Inc.		Establishment Registration Number 2081322		
Division Name (if applicable)		Phone Number (including area code)		
Street Address 1822 Aston Ave.		FAX Number (including area code)		
City Carlsbad		State / Province CA	ZIP Code 92008	Country USA
Contact Name Foster Boop		Contact Title Director of Regulatory Affairs and Quality Assurance		Contact E-mail Address Foster.Boop@orthoorganizers.com

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 1054415	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input checked="" type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name (b)(4)Trade		Establishment Registration Number (b)		
Division Name (if applicable)		Phone Number (including area code) (b)		
Street Address (b)(4)Trade		FAX Number (including area code) (b)		
City (b)		State / Province (b)	ZIP Code (b)	Country (b)
Contact Name (b)		Contact Title (b)(4)Trade		Contact E-mail Address (b)(4)Trade

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

SECTION I

UTILIZATION OF STANDARDS

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

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

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

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

Department of Health and Human Services
 Food and Drug Administration
 Office of the Chief Information Officer (HFA-710)
 5600 Fishers Lane
 Rockville, Maryland 20857

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.

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3. 510(k) Cover Letter

K110335



FDA CDRH DMC

FEB 04 2011

~~REMOVED~~

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

January 31, 2011

RE: Traditional 510(k) Premarket Notification – Ortho Organizers Ceramic Bracket

Dear Sir or Madam,

Pursuant to Section 510(k) of the Food, Drug and Cosmetics Act and 21 CFR 807, Ortho Organizers hereby notifies FDA of its intent to introduce a new device, the Ortho Organizers Ceramic Bracket, into commercial distribution. Enclosed are two copies of a Traditional 510(k) Premarket Notification. Ortho Organizers believes the new device is substantially equivalent, for the purpose of FDA's regulation of medical devices, to other devices that are cleared for marketing within the United States. The data and information in this submission is supplied in conformance with 21 CFR 807.87.

Manufacturer Name: Ortho Organizers
1822 Aston Avenue
Carlsbad, CA. 92008
Telephone 1 (760) 448-8600
Fax 1 (760) 448-8613

Submission Contact: Foster Boop
Director RA/QA
Telephone 1 (760) 448-8730

Device Name and Classification:	
Device	Bracket, Ceramic, Orthodontic
Regulation Description	Orthodontic plastic bracket
Definition	An orthodontic ceramic bracket is a device composed of ceramic, which is intended to be bonded to a tooth, upon which an orthodontic wire is used to move the tooth to a new position. (Note: the current classification only specifies plastic brackets)
Review Panel	Dental
Product Code	NJM
Regulation Number	872.5470
Device Class	Class 2

45



Design and Use of the Device

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

Ortho Organizers considers its intent to market this device as confidential commercial information and requests that this premarket notification presented herein be treated as confidential commercial information in accordance with 21 CFR 807.95. Neither Ortho Organizers nor, to the best of our knowledge, anyone else, has disclosed through advertising or any other manner, our intent to market the device to scientists, market analysts, exporters, or other individuals, except employees of, or paid consultants to, the establishment or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy. Ortho Organizers will immediately notify the Food and Drug Administration if such disclosure is made of our intent to market the device to anyone, except employees of, or paid consultants to, the establishment or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy. Ortho Organizers has taken precautions to protect the confidentiality of the intent to market the device; and understands that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Sincerely,

Foster Boop
 Director of Regulatory Affairs and Quality Assurance
 Ortho Organizers

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K110335

Device Name: Ceramic Brackets

Indications for Use:

These ceramic brackets will be used for correction of malocclusions as diagnosed and overseen by trained practitioners of orthodontics. These brackets will be directly bonded to teeth; will have interface with the archwire to direct applied forces. These devices are intended for single use only and are not delivered in a sterile state.

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
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5.510(k) Summary

K110335

510k Summary

Device Name: Ceramic Brackets

Submitter's Name, address, telephone number, contact person, and date the summary was prepared:

Submitter's Name: Ortho Organizers Inc.

Submitter's Address: 1822 Aston Ave. Carlsbad, CA 92008

Submitter's Telephone: 760-448-8600

760-448-8613 fax

Submitter's Contact: Foster Boop, Director of Regulatory Affairs and Quality Assurance

Email: Foster.Boop@OrthoOrganizers.com

Ph. 760-448-8600 ext 146

Date 510(K) Summary Prepared: January 31, 2011

Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Proprietary Name: Undetermined

Common or Usual Name: Ceramic Brackets

Classification Name: Bracket, Ceramic, Orthodontic

Classification Code: NJM

Identification of Legally Marketed Device: (Device Equivalence)

Proprietary Name: Transcend Ceramic Brackets

510K Number: K861965

Common or Usual Name: Ceramic Brackets

Classification Name: Bracket, Ceramic, Orthodontic

Classification Code: DYW

Device Manufacturer: 3M-Unitek Corp.

Proprietary Name: Transcend Ceramic Brackets
510K Number: K944286
Common or Usual Name: Ceramic Brackets
Classification Name: Bracket, Ceramic, Orthodontic
Classification Code: DYW
Device Manufacturer: 3M-Unitek

Proprietary Name: Clarity Modified Ceramic Brackets
510K Number: K062305
Common or Usual Name: Ceramic Brackets
Classification Name: Bracket, Ceramic, Orthodontic
Classification Code: NJM
Device Manufacturer: 3M-Unitek

Description of the Device:

The Ceramic Bracket line of products are single-use devices intended for use in conjunction with comprehensive orthodontics to control the movement of individual teeth.

These one-piece ceramic brackets are comprised of polycrystalline aluminum oxide. The general geometric composition of these devices is made of archwire slot, tie wings, and a pad (which provides a bonding surface). The archwire slot is a channel through the bracket used to engage the archwire. The tie wings are small hook shaped protrusion use as an anchor point for the ligature; ligatures work by tying the archwire into the archwire slot. The geometry of the pad is such that the bracket has a stable footprint. The pad is coated with aluminum oxide particles to facilitate bracket bonding with orthodontic adhesives.

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

Intended Use:

These devices are intended for the correction of orthodontic malocclusions as diagnosed by a dentist or orthodontist. They are used to transmit and provide axial directional control to the kinetic energy from an orthodontic archwire, for movement of individual teeth for treatment.

Summary of the technological characteristics of the device compared to the predicate devices:

The Ortho Organizer Ceramic Bracket System is substantially equivalent to the 3M Unitek Ceramic Bracket System. Table 1 summarizes the technological characteristics of this equivalence:

Table 1.

Product Parameter	Bracket	Predicate Product: 3M Unitek Transcend and Clarity*	Ortho Organizer's ceramic brackets	Substantial Equivalence Analysis
510k Number	All	K861965, K944286, K062305	Pending	N/A
Intended use per 872.5470	All	intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter the tooth's position	intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter the tooth's position	Equivalent
Bracket Body Material	All	99.9% Polycrystalline aluminum oxide	99.9% Polycrystalline aluminum oxide	Equivalent
Pad Coating Material	All	Irregular Microcyrstalline Aluminum Oxide	Irregular Microcyrstalline Aluminum Oxide	Equivalent
Biocompatibility	All	Yes	Yes	Equivalent
Single Use	All	Yes	Yes	Equivalent
Non-Sterile packaging	All	Yes	Yes	Equivalent
Color coded indicator for bracket identification	All	Yes	Yes, optional	Equivalent

* A claim of Substantial Equivalence to the 3M Unitek Ceramic Bracket system is not made for the metal insert feature available in this product line. The Transcend Bracket, like the Ortho Organizer Ceramic Bracket, does not include this feature.

Conclusion:

The Ortho Organizer Ceramic Bracket System has the same intended use and similar technological characteristics as the predicate device. The minor differences in technological characteristics do not raise new types of safety and effectiveness questions. Descriptive and performance testing demonstrate substantial equivalence.

6. Truthful and Accuracy Statement

Premarket Notification Truthful And Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Director of Regulatory Affairs and Quality Assurance of Ortho Organizers, 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.

Foster Boop

(Signature)

Foster Boop

(Typed Name)

January 31, 2011

(Date)

*(Premarket Notification [510(k)] Number)

**7. Class III Summary and Certification
(Not Applicable)**

**8. Financial Certification or Disclosure
(Not Applicable)**

**9. Declarations of Conformity and Summary Reports
(Not Applicable)**

10. Executive Summary

Executive Summary

Ortho Organizer's ceramic brackets are indicated for correction of malocclusions as diagnosed and overseen by trained practitioners of orthodontics. The ceramic brackets will be directly bonded to teeth and will interface with an archwire to direct applied forces. These brackets are intended for single use only and are not delivered in a sterile state. They have been designed to work in conjunction with commercially available archwires, wire ligatures, elastics, orthodontic appliances, auxiliaries, and accessories.

The one-piece brackets are comprised of polycrystalline aluminum oxide material. The geometry of the device is comprised of an archwire slot, tie wings, and a pad (bonding surface). The archwire slot is a channel through the bracket used to engage the archwire. The tie wings are small hook shaped protrusions used as anchor points for ligatures that secure the archwire into the archwire slot. The geometry of the pad is such that the bracket has a stable footprint. The pad of the bracket is (b)(4)Trade Secret Process

Diagram 1: Image of Maxillary Central Incisor Bracket

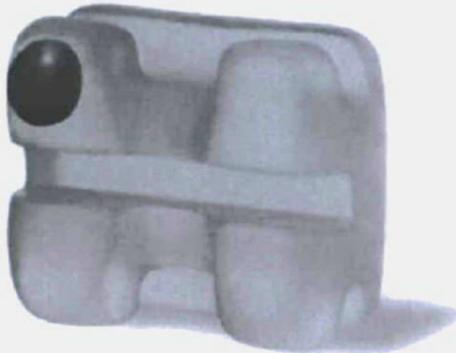
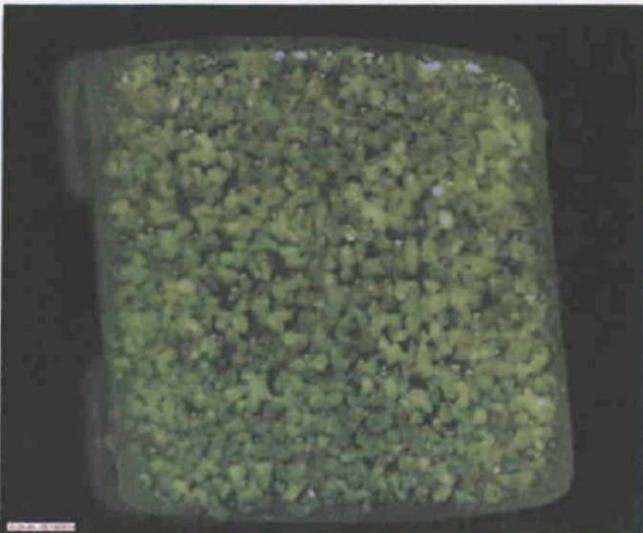


Diagram #2: Image of coated base (original magnification 60x)



Geometries and features vary from bracket to bracket, corresponding to the teeth for which they are intended. The geometries contribute to the fit of the bracket to the tooth and also impart the axial control of the energy from the archwire. Table 1 contains the range of available geometries and features.

Table 1: Range of available geometries and features

Geometry / Feature	Range of values
Torque	(b)(4)Trade Secret Process
Angulation	
In/Out	
Slot Depth	
Medial – Distal width	
Occlusal Gingival Height	
Mesial – Distal Base Radii	
Occlusal Gingival Base Radii	
Slot sizes	0.018 inches and 0.022 inches
Hooks	U3, U4/5, L3, L4, and L5 brackets may have two options: (i) No Hook (ii) Hook.

Table 2 provides the degrees of torque and angulation that will be available in the Roth and MBT prescriptions. Other generally accepted orthodontic prescriptions may also be offered and the geometry of the brackets will fall within the values provided in table 1.

Table 2 Description	Teeth	Roth Prescription		MBT Prescription	
		Torque	Angulation	Torque	Angulation
U 1 Cen	Maxillary Central Incisors	(b)(4)Trade Secret Process			
U 2 Lat	Maxillary Lateral Incisors				
U 3 Cus	Maxillary Cuspids				
U 3 Cus Hook	Maxillary Cuspids				
U 4/5 Bi	Maxillary Bicuspid				
U 4/5 Bi Hook	Maxillary BiCuspids				
L 3 Cus	Mandibular Cuspids				
L 3 Cus Hook	Mandibular Cuspids				
L 4 1Bi Univ	Mandibular 1 st Bicuspid				
L 4 1Bi Hk Univ	Mandibular 1 st Bicuspid				
L 5 2Bi Univ	Mandibular 2 nd Bicuspid				
L 5 2Bi Hk Univ	Mandibular 2 nd Bicuspid				
L 1 Ant	Mandibular Anteriors				
L 1 Ant Twin	Mandibular Anteriors				

Manufacturing:

Manufacturing of these ceramic brackets involve several processes. These processes can be grouped into two categories: (i) Fabrication of brackets and (ii) Application of base coating.

Fabrication of brackets involve several processes – (b)(4)Trade Secret Process
[Redacted]

Application of the base coating also involves several processes. These are – (b)(4)Trade Secret Process
[Redacted]

Packaging:

Packaging includes a variety of non sterile configurations. The brackets may be sold individually or in sets corresponding to an orthodontic prescription.

The brackets will not be sold as a component or in combination with other devices.

Color coding:

The brackets may have color code indicators providing positive bracket identification to facilitate accurate placement. The indicators may be permanent or removable.

Predicate Device Comparison Table:

Product Parameter	Bracket	Predicate Product: 3M Unitek Transcend	Ortho Organizer's ceramic brackets	Substantial Equivalence Analysis
Intended use per 872.5470	All	intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter the tooth's position	intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter the tooth's position	Equivalent
Bracket Body Material	All	99.9% Polycrystalline aluminum oxide	99.9% Polycrystalline aluminum oxide	Equivalent
Pad Coating Material	All	Irregular (b)(4)Trade Secret Process	Irregular (b)(4)Trade Secret Process	Equivalent
Bond Strength (mean +/- Stdev, lbf)	Maxillary Central Incisor - Left	(b)(4)Trade Secret Process		Equivalent
	Mandibular Anterior 1/2			Equivalent
Tie Wing Crush Strength (mean +/- Stdev, lbf)	Maxillary Central Incisor - Left			Equivalent
	Mandibular Anterior 1/2		Equivalent	
Hook Strength (mean +/- Stdev, lbf)	Mandibular Cuspid - Left / Maxillary Cuspid - Right			Equivalent
Single Use	All	Yes	Yes	Equivalent
Non-Sterile packaging	All	Yes	Yes	Equivalent
Color coded indicator for bracket identification	All	Yes	Yes, optional	Equivalent

Substantial Equivalence Discussion:

Intended Use – The predicate brackets and the Ortho Organizer Ceramic Brackets have identical intended use; both are intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter the tooth's position. Additionally, the predicate brackets and Ortho Organizer Ceramic Brackets are single use devices. Medical devices can be considered substantially equivalent when they have the same intended use.

Technological Characteristics – The predicate brackets and Ortho Organizer Ceramic Brackets have similar technological characteristics. The brackets are both manufactured from polycrystalline aluminum oxide. Both brackets use the same base coating material: (b)(4)Trade Secret Process. The Ortho Organizer Ceramic Bracket does not have a metal insert as found in the Clarity Bracket System. This feature is not present in the Transcend Bracket either. A single hook feature as found in the Clarity Bracket is also present in the Ortho Organizer Ceramic Bracket. This feature is not found in the Transcend Bracket. The minor differences in technological characteristics do not raise new types of safety and effectiveness questions. Performance testing demonstrate substantial equivalence.

Mechanical Properties – The predicate brackets and Ortho Organizer Ceramic Brackets have equivalent mechanical properties. Testing was conducted to assess mechanical performance.

Bond Strength: Results indicate the Ortho Organizer Ceramic Brackets have (b)(4)Trade Secret Process not considered to be significantly different. Testing was performed on brackets with the largest and smallest bonding bases.

Tie Wing Crush Strength: Result indicate the Ortho Organizer Ceramic Brackets (b)(4)Trade Secret Process brackets. The test assesses a combination of failure modes; ligation of the tie wings and torquing of the archwire. A (b)(4)Trade Secret Process Ceramic Bracket is not considered to be significantly different. Testing was performed on the smallest and largest brackets.

Hook Strength: Result indicate the Ortho Organizer Ceramic Brackets have (b)(4)Trade Secret Process. The (b)(4)Trade Secret Process generate a significant difference that could negatively impact safety or performance. The expected maximum continuous force applied to the single hook (b)(4)Trade Secret Process Ortho Organizer Ceramic Brackets will not break unless more than (b)(4)Trade Secret Process

continuous force is applied. The single hook design was selected for testing because it is weaker than the double (or universal) hook design.

Biocompatibility – The predicate device and Ortho Organizers Ceramic Brackets are both manufactured from Aluminum Oxide materials that have been well characterized chemically and physically in the published literature and have a long history of safe use in Orthodontics. To verify that the Ortho Organizers Ceramic Brackets are biocompatible a MEM Elution Test for cytotoxicity was performed. Testing results showed a grade 0 reactivity response indicating the test article is not cytotoxic.

11. Device Description

Device Description

Ortho Organizer's ceramic brackets are indicated for correction of malocclusions as diagnosed and overseen by trained practitioners of orthodontics. The ceramic brackets will be directly bonded to teeth and will interface with an archwire to direct applied forces. These brackets are intended for single use only and are not delivered in a sterile state. They have been designed to work in conjunction with commercially available archwires, wire ligatures, elastics, orthodontic appliances, auxiliaries, and accessories.

The geometry of the device is comprised of an archwire slot, tie wings, and a pad (bonding surface). The archwire slot is a channel through the bracket used to engage the archwire. The tie wings are small hook shaped protrusions used as anchor points for ligatures that secure the archwire into the archwire slot. The geometry of the pad is such that the bracket has a stable footprint.

Table 1: Range of available bracket geometries and features

Geometry / Feature	Range of values
Torque	(b)(4)Trade Secret Process
Angulation	
In/Out	
Slot Depth	
Medial – Distal width	
Occlusal Gingival Height	
Mesial – Distal Base Radii	
Occlusal Gingival Base Radii	
Slot sizes	0.018 inches and 0.022 inches
Hooks	Maxillary Cuspids (left and right), Maxillary Bicuspids (left and right), Mandibular Cuspids (left and right) Mandibular 1st Bicuspid (left and right), Mandibular 2nd Bicuspid (left and right) brackets may have two options: (i) No Hook (ii) Hook.

Brackets designs will be available for:
 Maxillary Central Incisors
 Maxillary Lateral Incisors (left and right)
 Maxillary Cuspids (left and right)
 Maxillary Bicuspids (left and right)
 Mandibular Cuspids (left and right)
 Mandibular 1st Bicuspid (left and right)
 Mandibular 2nd Bicuspid (left and right)
 Mandibular Anteriors

The one-piece brackets are comprised of polycrystalline aluminum oxide material. The pad of the bracket is coated (b)(4)Trade Secret [redacted] aluminum oxide particles to provide enhanced surface area and undercuts for orthodontic adhesive bonding and debonding. (b)(4)Trade Secret Process [redacted]

Table 1: Bracket materials

Bracket Component	Material	Composition
Body	polycrystalline aluminum oxide (Al ₂ O ₃)	(b)(4)Trade Secret Process
Base Coating	irregular aluminum oxide particles (Al ₂ O ₃)	
Dental Glass	(b)(4)Trade Secret Process	

Trade names:

The ceramic brackets may be marketed with Trade Names such as NeoLucent®2, NeoLucent® Plus™, NeoLucent® II, NeoLucent® Max™, NeoLucent® Clear™, Neo™ NeoLucent®, NeoLucent® Trans™, PCA™ Clear or other similar names. Definitive trade names have not been determined at the time of this notification.

12. Substantial Equivalence Discussion

Substantial Equivalence Discussion

Ortho Organizers submits the information in this Premarket Notification to demonstrate that, for purposes of FDA's regulation of medical devices, the Ortho Organizer Ceramic Brackets are substantially equivalent in intended use, materials and design principles to the 3M Unitek Transcend and Clarity Brackets.

The intended use, materials, design and functional characteristics of the Ortho Organizers Ceramic Brackets and the predicate device are substantially the same. Both are intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter the tooth's position. The basic design and materials are the same; both bracket systems include brackets for maxillary and mandible teeth: Maxillary Central Incisors, Maxillary Lateral Incisors (left and right), Maxillary Cuspids (left and right), Maxillary Bicuspid (left and right), Mandibular Cuspids (left and right), Mandibular 1st Bicuspid (left and right), Mandibular 2nd Bicuspid (left and right) and Mandibular Anteriors. The Ortho Organizer Ceramic Bracket will be available with both a single hook and a double (or universal hook) design like the Clarity Bracket that has a single hook design in addition to a universal hook design. The Transcend Bracket lacks a single hook design. The metal lined feature found in the Clarity Bracket will not be offered in the Ortho Organizer Ceramic Bracket. The Transcend Bracket also lacks a metal lined feature. Materials used in the construction of each bracket system are identical: 99.9% Polycrystalline aluminum oxide. Additionally, both bracket systems will be available with (b) microcrystalline aluminum oxide coating on their bases. (4)T d

The table on the following page summarizes the substantial equivalence of the Ortho Organizer Ceramic Bracket with the predicate device. Relevant information on the predicate device is also included.

Summary Table of Substantial Equivalence.

Product Parameter	Bracket	Predicate Product: 3M Unitek Transcend and Clarity*	Ortho Organizer's ceramic brackets	Substantial Equivalence Analysis
510k Number	All	K861965, K944286, K062305	Pending	N/A
Intended use per 872.5470	All	intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter the tooth's position	intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter the tooth's position	Equivalent
Bracket Body Material	All	99.9% Polycrystalline aluminum oxide	99.9% Polycrystalline aluminum oxide	Equivalent
Pad Coating Material	All	Irregular Microcyrstalline Aluminum Oxide	irregular Microcyrstalline Aluminum Oxide	Equivalent
Bond Strength (mean +/- Stdev, lbf)	Maxillary Central Incisor - Left	(b)(4)Trade Secret Process		Equivalent
	Mandibular Anterior 1/2			Equivalent
Tie Wing Crush Strength (mean +/- Stdev, lbf)	Maxillary Central Incisor - Left			Equivalent
	Mandibular Anterior 1/2			Equivalent
Hook Strength (mean +/- Stdev, lbf)	Mandibular Cuspid - Left / Maxillary Cuspid - Right			
Single Use	All	Yes	Yes	Equivalent
Non-Sterile packaging	All	Yes	Yes	Equivalent
Color coded indicator for bracket identification	All	Yes	Yes, optional	Equivalent

* A claim of equivalence to the Clarity metal insert feature is not made.

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Device Classification Name	<u>Bracket, Plastic, Orthodontic</u>
510(K) Number	K861965
Device Name	UNITEK CERAMIC BRACKET SYSTEM
Applicant	UNITEK CORP. 2724 South Peck Rd. Monrovia, CA 91016 509
Contact	Jerold S Horn
Regulation Number	<u>872.5470</u>
Classification Product Code	<u>DYW</u>
Date Received	05/19/1986
Decision Date	06/09/1986
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Dental
Review Advisory Committee	Dental
Type	Traditional
Reviewed By Third Party	No
Expedited Review	

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Device Classification Name	<u>Bracket, Plastic, Orthodontic</u>
510(K) Number	K944286
Device Name	METAL-LINED TRANSCEND CERAMIC BRACKET
Applicant	UNITEK CORP. 2724 South Peck Rd. Monrovia, CA 91016 509
Contact	Marlyn Scheff
Regulation Number	<u>872.5470</u>
Classification Product Code	<u>DYW</u>
Date Received	09/02/1994
Decision Date	11/29/1994
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Dental
Review Advisory Committee	Dental
Statement	<u>Statement</u>
Type	Traditional
Reviewed By Third Party	No
Expedited Review	



MAR 24 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Marlyn Scheff
Regulatory Affairs Manager
3M Unitek
3M Dental Products Division
2724 South Peck Road
Monrovia, California 91016-5097

Re: K944286
Trade/Device Name: Metal-Lined Transcend™ Ceramic Bracket
Regulation Number: 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: DYW
Dated: September 1, 1994
Received: September 2, 1994

Dear Ms. Scheff:

This letter corrects our substantially equivalent letter of September 1, 1994.

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 (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.

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.

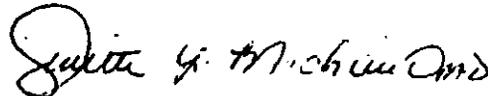
Page-2 Ms. Scheff

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); 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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital.

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

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Device Classification Name	Bracket, Ceramic, Orthodontic
510(K) Number	K062305
Device Name	CLARITY MODIFIED CERAMIC BRACKETS 3M UNITEK
Applicant	2724 South Peck Rd. Monrovia, CA 91016
Contact	L Marlyn Scheff
Regulation Number	872.5470
Classification Product Code	NJM
Date Received	08/08/2006
Decision Date	10/18/2006
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Dental
Review Advisory Committee	Dental
Statement	Statement
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. L. Marlyn Scheff
Regulatory Affairs Manager
3M Unitek Corporation
2724 South Peck Road
Monrovia, California 91016

OCT 18 2006

Re: K062305
Trade/Device Name: Clarity™ Modified Ceramic Brackets
Regulation Number: 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: August 4, 2006
Received: August 8, 2006

Dear Ms. Scheff:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

Page 2 – Ms. Scheff

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062305

Indications for Use

510(k) Number (if known): _____

Device Name: Clarity™ Modified Ceramic Brackets

Indications For Use:

Clarity Modified Ceramic Bracket is intended for use in orthodontic treatment.

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)

Page 1 of 1

Susan Pinner

Director, Office of Device Evaluation
Center for Devices and Radiological Control, General Hospital,
10150 Woodmont, Bethesda, Maryland 20814
Device Number: K062305

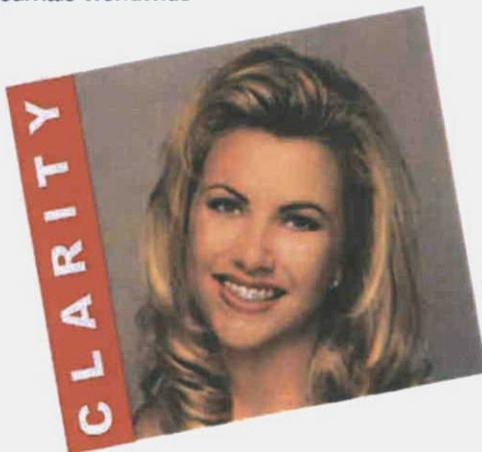
Ceramic Brackets

Clarity™ Metal-Reinforced Ceramic Brackets

There is a reason why the Clarity™ brand of ceramic brackets is associated with high-performance aesthetic treatment. Let's look at the evidence:

3

- Millions of cases treated
- Over 14 years of clinical experience
- Worldwide acceptance
- Numerous reviews in major orthodontic journals worldwide



Clarity™ Ceramic Brackets are one of the leading aesthetic brackets worldwide. Why? Clarity Brackets feature innovations from 3M that make an impact on practice efficiency, ease of use, patient satisfaction and the standard of care. The chart shows just a sampling of the technical features and benefits of Clarity Brackets.



Clarity™ Ceramic Brackets

Experience metal-like sliding mechanics. Clarity™ Brackets feature an innovative metal slot liner.

Expect reliable squeeze debonding thanks to the Clarity Bracket's innovative micro-crystalline bracket bonding surface and mesial-distal stress concentrator.

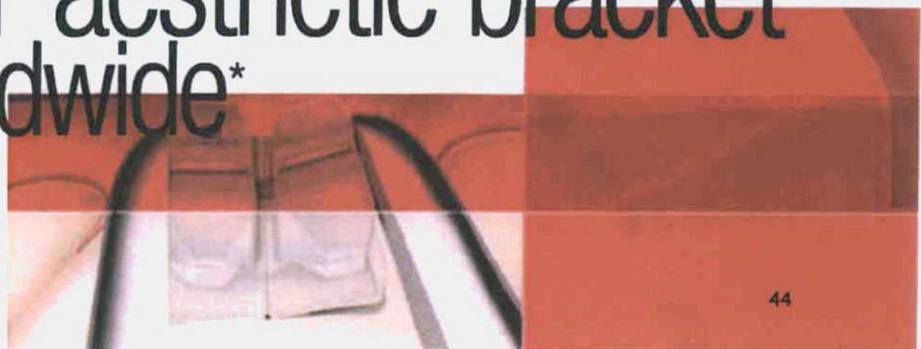
Choose both strength and beauty. Clarity features a strong and translucent poly-crystalline bracket material.

Benefit from efficiency on bonding day. 3M Unitek's family of ceramic brackets are the only ceramic brackets to offer the APC™ Adhesive pre-coat option.

Treat to your standards and preference. Clarity Brackets are available in a range of prescriptions, slot sizes, kit packages and hook configurations.

Start treatment with precise bracket placement. The metal slot liner of Clarity Brackets provide horizontal visual guidance for bracket positioning.

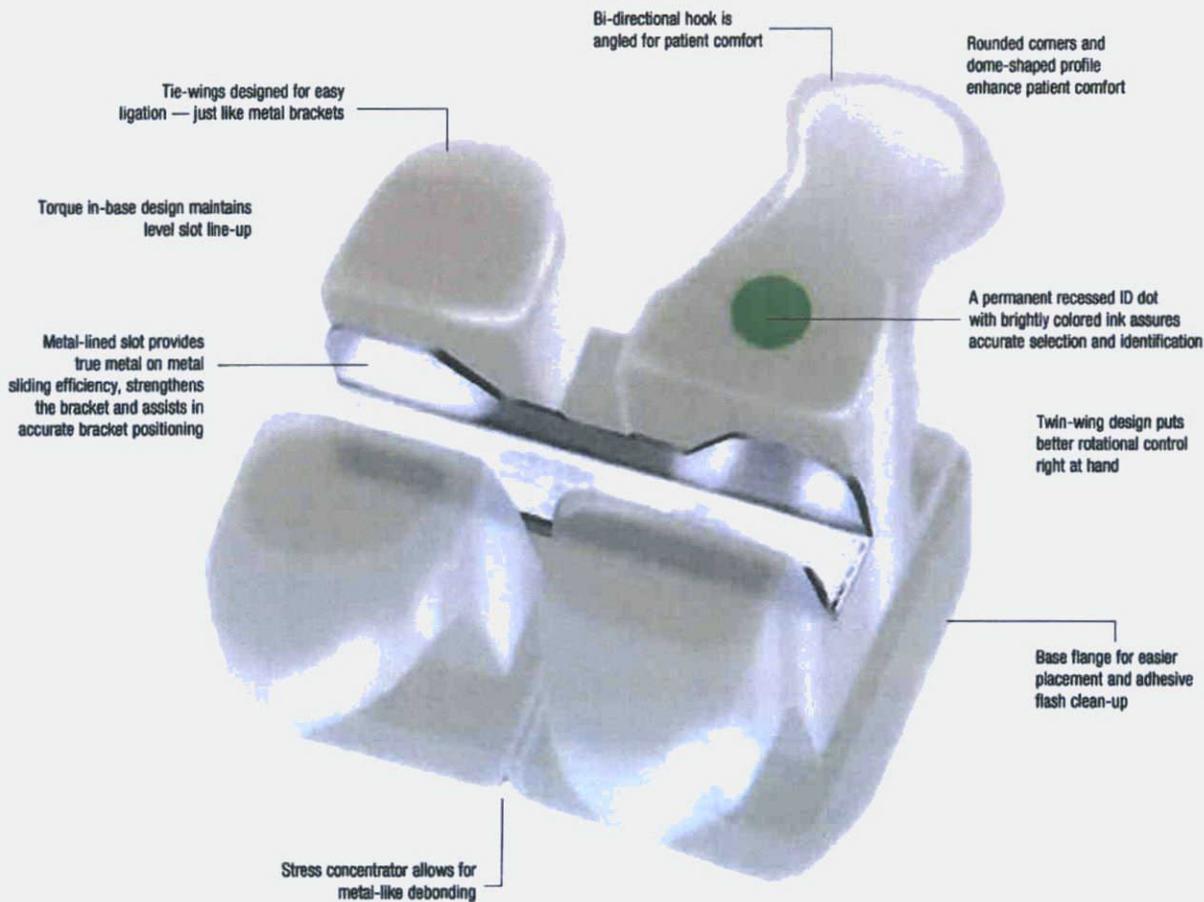
the #1 aesthetic bracket choice worldwide*



Ceramic Brackets

Clarity™ Metal-Reinforced Ceramic Brackets

3



Tie-wings designed for easy ligation — just like metal brackets

Bi-directional hook is angled for patient comfort

Rounded corners and dome-shaped profile enhance patient comfort

Torque in-base design maintains level slot line-up

A permanent recessed ID dot with brightly colored ink assures accurate selection and identification

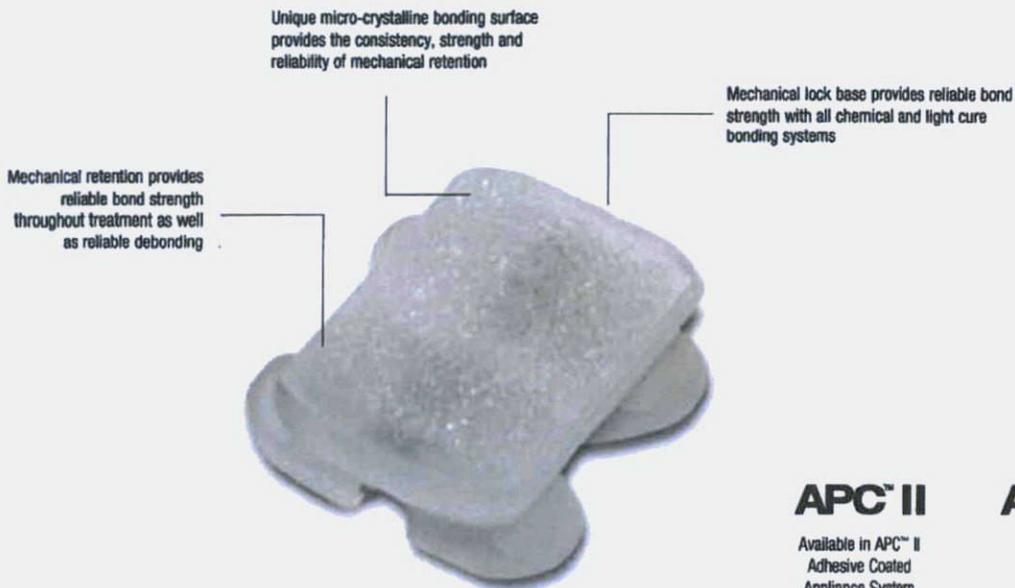
Metal-lined slot provides true metal on metal sliding efficiency, strengthens the bracket and assists in accurate bracket positioning

Twin-wing design puts better rotational control right at hand

Base flange for easier placement and adhesive flash clean-up

Stress concentrator allows for metal-like debonding

Also available with your choice of APC™ II Adhesive or with the APC™ PLUS System with color changing adhesive for reliable and efficient bonding



Unique micro-crystalline bonding surface provides the consistency, strength and reliability of mechanical retention

Mechanical lock base provides reliable bond strength with all chemical and light cure bonding systems

Mechanical retention provides reliable bond strength throughout treatment as well as reliable debonding

APC™ II
Available in APC™ II Adhesive Coated Appliance System

APC™ PLUS
Available in APC™ PLUS Adhesive Coated Appliance System

Ceramic Brackets

Clarity™ Metal-Reinforced Ceramic Brackets

Selection By Tooth – Maxillary .018 in.

3

	Torque	Ang.	In/Out		M/D Width	Hook	L/R	APC™ II	APC™ PLUS	Non-coated
			.018 in.	.018 in.				.018 in.		
Central 	+22°	5°	.044	1.12	3.5		UL	6700-651	6800-651	6400-651
	+22°	5°	.044	1.12	3.5		UR	6700-652	6800-652	6400-652
	+17°	4°	.044	1.12	3.5		UL	6700-801	6800-801	6400-801
	+17°	4°	.044	1.12	3.5		UR	6700-802	6800-802	6400-802
	+12°	5°	.044	1.12	3.5		UL	6700-601	6800-601	6400-601
	+12°	5°	.044	1.12	3.5		UR	6700-602	6800-602	6400-602
	0°	0°	.039	0.99	3.5		UL/UR	6700-820	6800-820	6400-820
Lateral 	+14°	8°	.058	1.47	3.0		UL	6700-653	6800-653	6400-653
	+14°	8°	.058	1.47	3.0		UR	6700-654	6800-654	6400-654
	+10°	8°	.058	1.47	3.0		UL	6700-803	6800-803	6400-803
	+10°	8°	.058	1.47	3.0		UR	6700-804	6800-804	6400-804
	+8°	9°	.058	1.47	3.0		UL	6700-603	6800-603	6400-603
	+8°	9°	.058	1.47	3.0		UR	6700-604	6800-604	6400-604
	0°	0°	.039	0.99	3.0		UL/UR	6700-821	6800-821	6400-821
Cuspid  	+7°	5°	.041	1.04	3.5		UL	6700-671	6800-671	6400-671
	+7°	5°	.041	1.04	3.5		UR	6700-670	6800-670	6400-670
	+7°	5°	.041	1.04	3.5	D	UL	6700-655	6800-655	6400-655
	+7°	5°	.041	1.04	3.5	D	UR	6700-656	6800-656	6400-656
	0°	11°	.041	1.04	3.5		UL	6700-607	6800-607	6400-607
	0°	11°	.041	1.04	3.5		UR	6700-608	6800-608	6400-608
	0°	11°	.041	1.04	3.5	D	UL	6700-605	6800-605	6400-605
	0°	11°	.041	1.04	3.5	D	UR	6700-606	6800-606	6400-606
	0°	8°	.041	1.04	3.5	D	UL	6700-807	6800-807	6400-807
	0°	8°	.041	1.04	3.5	D	UR	6700-808	6800-808	6400-808
	0°	8°	.041	1.04	3.5		UL	6700-817	6800-817	6400-817
	0°	8°	.041	1.04	3.5		UR	6700-818	6800-818	6400-818
	0°	0°	.039	0.99	3.5		UNIV	6700-822	6800-822	6400-822
	-7°	8°	.041	1.04	3.5	D	UL	6700-683	6800-683	6400-683
	-7°	8°	.041	1.04	3.5	D	UR	6700-682	6800-682	6400-682
-7°	8°	.041	1.04	3.5		UL	6700-805	6800-805	6400-805	
-7°	8°	.041	1.04	3.5		UR	6700-806	6800-806	6400-806	
Bicuspid  	0°	0°	.041	1.04	3.5	D	UL	6700-675	6800-675	6400-675
	0°	0°	.041	1.04	3.5	D	UR	6700-674	6800-674	6400-674
	0°	0°	.039	0.99	3.0		UNIV	6700-823	6800-823	6400-823
	-7°	0°	.041	1.04	3.0		UL/UR	6700-611	6800-611	6400-611
	-7°	0°	.041	1.04	3.5	D	UL	6700-609	6800-609	6400-609
	-7°	0°	.041	1.04	3.5	D	UR	6700-610	6800-610	6400-610

6700

Use this prefix to order APC™ II Adhesive Coated Appliance System.

6800

Use this prefix to order APC™ PLUS Adhesive Coated Appliance System with color change adhesive.

.018 Kits – Page 3.16

Note

APC™ System Brackets sold in units of five.

Measurements are in millimeters unless otherwise noted.

Ceramic Brackets

Clarity™ Metal-Reinforced Ceramic Brackets

Selection By Tooth – Mandibular .018 in.

	Torque	Ang.	In/Out		M/D Width	Hook	L/R	APC™ II	APC™ PLUS	Non-coated
			.018 in.	mm				.018 in.	.018 in.	
Anterior 	0°	0°	.039	0.99	2.5		LL/LR	6700-824	6800-824	6400-824
	-1°	0°	.052	1.32	2.5		LL/LR	6700-621	6800-621	6400-621
	-6°	0°	.060	1.52	2.5		LL/LR	6700-810	6800-810	6400-810
Cuspid   	+7°	5°	.041	1.04	3.5		LL	6700-673	6800-673	6400-673
	+7°	5°	.041	1.04	3.5		LR	6700-672	6800-672	6400-672
	+7°	5°	.041	1.04	3.5	D	LL	6700-657	6800-657	6400-657
	+7°	5°	.041	1.04	3.5	D	LR	6700-658	6800-658	6400-658
	0°	3°	.031	0.79	3.5		LL	6700-697	6800-697	6400-697
	0°	3°	.031	0.79	3.5		LR	6700-698	6800-698	6400-698
	0°	3°	.031	0.79	3.5	D	LL	6700-699	6800-699	6400-699
	0°	3°	.031	0.79	3.5	D	LR	6700-700	6800-700	6400-700
	0°	0°	.039	0.99	3.5		UNIV	6700-822	6800-822	6400-822
	-6°	3°	.031	0.79	3.5		LL	6700-695	6800-695	6400-695
	-6°	3°	.031	0.79	3.5		LR	6700-696	6800-696	6400-696
	-6°	3°	.031	0.79	3.5	D	LL	6700-685	6800-685	6400-685
	-6°	3°	.031	0.79	3.5	D	LR	6700-684	6800-684	6400-684
	-11°	7°	.041	1.04	3.5		LL	6700-627	6800-627	6400-627
-11°	7°	.041	1.04	3.5		LR	6700-628	6800-628	6400-628	
-11°	7°	.041	1.04	3.5	D	LL	6700-625	6800-625	6400-625	
-11°	7°	.041	1.04	3.5	D	LR	6700-626	6800-626	6400-626	
First Bicuspid  	-7°	0°	.041	1.04	3.0		LL/LR	6700-660	6800-660	6400-660
	-7°	0°	.041	1.04	3.5	D	LL	6700-661	6800-661	6400-661
	-7°	0°	.041	1.04	3.5	D	LR	6700-662	6800-662	6400-662
	-12°	2°	.041	1.04	3.0		LL	6700-687	6800-687	6400-687
	-12°	2°	.041	1.04	3.0		LR	6700-686	6800-686	6400-686
	-12°	2°	.041	1.04	3.5	D	LL	6700-689	6800-689	6400-689
	-12°	2°	.041	1.04	3.5	D	LR	6700-688	6800-688	6400-688
	-17°	0°	.041	1.04	3.0		LL/LR	6700-636	6800-636	6400-636
	-17°	0°	.041	1.04	3.5	D	LL	6700-629	6800-629	6400-629
-17°	0°	.041	1.04	3.5	D	LR	6700-630	6800-630	6400-630	
Bicuspid 	0°	0°	.039	0.99	3.0		UNIV	6700-823	6800-823	6400-823
Second Bicuspid  	-11°	0°	.041	1.04	3.0		LL/LR	6700-659	6800-659	6400-659
	-11°	0°	.041	1.04	3.5	D	LL	6700-677	6800-677	6400-677
	-11°	0°	.041	1.04	3.5	D	LR	6700-676	6800-676	6400-676
	-17°	2°	.041	1.04	3.0		LL	6700-691	6800-691	6400-691
	-17°	2°	.041	1.04	3.0		LR	6700-690	6800-690	6400-690
	-17°	2°	.041	1.04	3.5	D	LL	6700-693	6800-693	6400-693
	-17°	2°	.041	1.04	3.5	D	LR	6700-692	6800-692	6400-692
	-22°	0°	.041	1.04	3.0		LL/LR	6700-644	6800-644	6400-644
	-22°	0°	.041	1.04	3.5	D	LL	6700-637	6800-637	6400-637
-22°	0°	.041	1.04	3.5	D	LR	6700-638	6800-638	6400-638	

6700
Use this prefix to order APC™ II Adhesive Coated Appliance System.

6800
Use this prefix to order APC™ PLUS Adhesive Coated Appliance System with color change adhesive.

.018 Kits – Page 3.16

Note

APC™ System Brackets sold in units of five.

Measurements are in millimeters unless otherwise noted.

32



Ceramic Brackets

Clarity™ Metal-Reinforced Ceramic Brackets

Selection by MBT™ Versatile+ Appliance System Brackets .018 in.

3

Maxillary	Torque	Ang.	In/Out		M/D Width	Hook	L/R	APC™ II	APC™ PLUS	Non-coated
			.in.	mm				.018 in.	.018 in.	.018 in.
Central 	+17°	4°	.044	1.12	3.5		UL	6700-801	6800-801	6400-801
	+17°	4°	.044	1.12	3.5		UR	6700-802	6800-802	6400-802
Lateral 	+10°	8°	.058	1.47	3.0		UL	6700-803	6800-803	6400-803
	+10°	8°	.058	1.47	3.0		UR	6700-804	6800-804	6400-804
Cuspid 	0°	8°	.041	1.04	3.5	D	UL	6700-807	6800-807	6400-807
	0°	8°	.041	1.04	3.5	D	UR	6700-808	6800-808	6400-808
	0°	8°	.041	1.04	3.5		UL	6700-817	6800-817	6400-817
	0°	8°	.041	1.04	3.5		UR	6700-818	6800-818	6400-818
	-7°	8°	.041	1.04	3.5	D	UL	6700-683	6800-683	6400-683
	-7°	8°	.041	1.04	3.5	D	UR	6700-682	6800-682	6400-682
	-7°	8°	.041	1.04	3.5		UL	6700-805	6800-805	6400-805
	-7°	8°	.041	1.04	3.5		UR	6700-806	6800-806	6400-806
Bicuspid 	-7°	0°	.041	1.04	3.0		UL/UR	6700-611	6800-611	6400-611
	-7°	0°	.041	1.04	3.5	D	UL	6700-609	6800-609	6400-609
	-7°	0°	.041	1.04	3.5	D	UR	6700-610	6800-610	6400-610
Mandibular										
Anterior 	-6°	0°	.060	1.52	2.5		LL/LR	6700-810	6800-810	6400-810
Cuspid 	0°	3°	.031	0.79	3.5		LL	6700-697	6800-697	6400-697
	0°	3°	.031	0.79	3.5		LR	6700-698	6800-698	6400-698
	0°	3°	.031	0.79	3.5	D	LL	6700-699	6800-699	6400-699
	0°	3°	.031	0.79	3.5	D	LR	6700-700	6800-700	6400-700
	-6°	3°	.031	0.79	3.5		LL	6700-695	6800-695	6400-695
	-6°	3°	.031	0.79	3.5		LR	6700-696	6800-696	6400-696
	-6°	3°	.031	0.79	3.5	D	LL	6700-685	6800-685	6400-685
	-6°	3°	.031	0.79	3.5	D	LR	6700-684	6800-684	6400-684
First Bicuspid 	-12°	2°	.041	1.04	3.0		LL	6700-687	6800-687	6400-687
	-12°	2°	.041	1.04	3.0		LR	6700-686	6800-686	6400-686
	-12°	2°	.041	1.04	3.5	D	LL	6700-689	6800-689	6400-689
	-12°	2°	.041	1.04	3.5	D	LR	6700-688	6800-688	6400-688
Second Bicuspid 	-17°	2°	.041	1.04	3.0		LL	6700-691	6800-691	6400-691
	-17°	2°	.041	1.04	3.0		LR	6700-690	6800-690	6400-690
	-17°	2°	.041	1.04	3.5	D	LL	6700-693	6800-693	6400-693
	-17°	2°	.041	1.04	3.5	D	LR	6700-692	6800-692	6400-692

6700
Use this prefix to order APC™ II Adhesive Coated Appliance System.

6800
Use this prefix to order APC™ PLUS Adhesive Coated Appliance System with color change adhesive.

.018 Kits – Page 3.16

Note:	
APC™ System Brackets sold in units of five.	Measurements are in millimeters unless otherwise noted.
For Clarity™ MBT™ Brackets One Case Kits see page 3.16 and 3.17.	

Ceramic Brackets

Clarity™ Metal-Reinforced Ceramic Brackets

Selection by Roth* Prescription .018 in.

Maxillary	Torque	Ang.	In/Out		M/D Width	Hook	L/R	APC™ II	APC™ PLUS	Non-coated
			.018 in.	.018 in.				.018 in.		
	+12°	5°	.044	1.12	3.5		UL	6700-601	6800-601	6400-601
	+12°	5°	.044	1.12	3.5		UR	6700-602	6800-602	6400-602
	+8°	9°	.058	1.47	3.0		UL	6700-603	6800-603	6400-603
	+8°	9°	.058	1.47	3.0		UR	6700-604	6800-604	6400-604
	0°	11°	.041	1.04	3.5		UL	6700-607	6800-607	6400-607
	0°	11°	.041	1.04	3.5		UR	6700-608	6800-608	6400-608
	0°	11°	.041	1.04	3.5	D	UL	6700-605	6800-605	6400-605
	0°	11°	.041	1.04	3.5	D	UR	6700-606	6800-606	6400-606
	-7°	0°	.041	1.04	3.0		UL/UR	6700-611	6800-611	6400-611
	-7°	0°	.041	1.04	3.5	D	UL	6700-609	6800-609	6400-609
	-7°	0°	.041	1.04	3.5	D	UR	6700-610	6800-610	6400-610
Mandibular										
	-1°	0°	.052	1.32	2.5		LL/LR	6700-621	6800-621	6400-621
	-11°	7°	.041	1.04	3.5		LL	6700-627	6800-627	6400-627
	-11°	7°	.041	1.04	3.5		LR	6700-628	6800-628	6400-628
	-11°	7°	.041	1.04	3.5	D	LL	6700-625	6800-625	6400-625
	-11°	7°	.041	1.04	3.5	D	LR	6700-626	6800-626	6400-626
	-17°	0°	.041	1.04	3.0		LL/LR	6700-636	6800-636	6400-636
	-17°	0°	.041	1.04	3.5	D	LL	6700-629	6800-629	6400-629
	-17°	0°	.041	1.04	3.5	D	LR	6700-630	6800-630	6400-630
	-22°	0°	.041	1.04	3.0		LL/LR	6700-644	6800-644	6400-644
	-22°	0°	.041	1.04	3.5	D	LL	6700-637	6800-637	6400-637
	-22°	0°	.041	1.04	3.5	D	LR	6700-638	6800-638	6400-638

6700
Use this prefix to order APC™ II Adhesive Coated Appliance System.

6800
Use this prefix to order APC™ PLUS Adhesive Coated Appliance System with color change adhesive.



Note	
APC™ System Brackets sold in units of five.	Measurements are in millimeters unless otherwise noted.
For Clarity™ Roth™ Brackets One Case Kits see page 3.16 and 3.17.	* 3M Unitek version of this prescription. No endorsement by the Doctor is implied.

Ceramic Brackets

Clarity™ Metal-Reinforced Ceramic Brackets
 Selection by Ricketts* Prescription .018 in.

3

Maxillary	Torque	Ang.	In/Out		M/D	Hook	L/R	APC™ II	APC™ PLUS	Non-coated
			in.	mm				.018 in.	.018 in.	.018 in.
	+22°	5°	.044	1.12	3.5		UL	6700-651	6800-651	6400-651
	+22°	5°	.044	1.12	3.5		UR	6700-652	6800-652	6400-652
	+14°	8°	.058	1.47	3.0		UL	6700-653	6800-653	6400-653
	+14°	8°	.058	1.47	3.0		UR	6700-654	6800-654	6400-654
	+7°	5°	.041	1.04	3.5		UL	6700-671	6800-671	6400-671
	+7°	5°	.041	1.04	3.5		UR	6700-670	6800-670	6400-670
	+7°	5°	.041	1.04	3.5	D	UL	6700-655	6800-655	6400-655
	+7°	5°	.041	1.04	3.5	D	UR	6700-656	6800-656	6400-656
	0°	0°	.039	0.99	3.0		UL/UR	6700-823	6800-823	6400-823
	0°	0°	.041	1.04	3.5	D	UL	6700-675	6800-675	6400-675
	0°	0°	.041	1.04	3.5	D	UR	6700-674	6800-674	6400-674
Mandibular										
Anterior	0°	0°	.039	0.99	2.5		LL/LR	6700-824	6800-824	6400-824
	+7°	5°	.041	1.04	3.5		LL	6700-673	6800-673	6400-673
	+7°	5°	.041	1.04	3.5		LR	6700-672	6800-672	6400-672
	+7°	5°	.041	1.04	3.5	D	LL	6700-657	6800-657	6400-657
	+7°	5°	.041	1.04	3.5	D	LR	6700-658	6800-658	6400-658
1st Bicuspid 	-7°	0°	.041	1.04	3.0		LL/LR	6700-660	6800-660	6400-660
	-7°	0°	.041	1.04	3.5	D	LL	6700-661	6800-661	6400-661
	-7°	0°	.041	1.04	3.5	D	LR	6700-662	6800-662	6400-662
2nd Bicuspid 	-11°	0°	.041	1.04	3.0		LL/LR	6700-659	6800-659	6400-659
	-11°	0°	.041	1.04	3.5	D	LL	6700-677	6800-677	6400-677
	-11°	0°	.041	1.04	3.5	D	LR	6700-676	6800-676	6400-676

6700
 Use this prefix to order APC™ II Adhesive Coated Appliance System.

6800
 Use this prefix to order APC™ PLUS Adhesive Coated Appliance System with color change adhesive.

.018 Kits – Page 3.16

Note	
APC™ System Brackets sold in units of five.	Measurements are in millimeters unless otherwise noted.
For Clarity™ Ricketts® Brackets One Case Kits see page 3.16 and 3.17.	* 3M Unitek version of this prescription. No endorsement by the Doctor is implied.

85

Ceramic Brackets

Clarity™ Metal-Reinforced Ceramic Brackets

Selection by Standard Edgewise Prescription .018 in.

	Torque	Ang.	In/Out		M/D	Hook	L/R	APC™ II .018 in.	APC™ PLUS .018 in.	Non-coated .018 in.
			in.	mm	Width					
Central										
	0°	0°	.039	0.99	3.5		UL/UR	6700-820	6800-820	6400-820
Lateral										
	0°	0°	.039	0.99	3.0		UL/UR	6700-821	6800-821	6400-821
Cuspid										
	0°	0°	.039	0.99	3.5		UNV	6700-822	6800-822	6400-822
Bicuspid										
	0°	0°	.039	0.99	3.0		UNV	6700-823	6800-823	6400-823
Anterior										
	0°	0°	.039	0.99	2.5		LL/LR	6700-824	6800-824	6400-824
								6700 Use this prefix to order APC™ II Adhesive Coated Appliance System	6800 Use this prefix to order APC™ PLUS Adhesive Coated Appliance System with color change adhesive	



.018 Kits – Page 3.16

Note	
APC™ System Brackets sold in units of five.	Measurements are in millimeters unless otherwise noted.
For Clarity™ Standard Edgewise Brackets One Case Kits see page 3.16 and 3.17.	

Ceramic Brackets

Clarity™ Metal-Reinforced Ceramic Brackets

Selection By Tooth – Maxillary .022 in.

3

	Torque	Ang.	In/Out		M/D Width	Hook	L/R	APC™ II	APC™ PLUS	Non-coated
			.022 in.	.022 in.				.022 in.		
Central 	+22°	5°	.044	1.12	3.5		UL	6700-751	6800-751	6400-751
	+22°	5°	.044	1.12	3.5		UR	6700-752	6800-752	6400-752
	+17°	4°	.044	1.12	3.5		UL	6700-901	6800-901	6400-901
	+17°	4°	.044	1.12	3.5		UR	6700-902	6800-902	6400-902
	+12°	5°	.044	1.12	3.5		UL	6700-701	6800-701	6400-701
	+12°	5°	.044	1.12	3.5		UR	6700-702	6800-702	6400-702
	0°	0°	.039	0.99	3.5		UL/UR	6700-920	6800-920	6400-920
Lateral 	+14°	8°	.058	1.47	3.0		UL	6700-753	6800-753	6400-753
	+14°	8°	.058	1.47	3.0		UR	6700-754	6800-754	6400-754
	+10°	8°	.058	1.47	3.0		UL	6700-903	6800-903	6400-903
	+10°	8°	.058	1.47	3.0		UR	6700-904	6800-904	6400-904
	+8°	9°	.058	1.47	3.0		UL	6700-703	6800-703	6400-703
	+8°	9°	.058	1.47	3.0		UR	6700-704	6800-704	6400-704
	0°	0°	.039	0.99	3.0		UL/UR	6700-921	6800-921	6400-921
Cuspid  	+7°	5°	.041	1.04	3.5		UL	6700-771	6800-771	6400-771
	+7°	5°	.041	1.04	3.5		UR	6700-770	6800-770	6400-770
	+7°	5°	.041	1.04	3.5	D	UL	6700-755	6800-755	6400-755
	+7°	5°	.041	1.04	3.5	D	UR	6700-756	6800-756	6400-756
	0°	11°	.041	1.04	3.5		UL	6700-707	6800-707	6400-707
	0°	11°	.041	1.04	3.5		UR	6700-708	6800-708	6400-708
	0°	11°	.041	1.04	3.5	D	UL	6700-705	6800-705	6400-705
	0°	11°	.041	1.04	3.5	D	UR	6700-706	6800-706	6400-706
	0°	8°	.041	1.04	3.5	D	UL	6700-907	6800-907	6400-907
	0°	8°	.041	1.04	3.5	D	UR	6700-908	6800-908	6400-908
	0°	8°	.041	1.04	3.5		UL	6700-917	6800-917	6400-917
	0°	8°	.041	1.04	3.5		UR	6700-918	6800-918	6400-918
	0°	0°	.039	0.99	3.5		UNV	6700-922	6800-922	6400-922
	-7°	8°	.041	1.04	3.5	D	UL	6700-783	6800-783	6400-783
-7°	8°	.041	1.04	3.5	D	UR	6700-782	6800-782	6400-782	
-7°	8°	.041	1.04	3.5		UL	6700-905	6800-905	6400-905	
-7°	8°	.041	1.04	3.5		UR	6700-906	6800-906	6400-906	
Bicuspid  	0°	0°	.041	1.04	3.5	D	UL	6700-775	6800-775	6400-775
	0°	0°	.041	1.04	3.5	D	UR	6700-774	6800-774	6400-774
	0°	0°	.039	0.99	3.0		UNV	6700-923	6800-923	6400-923
	-7°	0°	.041	1.04	3.0		UL/UR	6700-711	6800-711	6400-711
	-7°	0°	.041	1.04	3.5	D	UL	6700-709	6800-709	6400-709
	-7°	0°	.041	1.04	3.5	D	UR	6700-710	6800-710	6400-710

6700
Use this prefix to order APC™ II Adhesive Coated Appliance System.

6800
Use this prefix to order APC™ PLUS Adhesive Coated Appliance System with prior change adhesive.

.022 Kits – Page 3.17

Note
APC™ System Brackets sold in units of five. Measurements are in millimeters unless otherwise noted.

87

Ceramic Brackets

Clarity™ Metal-Reinforced Ceramic Brackets

Selection By Tooth – Mandibular .022 in.

	Torque	Ang.	In/Out		M/D Width	Hook	L/R	APC™ II	APC™ PLUS	Non-coated
			.022 in.	.022 in.				.022 in.		
Anterior 	0°	0°	.039	0.99	2.5		LL/LR	6700-924	6800-924	6400-924
	-1°	0°	.052	1.32	2.5		LL/LR	6700-721	6800-721	6400-721
	-6°	0°	.060	1.52	2.5		LL/LR	6700-910	6800-910	6400-910
Cuspid 	+7°	5°	.041	1.04	3.5		LL	6700-773	6800-773	6400-773
	+7°	5°	.041	1.04	3.5		LR	6700-772	6800-772	6400-772
	+7°	5°	.041	1.04	3.5	D	LL	6700-757	6800-757	6400-757
	+7°	5°	.041	1.04	3.5	D	LR	6700-758	6800-758	6400-758
	0°	3°	.031	0.79	3.5		LL	6700-797	6800-797	6400-797
	0°	3°	.031	0.79	3.5	D	LR	6700-798	6800-798	6400-798
	0°	3°	.031	0.79	3.5	D	LL	6700-799	6800-799	6400-799
	0°	3°	.031	0.79	3.5	D	LR	6700-800	6800-800	6400-800
	0°	0°	.039	0.99	3.5		UNV	6700-922	6800-922	6400-922
	-6°	3°	.031	0.79	3.5		LL	6700-795	6800-795	6400-795
	-6°	3°	.031	0.79	3.5		LR	6700-796	6800-796	6400-796
	-6°	3°	.031	0.79	3.5	D	LL	6700-785	6800-785	6400-785
	-6°	3°	.031	0.79	3.5	D	LR	6700-784	6800-784	6400-784
	-11°	7°	.041	1.04	3.5		LL	6700-727	6800-727	6400-727
	-11°	7°	.041	1.04	3.5		LR	6700-728	6800-728	6400-728
-11°	7°	.041	1.04	3.5	D	LL	6700-725	6800-725	6400-725	
-11°	7°	.041	1.04	3.5	D	LR	6700-726	6800-726	6400-726	
First Bicuspid 	-7°	0°	.041	1.04	3.0		LL/LR	6700-760	6800-760	6400-760
	-7°	0°	.041	1.04	3.5	D	LL	6700-761	6800-761	6400-761
	-7°	0°	.041	1.04	3.5	D	LR	6700-762	6800-762	6400-762
	-12°	2°	.041	1.04	3.0		LL	6700-787	6800-787	6400-787
	-12°	2°	.041	1.04	3.0		LR	6700-786	6800-786	6400-786
	-12°	2°	.041	1.04	3.5	D	LL	6700-789	6800-789	6400-789
	-12°	2°	.041	1.04	3.5	D	LR	6700-788	6800-788	6400-788
	-17°	0°	.041	1.04	3.0		LL/LR	6700-736	6800-736	6400-736
	-17°	0°	.041	1.04	3.5	D	LL	6700-729	6800-729	6400-729
-17°	0°	.041	1.04	3.5	D	LR	6700-730	6800-730	6400-730	
Bicuspid 	0°	0°	.039	0.99	3.0		UNV	6700-923	6800-923	6400-923
Second Bicuspid 	-11°	0°	.041	1.04	3.0		LL/LR	6700-759	6800-759	6400-759
	-11°	0°	.041	1.04	3.5	D	LL	6700-777	6800-777	6400-777
	-11°	0°	.041	1.04	3.5	D	LR	6700-776	6800-776	6400-776
	-17°	2°	.041	1.04	3.0		LL	6700-791	6800-791	6400-791
	-17°	2°	.041	1.04	3.0		LR	6700-790	6800-790	6400-790
	-17°	2°	.041	1.04	3.5	D	LL	6700-793	6800-793	6800-793
	-17°	2°	.041	1.04	3.5	D	LR	6700-792	6800-792	6400-792
	-22°	0°	.041	1.04	3.0		LL/LR	6700-744	6800-744	6400-744
	-22°	0°	.041	1.04	3.5	D	LL	6700-737	6800-737	6400-737
	-22°	0°	.041	1.04	3.5	D	LR	6700-738	6800-738	6400-738

6700
Use this prefix to order APC™ II Adhesive Coated Appliance System

6800
Use this prefix to order APC™ PLUS Adhesive Coated Appliance System with color change adhesive

.022 Kits – Page 3.17

Note

APC™ System Brackets sold in units of five.

Measurements are in millimeters unless otherwise noted.



Ceramic Brackets

Clarity™ Metal-Reinforced Ceramic Brackets

Selection by MBT™ Versatile+ Appliance System Brackets .022 in.

3

Maxillary	Torque	Ang.	In/Out		M/D	Hook	L/R	APC™ II	APC™ PLUS	Non-coated
			in.	mm				.022 in.	.022 in.	.022 in.
	+17°	4°	.044	1.12	3.5		UL	6700-901	6800-901	6400-901
	+17°	4°	.044	1.12	3.5		UR	6700-902	6800-902	6400-902
	+10°	8°	.058	1.47	3.0		UL	6700-903	6800-903	6400-903
	+10°	8°	.058	1.47	3.0		UR	6700-904	6800-904	6400-904
	0°	8°	.041	1.04	3.5	D	UL	6700-907	6800-907	6400-907
	0°	8°	.041	1.04	3.5	D	UR	6700-908	6800-908	6400-908
	0°	8°	.041	1.04	3.5		UL	6700-917	6800-917	6400-917
	0°	8°	.041	1.04	3.5		UR	6700-918	6800-918	6400-918
	-7°	8°	.041	1.04	3.5	D	UL	6700-783	6800-783	6400-783
	-7°	8°	.041	1.04	3.5	D	UR	6700-782	6800-782	6400-782
	-7°	8°	.041	1.04	3.5		UL	6700-905	6800-905	6400-905
	-7°	8°	.041	1.04	3.5		UR	6700-906	6800-906	6400-906
	-7°	0°	.041	1.04	3.0		UL/UR	6700-711	6800-711	6400-711
	-7°	0°	.041	1.04	3.5	D	UL	6700-709	6800-709	6400-709
	-7°	0°	.041	1.04	3.5	D	UR	6700-710	6800-710	6400-710
Mandibular										
	-6°	0°	.060	1.52	2.5		LL/LR	6700-910	6800-910	6400-910
	0°	3°	.031	0.79	3.5		LL	6700-797	6800-797	6400-797
	0°	3°	.031	0.79	3.5		LR	6700-798	6800-798	6400-798
	0°	3°	.031	0.79	3.5	D	LL	6700-799	6800-799	6400-799
	0°	3°	.031	0.79	3.5	D	LR	6700-800	6800-800	6400-800
	-6°	3°	.031	0.79	3.5		LL	6700-795	6800-795	6400-795
	-6°	3°	.031	0.79	3.5		LR	6700-796	6800-796	6400-796
	-6°	3°	.031	0.79	3.5	D	LL	6700-785	6800-785	6400-785
	-6°	3°	.031	0.79	3.5	D	LR	6700-784	6800-784	6400-784
	-12°	2°	.041	1.04	3.0		LL	6700-787	6800-787	6400-787
	-12°	2°	.041	1.04	3.0		LR	6700-786	6800-786	6400-786
	-12°	2°	.041	1.04	3.5	D	LL	6700-789	6800-789	6400-789
	-12°	2°	.041	1.04	3.5	D	LR	6700-788	6800-788	6400-788
	-17°	2°	.041	1.04	3.0		LL	6700-791	6800-791	6400-791
	-17°	2°	.041	1.04	3.0		LR	6700-790	6800-790	6400-790
	-17°	2°	.041	1.04	3.5	D	LL	6700-793	6800-793	6400-793
	-17°	2°	.041	1.04	3.5	D	LR	6700-792	6800-792	6400-792

6700
Use this prefix to order APC™ II Adhesive Coated Appliance System.

6800
Use this prefix to order APC™ PLUS Adhesive Coated Appliance System with color change adhesive.

.022 Kits – Page 3.17

Note	
APC™ System Brackets sold in units of five.	Measurements are in millimeters unless otherwise noted.
For Clarity™ MBT™ Brackets One Case Kits see page 3.16 and 3.17. 	

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Ceramic Brackets

Clarity™ Metal-Reinforced Ceramic Brackets

Selection by Roth* Prescription .022 in.

Maxillary	Torque	Ang.	In/Out		M/D Width	Hook	L/R	APC™ II	APC™ PLUS	Non-coated
			.022 in.	.022 in.				.022 in.		
Central 	+12°	5°	.044	1.12	3.5		UL	6700-701	6800-701	6400-701
	+12°	5°	.044	1.12	3.5		UR	6700-702	6800-702	6400-702
Lateral 	+8°	9°	.058	1.47	3.0		UL	6700-703	6800-703	6400-703
	+8°	9°	.058	1.47	3.0		UR	6700-704	6800-704	6400-704
Cuspid 	0°	11°	.041	1.04	3.5		UL	6700-707	6800-707	6400-707
	0°	11°	.041	1.04	3.5		UR	6700-708	6800-708	6400-708
	0°	11°	.041	1.04	3.5	D	UL	6700-705	6800-705	6400-705
	0°	11°	.041	1.04	3.5	D	UR	6700-706	6800-706	6400-706
Bicuspid 	-7°	0°	.041	1.04	3.0		UL/UR	6700-711	6800-711	6400-711
	-7°	0°	.041	1.04	3.5	D	UL	6700-709	6800-709	6400-709
	-7°	0°	.041	1.04	3.5	D	UR	6700-710	6800-710	6400-710
Mandibular										
Anterior 	-1°	0°	.052	1.32	2.5		LL/LR	6700-721	6800-721	6400-721
Cuspid 	-11°	7°	.041	1.04	3.5		LL	6700-727	6800-727	6400-727
	-11°	7°	.041	1.04	3.5		LR	6700-728	6800-728	6400-728
	-11°	7°	.041	1.04	3.5	D	LL	6700-725	6800-725	6400-725
	-11°	7°	.041	1.04	3.5	D	LR	6700-726	6800-726	6400-726
First Bicuspid 	-17°	0°	.041	1.04	3.0		LL/LR	6700-736	6800-736	6400-736
	-17°	0°	.041	1.04	3.5	D	LL	6700-729	6800-729	6400-729
Second Bicuspid 	-17°	0°	.041	1.04	3.5	D	LR	6700-730	6800-730	6400-730
	-22°	0°	.041	1.04	3.0		LL/LR	6700-744	6800-744	6400-744
	-22°	0°	.041	1.04	3.5	D	LL	6700-737	6800-737	6400-737
	-22°	0°	.041	1.04	3.5	D	LR	6700-738	6800-738	6400-738

6700

Use this prefix to order APC™ II Adhesive Coated Appliance System.

6800

Use this prefix to order APC™ PLUS Adhesive Coated Appliance System with color change adhesive.

.022 Kits – Page 3.17

Note

APC™ System Brackets sold in units of five.	Measurements are in millimeters unless otherwise noted.
For Clarity™ Roth® Brackets One Case Kits see page 3.16 and 3.17. 	* 3M Unitek version of this prescription. No endorsement by the Doctor is implied.



Ceramic Brackets

Clarity™ Metal-Reinforced Ceramic Brackets
Selection by Ricketts* Prescription .022 in.

3

Maxillary	Torque	Ang.	In/Out		M/D Width	Hook	L/R	APC™ II	APC™ PLUS	Non-coated
			.022 in.	.022 in.				.022 in.		
Central 	+22°	5°	.044	1.12	3.5		UL	6700-751	6800-751	6400-751
	+22°	5°	.044	1.12	3.5		UR	6700-752	6800-752	6400-752
Lateral 	+14°	8°	.058	1.47	3.0		UL	6700-753	6800-753	6400-753
	+14°	8°	.058	1.47	3.0		UR	6700-754	6800-754	6400-754
Cuspid 	+7°	5°	.041	1.04	3.5		UL	6700-771	6800-771	6400-771
	+7°	5°	.041	1.04	3.5		UR	6700-770	6800-770	6400-770
	+7°	5°	.041	1.04	3.5	D	UL	6700-755	6800-755	6400-755
	+7°	5°	.041	1.04	3.5	D	UR	6700-756	6800-756	6400-756
Bicuspid 	0°	0°	.041	1.04	3.0		UL/UR	6700-923	6800-923	6400-923
	0°	0°	.041	1.04	3.5	D	UL	6700-775	6800-775	6400-775
	0°	0°	.041	1.04	3.5	D	UR	6700-774	6800-774	6400-774
Mandibular										
Anterior 	0°	0°	.039	0.99	2.5		LL/LR	6700-924	6800-924	6400-924
Cuspid 	+7°	5°	.041	1.04	3.5		LL	6700-773	6800-773	6400-773
	+7°	5°	.041	1.04	3.5		LR	6700-772	6800-772	6400-772
	+7°	5°	.041	1.04	3.5	D	LL	6700-757	6800-757	6400-757
	+7°	5°	.041	1.04	3.5	D	LR	6700-758	6800-758	6400-758
1st Bicuspid 	-7°	0°	.041	1.04	3.0		LL/LR	6700-760	6800-760	6400-760
	-7°	0°	.041	1.04	3.5	D	LL	6700-761	6800-761	6400-761
	-7°	0°	.041	1.04	3.5	D	LR	6700-762	6800-762	6400-762
2nd Bicuspid 	-11°	0°	.041	1.04	3.0		LL/LR	6700-759	6800-759	6400-759
	-11°	0°	.041	1.04	3.5	D	LL	6700-777	6800-777	6400-777
	-11°	0°	.041	1.04	3.5	D	LR	6700-776	6800-776	6400-776

6700
Use this prefix to order APC™ II Adhesive Coated Appliance System.

6800
Use this prefix to order APC™ PLUS Adhesive Coated Appliance System with color change adhesive.

.022 Kits – Page 3.17

Note	
APC™ System Brackets sold in units of five.	Measurements are in millimeters unless otherwise noted.
For Clarity™ Ricketts® Brackets One Case Kits see page 3.16 and 3.17.	
	* 3M Unitek version of this prescription. No endorsement by the Doctor is implied.

Ceramic Brackets

Clarity™ Metal-Reinforced Ceramic Brackets

Selection by Standard Edgewise Prescription .022 in.

	Torque	Ang.	In/Out		M/D	L/R	APC™ II .022 in.	APC™ PLUS .022 in.	Non-coated .022 in.
			in.	mm	Width				
Central 	0°	0°	.039	0.99	3.5	UL/UR	6700-920	6800-920	6400-920
Lateral 	0°	0°	.039	0.99	3.0	UL/UR	6700-921	6800-921	6400-921
Cuspid 	0°	0°	.039	0.99	3.5	UNV	6700-922	6800-922	6400-922
Bicuspid 	0°	0°	.039	0.99	3.0	UNV	6700-923	6800-923	6400-923
Anterior 	0°	0°	.039	0.99	2.5	LL/LR	6700-924 6700 Use this prefix to order APC™ II Adhesive Coated Appliance System.	6800-924 6800 Use this prefix to order APC™ PLUS Adhesive Coated Appliance System with color change adhesive.	6400-924



.022 Kits – Page 3.17

Note	
APC™ System Brackets sold in units of five.	Measurements are in millimeters unless otherwise noted.
For Clarity™ Standard Edgewise Brackets One Case Kits see page 3.16 and 3.17. 	

Ceramic Brackets

Clarity™ Metal-Reinforced Ceramic Brackets

One Case Kits .018 in.

3

Clarity MBT Brackets One Case Kits					
	Type	Hook	APC™ II .018 in.	APC™ PLUS .018 in.	Non-coated .018 in
U	3 x 3		6700-208	6800-208	6400-208
U	3 x 3	Cuspid	6700-212	6800-212	6400-212
U	5 x 5		6700-210	6800-210	6400-210
U	5 x 5	Cuspid	6700-214	6800-214	6400-214
U/L	3 x 3		6700-209	6800-209	6400-209
U/L	3 x 3	Cuspid	6700-213	6800-213	6400-213
U/L	5 x 5		6700-211	6800-211	6400-211
U/L	5 x 5	Cuspid	6700-215	6800-215	6400-215

Clarity Roth* Brackets One Case Kits					
	Type	Hook	APC™ II .018 in.	APC™ PLUS .018 in.	Non-coated .018 in
U	3 x 3		6700-102	6800-102	6400-102
U	3 x 3	Cuspid	6700-103	6800-103	6400-103
U	5 x 5		6700-104	6800-104	6400-104
U	5 x 5	Cuspid	6700-134	6800-134	6400-134
U	5 x 5	Cuspid & Bicuspid	6700-105	6800-105	6400-105
U/L	3 x 3		6700-106	6800-106	6400-106
U/L	3 x 3	Cuspid	6700-107	6800-107	6400-107
U/L	5 x 5		6700-100	6800-100	6400-100
U/L	5 x 5	Cuspid	6700-132	6800-132	6400-132
U/L	5 x 5	Cuspid & Bicuspid	6700-101	6800-101	6400-101

Clarity Ricketts* Brackets One Case Kits					
	Type	Hook	APC™ II .018 in.	APC™ PLUS .018 in.	Non-coated .018 in
U	3 x 3		6700-407	6800-407	6400-407
U	3 x 3	Cuspid	6700-403	6800-403	6400-403
U	5 x 5		6700-404	6800-404	6400-404
U	5 x 5	Cuspid	6700-400	6800-400	6400-400
U/L	3 x 3		6700-406	6800-406	6400-406
U/L	3 x 3	Cuspid	6700-402	6800-402	6400-402
U/L	5 x 5		6700-405	6800-405	6400-405
U/L	5 x 5	Cuspid	6700-401	6800-401	6400-401

Clarity Standard Edgewise Brackets One Case Kits					
	Type	Hook	APC™ II .018 in.	APC™ PLUS .018 in.	Non-coated .018 in
U/L	5 x 5		6700-300	6800-300	6400-300

6700
Use this prefix to order APC™ II Adhesive Coated Appliance System.

6800
Use this prefix to order APC™ PLUS Adhesive Coated Appliance System with color change adhesive.

Note
* 3M Unitek version of this prescription. No endorsement by the Doctor is implied.

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Ceramic Brackets

Clarity™ Metal-Reinforced Ceramic Brackets

One Case Kits .022 in.

Clarity MBT Brackets One Case Kits					
	Type	Hook	APC™ II .022 in.	APC™ PLUS .022 in.	Non-coated .022 in
U	3 x 3		6700-200	6800-200	6400-200
U	3 x 3	Cuspid	6700-204	6800-204	6400-204
U	5 x 5		6700-202	6800-202	6400-202
U	5 x 5	Cuspid	6700-206	6800-206	6400-206
U/L	3 x 3		6700-201	6800-201	6400-201
U/L	3 x 3	Cuspid	6700-205	6800-205	6400-205
U/L	5 x 5		6700-203	6800-203	6400-203
U/L	5 x 5	Cuspid	6700-207	6800-207	6400-207

Clarity Roth* Brackets One Case Kits					
	Type	Hook	APC™ II .022 in.	APC™ PLUS .022 in.	Non-coated .022 in
U	3 x 3		6700-122	6800-122	6400-122
U	3 x 3	Cuspid	6700-123	6800-123	6400-123
U	5 x 5		6700-124	6800-124	6400-124
U	5 x 5	Cuspid	6700-135	6800-135	6400-135
U	5 x 5	Cuspid & Bicuspid	6700-125	6800-125	6400-125
U/L	3 x 3		6700-126	6800-126	6400-126
U/L	3 x 3	Cuspid	6700-127	6800-127	6400-127
U/L	5 x 5		6700-120	6800-120	6400-120
U/L	5 x 5	Cuspid	6700-133	6800-133	6400-133
U/L	5 x 5	Cuspid & Bicuspid	6700-121	6800-121	6400-121

Clarity Ricketts* Brackets One Case Kits					
	Type	Hook	APC™ II .022 in.	APC™ PLUS .022 in.	Non-coated .022 in
U	3 x 3		6700-427	6800-427	6400-427
U	3 x 3	Cuspid	6700-423	6800-423	6400-423
U	5 x 5		6700-424	6800-424	6400-424
U	5 x 5	Cuspid	6700-420	6800-420	6400-420
U/L	3 x 3		6700-426	6800-426	6400-426
U/L	3 x 3	Cuspid	6700-422	6800-422	6400-422
U/L	5 x 5		6700-425	6800-425	6400-425
U/L	5 x 5	Cuspid	6700-421	6800-421	6400-421

Clarity Standard Edgewise Brackets One Case Kits					
	Type	Hook	APC™ II .022 in.	APC™ PLUS .022 in.	Non-coated .022 in
U/L	5 x 5		6700-320	6800-320	6400-320

6700

Use this prefix to order APC™ II Adhesive Coated Appliance System

6800

Use this prefix to order APC™ PLUS Adhesive Coating Appliance System with color change adhesive

Note

* 3M Unitek version of this prescription. No endorsement by the Doctor is implied.



Ceramic Brackets

Transcend™ Series 6000 Ceramic Brackets

3



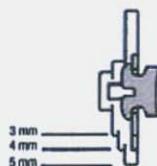
Radiused corners and edges enhance patient comfort and aesthetics

Unique micro-crystalline bonding surface provides the consistency, strength and reliability of mechanical retention

Underwire tie-wing protection ensures the labial tooth surface will never come in contact with Aestik™ Ligatures



Mechanical lock base provides reliable bond strength with all chemical and light cure bonding adhesive systems



- Removable color coded indicators provide positive bracket identification and allow easier, accurate placement
- Millimeter ledges aid in obtaining proper occlusal-gingival height and eliminate the need for Unitek™ Boone Gauge or other placement instruments

APC™ II

Available in APC™ II Adhesive Coated Appliance System

Ceramic Brackets

Transcend™ Series 6000 Ceramic Brackets

Selection By Tooth – Maxillary

	Torque	Ang.	In/Out		M/D Width	Hook	L/R	.018 in.		.022 in.	
			in.	mm							
Central 	+22°	0°	.036	0.91	3.5		UL/UR	3300-650	-	6001-650	-
	+12°	5°	.041	1.04	3.5		UL	3300-601	3300-701	6001-601	6001-701
	+12°	5°	.041	1.04	3.5		UR	3300-602	3300-702	6001-602	6001-702
	0°	0°	.031	0.79	3.5		UL/UR	3300-801	3300-901	6001-801	6001-901
Lateral 	+14°	8°	.034	0.86	3.5		UL	3300-651	-	6001-651	-
	+14°	8°	.034	0.86	3.5		UR	3300-652	-	6001-652	-
	+8°	9°	.056	1.42	3.5		UL	3300-603	3300-703	6001-603	6001-703
	+8°	9°	.056	1.42	3.5		UR	3300-604	3300-704	6001-604	6001-704
	0°	0°	.031	0.79	3.5		UL/UR	3300-801	3300-901	6001-801	6001-901
Cuspid  	+7°	7°	.033	0.84	3.5		UL	3300-653	-	6001-653	-
	+7°	7°	.033	0.84	3.5		UR	3300-654	-	6001-654	-
	+7°	7°	.033	0.84	3.5	Hk	UL	3300-655	-	6001-655	-
	+7°	7°	.033	0.84	3.5	Hk	UR	3300-656	-	6001-656	-
	0°	11°	.037	0.94	3.5		UL	3300-607	3300-707	6001-607	6001-707
	0°	11°	.037	0.94	3.5		UR	3300-608	3300-708	6001-608	6001-708
	0°	11°	.037	0.94	3.5	Hk	UL	3300-605	3300-705	6001-605	6001-705
	0°	11°	.037	0.94	3.5	Hk	UR	3300-606	3300-706	6001-606	6001-706
	0°	0°	.031	0.79	3.5		UL/UR	3300-805	3300-905	6001-805	6001-905
Bicuspid  	0°	0°	.031	0.79	3.5		UL/UR	3300-805	3300-905	6001-805	6001-905
	-7°	0°	.037	0.94	3.5		UL/UR	3300-616	3300-716	6001-616	6001-716
	-7°	0°	.037	0.94	3.5	Hk	UL/UR	3300-615	3300-715	6001-615	6001-715
	-7°	0°	.037	0.94	2.5		UL/UR	3300-618	3300-718	6001-618	6001-718
	-7°	0°	.037	0.94	2.5	Hk	UL/UR	3300-617	3300-717	6001-617	6001-717

APC: II Adhesive Coated
Appliance System

Debonding Instrument:

See page 3.26 for proper debonding instrument.

Note

Transcend™ APC™ II Brackets sold in units of four.

Measurements are in millimeters unless otherwise noted.

Ceramic Brackets

Transcend™ Series 6000 Ceramic Brackets

Selection By Tooth – Mandibular

3

	Torque	Ang.	In/Out		M/D Width	Hook	L/R	.018 in.		.022 in.	
			in.	mm				.018 in.	.022 in.	.018 in.	.022 in.
Anterior 	0°	0°	.031	0.79	2.5		LL/LR	3300-821	3300-921	6001-821	6001-921
	-1°	0°	.056	1.42	2.5		LL/LR	3300-621	3300-721	6001-621	6001-721
Cuspid   	+7°	7°	.033	0.84	3.5		LL	3300-654	-	6001-654	-
	+7°	7°	.033	0.84	3.5		LR	3300-653	-	6001-653	-
	+7°	7°	.033	0.84	3.5	Hk	LL	3300-656	-	6001-656	-
	+7°	7°	.033	0.84	3.5	Hk	LR	3300-655	-	6001-655	-
	0°	0°	.031	0.79	3.5		LL/LR	3300-805	3300-905	6001-805	6001-905
	-11°	7°	.032	0.81	3.5		LL	3300-627	3300-727	6001-627	6001-727
	-11°	7°	.032	0.81	3.5		LR	3300-628	3300-728	6001-628	6001-728
	-11°	7°	.032	0.81	3.5	Hk	LL	3300-625	3300-725	6001-625	6001-725
	-11°	7°	.032	0.81	3.5	Hk	LR	3300-626	3300-726	6001-626	6001-726
Bicuspid 	0°	0°	.031	0.79	3.5		LL/LR	3300-805	3300-905	6001-805	6001-905
First Bicuspid    	0°	0°	.036	0.91	3.5		LL/LR	3300-805	-	6001-805	-
	-17°	0°	.034	0.86	3.5		LL/LR	3300-636	3300-736	6001-636	6001-736
	-17°	0°	.034	0.86	3.5	Hk	LL/LR	3300-635	3300-735	6001-635	6001-735
	-17°	0°	.034	0.86	2.5		LL/LR	3300-638	3300-738	6001-638	6001-738
	-17°	0°	.034	0.86	2.5	Hk	LL/LR	3300-637	3300-737	6001-637	6001-737
Second Bicuspid    	-17°	0°	.034	0.86	3.5		LL/LR	3300-636	-	6001-636	-
	-22°	0°	.034	0.86	3.5		LL/LR	3300-644	3300-744	6001-644	6001-744
	-22°	0°	.034	0.86	3.5	Hk	LL/LR	3300-643	3300-743	6001-643	6001-743
	-22°	0°	.034	0.86	2.5		LL/LR	3300-646	3300-746	6001-646	6001-746
	-22°	0°	.034	0.86	2.5	Hk	LL/LR	3300-645	3300-745	6001-645	6001-745

APC™ II Adhesive Coated Appliance System

Debonding Instrument:
See page 3.26 for proper debonding instrument.

Note
Transcend™ APC™ II Brackets sold in units of four. Measurements are in millimeters unless otherwise noted.

Ceramic Brackets

Transcend™ Series 6000 Ceramic Brackets

Selection By Roth* Prescription

Maxillary	Torque	Ang.	In/Out		Hook	L/R	.018 in.		.022 in.	
			in.	mm						
	+12°	5°	.041	1.04		UL	3300-601	3300-701	6001-601	6001-701
	+12°	5°	.041	1.04		UR	3300-602	3300-702	6001-602	6001-702
	+8°	9°	.056	1.42		UL	3300-603	3300-703	6001-603	6001-703
	+8°	9°	.056	1.42		UR	3300-604	3300-704	6001-604	6001-704
	0°	11°	.037	0.94		UL	3300-607	3300-707	6001-607	6001-707
	0°	11°	.037	0.94		UR	3300-608	3300-708	6001-608	6001-708
	0°	11°	.037	0.94	Hk	UL	3300-605	3300-705	6001-605	6001-705
	0°	11°	.037	0.94	Hk	UR	3300-606	3300-706	6001-606	6001-706
	-7°	0°	.037	0.94		UL/UR	3300-616	3300-716	6001-616	6001-716
	-7°	0°	.037	0.94	Hk	UL/UR	3300-615	3300-715	6001-615	6001-715
	-7°	0°	.037	0.94		UL/UR	3300-618	3300-718	6001-618	6001-718
	-7°	0°	.037	0.94	Hk	UL/UR	3300-617	3300-717	6001-617	6001-717
Mandibular										
	-1°	0°	.056	1.42		LL/LR	3300-621	3300-721	6001-621	6001-721
	-11°	7°	.032	0.81		LL	3300-627	3300-727	6001-627	6001-727
	-11°	7°	.032	0.81		LR	3300-628	3300-728	6001-628	6001-728
	-11°	7°	.032	0.81	Hk	LL	3300-625	3300-725	6001-625	6001-725
	-11°	7°	.032	0.81	Hk	LR	3300-626	3300-726	6001-626	6001-726
	-17°	0°	.034	0.86		LL/LR	3300-636	3300-736	6001-636	6001-736
	-17°	0°	.034	0.86	Hk	LL/LR	3300-635	3300-735	6001-635	6001-735
	-17°	0°	.034	0.86		LL/LR	3300-638	3300-738	6001-638	6001-738
	-17°	0°	.034	0.86	Hk	LL/LR	3300-637	3300-737	6001-637	6001-737
	-22°	0°	.034	0.86		LL/LR	3300-644	3300-744	6001-644	6001-744
	-22°	0°	.034	0.86	Hk	LL/LR	3300-643	3300-743	6001-643	6001-743
	-22°	0°	.034	0.86	NAR	LL/LR	3300-646	3300-746	6001-646	6001-746
	-22°	0°	.034	0.86	Hk/NAR	LL/LR	3300-645	3300-745	6001-645	6001-745

APC™ II Adhesive Coated Appliance System

Victory Series™ Buccal Tubes Roth* Prescription

Torque	Offset	L/R	APC™ II Adhesive Coated Appliance System		APC™ PLUS Adhesive Coated Appliance System		Page	
			.018 in.	.022 in.	.018 in.	.022 in.		
Upper 1 st	-10°	7°	L	068-805	068-905	068-805	068-905	5.4
	-10°	7°	R	068-806	068-906	068-806	068-906	
Upper 2 nd	-10°	6°	L	3 067-829 1	3 067-929 1	5 067-829 1	5 067-929 1	5.11
	-10°	6°	R	3 067-830 2	3 067-930 2	5 067-830 2	5 067-930 2	
Lower 1 st	-25°	6°	L	3 067-801 3	3 067-901 3	5 067-801 3	5 067-901 3	5.8
	-25°	6°	R	3 067-802 4	3 067-902 4	5 067-802 4	5 067-902 4	
Lower 2 nd	-30°	6°	L	3 067-835 3	3 067-935 3	5 067-835 3	5 067-935 3	5.12
	-30°	6°	R	3 067-836 4	3 067-936 4	5 067-836 4	5 067-936 4	

3 Use this prefix to order APC™ II Adhesive Coated Appliance System

5 Use this prefix to order APC™ PLUS Adhesive Coated Appliance System with color change adhesive

Note:

Transcend™ APC™ II Brackets sold in units of four.	Measurements are in millimeters unless otherwise noted.
APC™ II Buccal Tubes sold in units of five. APC™ PLUS Buccal Tubes sold in units of four. Non-Coated Buccal Tubes sold individually.	
For detailed buccal tube information see the Buccal Tubes section.	 1 2 3 4 Buccal Tube is available with a bondable base.
For Transcend™ Series 6000 Roth* Brackets One/Ten Case Kits see page 3.24.	* 3M Unitek version of this prescription. No endorsement by the Doctor is implied.

Debonding Instrument:
See page 3.26 for proper debonding instrument.



Ceramic Brackets

Transcend™ Series 6000 Ceramic Brackets

Selection By High Torque/Ricketts* Prescription

3

Maxillary	Torque	Ang.	In/Out		Hook	L/R	.018 in.		.022 in.	
			in.	mm						
Central	+22°	0°	.036	.091		UL/UR	3300-650	-	6001-650	-
Lateral	+14°	8°	.034	0.86		UL	3300-651	-	6001-651	-
	+14°	8°	.034	0.86		UR	3300-652	-	6001-652	-
Cuspid	+7°	7°	.033	0.84		UL	3300-653	-	6001-653	-
	+7°	7°	.033	0.84		UR	3300-654	-	6001-654	-
	+7°	7°	.033	0.84	Hk	UL	3300-655	-	6001-655	-
	+7°	7°	.033	0.84	Hk	UR	3300-656	-	6001-656	-
Bicuspid	0°	0°	.031	0.79		UL/UR	3300-805	-	6001-805	-
Mandibular										
Anterior	0°	0°	.031	0.79		LL/LR	3300-821	-	6001-821	-
Cuspid	+7°	7°	.033	0.84		LL	3300-654	-	6001-654	-
	+7°	7°	.033	0.84		LR	3300-653	-	6001-653	-
	+7°	7°	.033	0.84	Hk	LL	3300-656	-	6001-656	-
	+7°	7°	.033	0.84	Hk	LR	3300-655	-	6001-655	-
First Bicuspid	0°	0°	.031	0.79		LL/LR	3300-805	-	6001-805	-
Second Bicuspid	-17°	0°	.034	0.86		LL/LR	3300-636	-	6001-636	-

APC™ II Adhesive Coated Appliance System

Victory Series™ Buccal Tubes Ricketts* Prescription

Torque	Offset	L/R	APC™ II Adhesive Coated Appliance System		APC™ PLUS Adhesive Coated Appliance System		Page
			.018 in.	.022 in.	.018 in.	.022 in.	
Upper 1 st	0°	L	068-601	-	068-601	-	5.8
	0°	R	068-602	-	068-602	-	
Upper 2 nd	0°	L	3 067-825 1	-	5 067-825 1	-	5.11
Lower 1 st	0°	R	3 067-826 2	-	5 067-826 2	-	
	0°	L/R	067-843	-	067-843	-	5.10
Lower 2 nd	0°	L/R	067-843	-	067-843	-	
	0°	L	3 067-826 3	-	5 067-826 3	-	5.11
	0°	R	3 067-825 4	-	5 067-825 4	-	

3 Use this prefix to order APC™ II Adhesive Coated Appliance System.

5 Use this prefix to order APC™ PLUS Adhesive Coated Appliance System with rotor change adhesive.

Note	
Transcend™ APC™ II Brackets sold in units of four.	Measurements are in millimeters unless otherwise noted.
APC™ II Buccal Tubes sold in units of five. APC™ PLUS Buccal Tubes sold in units of four. Non-Coated Buccal Tubes sold individually.	
For detailed buccal tube information see the Buccal Tubes section.	1 2 3 4 Buccal Tube is available with a bondable base.
For Transcend™ Series 6000 High Torque/Ricketts* Brackets One Case Kits see page 3.25.	* 3M Unitek version of this prescription. No endorsement by the Doctor is implied.

Debonding Instrument:
See page 3.26 for proper debonding instrument.

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Ceramic Brackets

Transcend™ Series 6000 Ceramic Brackets Selection By Standard Edgewise Prescription

Maxillary	Torque	Ang.	In/Out		Hook	L/R	.018 in.		.022 in.	
			in.	mm						
Central Laterals										
	0°	0°	.031	0.79		UL/UR	3300-801	3300-901	6001-801	6001-901
Cuspids Bicusplds										
	0°	0°	.031	0.79		UL/UR	3300-805	3300-905	6001-805	6001-905
Mandibular										
Anteriors										
	0°	0°	.031	0.79		LL/LR	3300-821	3300-921	6001-821	6001-921
Cuspids Bicusplds										
	0°	0°	.031	0.79		LL/LR	3300-805	3300-905	6001-805	6001-905

APC® II Adhesive Coated Appliance System

Victory Series™ Buccal Tubes Roth* Prescription

Torque	Offset	L/R	APC® II Adhesive Coated Appliance System		APC® PLUS Adhesive Coated Appliance System		Page	
			.018 in.	.022 in.	.018 in.	.022 in.		
Upper 1 ST	0°	7°	L	068-801	068-901	068-801	068-901	5.4
	0°	7°	R	068-802	068-902	068-802	068-902	
Upper 2 ND	0°	6°	L	3 067-827 1	3 067-927 1	5 067-827 1	5 067-927 1	5.11
	0°	6°	R	3 067-828 2	3 067-928 2	5 067-828 2	5 067-928 2	
Lower 1 ST	0°	6°	L	3 067-809 3	3 067-909 3	5 067-809 3	5 067-909 3	5.8
	0°	6°	R	3 067-810 4	3 067-910 4	5 067-810 4	5 067-910 4	
Lower 2 ND	0°	6°	L	3 067-828 3	3 067-928 3	5 067-828 3	5 067-928 3	5.10
	0°	6°	R	3 067-827 4	3 067-927 4	5 067-827 4	5 067-927 4	

3 Use this prefix to order APC® II Adhesive Coated Appliance System.

5 Use this prefix to order APC® PLUS Adhesive Coated Appliance System with color change adhesive.

Debonding Instrument:

See page 3.26 for proper debonding instrument.

Note	
APC® II Transcend™ Brackets sold in units of four.	Measurements are in millimeters unless otherwise noted.
APC® II Buccal Tubes sold in units of five. APC® PLUS Buccal Tubes sold in units of four. Non-Coated Buccal Tubes sold individually.	
For detailed buccal tube information see the Buccal Tubes section.	1 2 3 4 Buccal Tube is available with a bondable base.
For Transcend™ Series 6000 Standard Edgewise Brackets One Case Kits see page 3.25.	



Ceramic Brackets

Transcend™ Series 6000 Ceramic Brackets

Case Kits

3

Transcend Series 6000 Roth* Brackets One Case Kits						
	Type	Hook	.018 in.	.022 in.	.018 in.	.022 in.
U	3 x 3		3300-972	3300-992	-	-
U	3 x 3	Cuspid	3300-973	3300-993	-	-
U/L	3 x 3		3300-976	3300-996	-	-
U/L	3 x 3	Cuspid	3300-977	3300-997	-	-
U/L	5 x 5		-	-	6010-602	6010-702
U/L	5 x 5	Cuspid/Bicuspid	-	-	6010-601	6010-701

APC™ = Adhesive Coated Appliance System

Transcend Series 6000 Roth* Brackets One Case Kits (Narrow Bicuspid Brackets Included)						
	Type	Hook	.018 in.	.022 in.	.018 in.	.022 in.
U	5 x 5		3300-974	3300-994	-	-
U	5 x 5	Cuspid/Bicuspid	3300-975	3300-995	-	-
U/L	5 x 5		3300-978	3300-998	6010-604	6010-704
U/L	5 x 5	Cuspid/Bicuspid	3300-979	3300-999	-	-
U/L	5 x 5	Bicuspid	-	-	6010-603	6010-703

APC™ = Adhesive Coated Appliance System

Transcend Series 6000 Roth* Brackets Ten Case Kits						
	Type	Hook	.018 in.	.022 in.	.018 in.	.022 in.
U	5 x 5	Cuspid/Bicuspid	-	-	6010-610	6010-710
U	5 x 5		-	-	6010-612	6010-712

Note
 * 3M Unitek version of this prescription. No endorsement by the Doctor is implied.

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Ceramic Brackets

Transcend™ Series 6000 Ceramic Brackets

Case Kits

Transcend Series 6000 Standard Edgewise Brackets One Case Kits						
	Type	Hook	.018 in.	.022 in.	.018 in.	.022 in.
U/L	5 x 5		3300-969	3300-989	6010-801	6010-901
APC - II Adhesive Coated Appliance System						



Transcend Series 6000 High Torque/Ricketts* Brackets One Case Kits						
	Type	Hook	.018 in.	.022 in.	.018 in.	.022 in.
U/L	5 x 5		3300-959	-	6010-802	-
APC - II Adhesive Coated Appliance System						

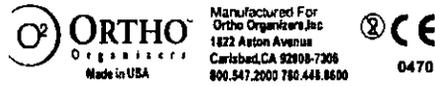
Debonding Instrument:
See page 3.26 for proper debonding instrument.

Note
* 3M Unitek version of this prescription. No endorsement by the Doctor is implied.

13. Proposed Labeling

Proposed Labeling

This proposed labeling section includes a representative copy of the draft product labels for the ceramic line of brackets.



REF 700-205 **Qty:** 1

.018 CERAMIC BRACKET, UPPER CENTRAL RIGHT,
+12T, +5A / DIRECT BOND



REF 700-206 **Qty:** 1

.018 CERAMIC BRACKET, UPPER CENTRAL LEFT, +12T,
+5A / DIRECT BOND



REF 700-305 **Qty:** 1

.022 CERAMIC BRACKET, UPPER CENTRAL RIGHT,
+12T, +5A / DIRECT BOND



REF 700-306 **Qty:** 1

.022 CERAMIC BRACKET, UPPER CENTRAL LEFT, +12T,
+5A / DIRECT BOND



lot

Proposed Labeling

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-221 Qty: 1

.018 CERAMIC BRACKET, UPPER LATERAL RIGHT, +8T,
+9A / DIRECT BOND

LOT 123456



EC REP

mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-222 Qty: 1

.018 CERAMIC BRACKET, UPPER LATERAL LEFT, +8T,
+9A / DIRECT BOND

LOT 123456



EC REP

mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-321 Qty: 1

.022 CERAMIC BRACKET, UPPER LATERAL RIGHT, +8T,
+9A / DIRECT BOND

LOT 123456



EC REP

mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-322 Qty: 1

.022 CERAMIC BRACKET, UPPER LATERAL LEFT, +8T,
+9A / DIRECT BOND

LOT 123456



EC REP

mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-235 Qty: 1

.018 CERAMIC BRACKET, UPPER CUSPID RIGHT, 0T,
+11A / DIRECT BOND

LOT 123456



EC REP

mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-236 Qty: 1

.018 CERAMIC BRACKET, UPPER CUSPID LEFT, 0T,
+11A / DIRECT BOND

LOT 123456



EC REP

mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

Proposed Labeling

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8800

 0470

REF 700-335 **Qty:** 1

.022 CERAMIC BRACKET, UPPER CUSPID RIGHT, 0T,
+11A / DIRECT BOND

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8800

 0470

REF 700-236HK **Qty:** 1

.018 CERAMIC BRACKET, UPPER CUSPID LEFT, HOOK,
0T, +11A / DIRECT BOND

LOT 123456



EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

LOT 123456



EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8800

 0470

REF 700-336 **Qty:** 1

.022 CERAMIC BRACKET, UPPER CUSPID LEFT, 0T,
+11A / DIRECT BOND

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8800

 0470

REF 700-335HK **Qty:** 1

.022 CERAMIC BRACKET, UPPER CUSPID RIGHT,
HOOK, 0T, +11A / DIRECT BOND

LOT 123456



EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

LOT 123456



EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8800

 0470

REF 700-235HK **Qty:** 1

.018 CERAMIC BRACKET, UPPER CUSPID RIGHT,
HOOK, 0T, +11A / DIRECT BOND

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8800

 0470

REF 700-336HK **Qty:** 1

.022 CERAMIC BRACKET, UPPER CUSPID LEFT, HOOK,
0T, +11A / DIRECT BOND

LOT 123456



EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

LOT 123456



EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

106

Proposed Labeling

 **ORTHOTO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7308
800.547.2000 760.448.8600

 0470

REF 700-257

Qty: 1

.018 CERAMIC BRACKET, UPPER BICUSPID RIGHT, -7T,
0A / DIRECT BOND

LOT 123456



EC REP

mdi Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

 **ORTHOTO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7308
800.547.2000 760.448.8600

 0470

REF 700-258

Qty: 1

.018 CERAMIC BRACKET, UPPER BICUSPID LEFT, -7T,
0A / DIRECT BOND

LOT 123456



EC REP

mdi Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

 **ORTHOTO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7308
800.547.2000 760.448.8600

 0470

REF 700-357

Qty: 1

.022 CERAMIC BRACKET, UPPER BICUSPID RIGHT, -7T,
0A / DIRECT BOND

LOT 123456



EC REP

mdi Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

 **ORTHOTO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7308
800.547.2000 760.448.8600

 0470

REF 700-358

Qty: 1

.022 CERAMIC BRACKET, UPPER BICUSPID LEFT, -7T,
0A / DIRECT BOND

LOT 123456



EC REP

mdi Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

 **ORTHOTO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7308
800.547.2000 760.448.8600

 0470

REF 700-257HK

Qty: 1

.018 CERAMIC BRACKET, UPPER BICUSPID RIGHT,
HOOK, -7T, 0A / DIRECT BOND

LOT 123456



EC REP

mdi Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

 **ORTHOTO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7308
800.547.2000 760.448.8600

 0470

REF 700-258HK

Qty: 1

.018 CERAMIC BRACKET, UPPER BICUSPID LEFT,
HOOK, -7T, 0A / DIRECT BOND

LOT 123456



EC REP

mdi Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

Proposed Labeling

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-357HK Qty: 1

.022 CERAMIC BRACKET, UPPER BICUSPID RIGHT,
HOOK, -7T, 0A / DIRECT BOND

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-234 Qty: 1

.018 CERAMIC BRACKET, LOWER ANTERIOR LEFT, 0T,
0A / DIRECT BOND

LOT 123456



 EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-358HK Qty: 1

.022 CERAMIC BRACKET, UPPER BICUSPID LEFT,
HOOK, -7T, 0A / DIRECT BOND

LOT 123456



 EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-333 Qty: 1

.022 CERAMIC BRACKET, LOWER ANTERIOR RIGHT,
0T, 0A / DIRECT BOND

LOT 123456



 EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-233 Qty: 1

.018 CERAMIC BRACKET, LOWER ANTERIOR RIGHT, 0T,
0A / DIRECT BOND

LOT 123456



 EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-334 Qty: 1

.022 CERAMIC BRACKET, LOWER ANTERIOR LEFT, 0T,
0A / DIRECT BOND

LOT 123456



 EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

LOT 123456



 EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

108

Proposed Labeling


 Manufactured For
 Ortho Organizers, Inc
 1822 Aston Avenue
 Carlsbad, CA 92008-7306
 800.547.2000 760.448.8600


 0470

REF 700-267 Qty: 1

.018 CERAMIC BRACKET, LOWER CUSPID RIGHT, -11T, +5A / DIRECT BOND

LOT 123456



EC REP

mdf Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A


 Manufactured For
 Ortho Organizers, Inc
 1822 Aston Avenue
 Carlsbad, CA 92008-7306
 800.547.2000 760.448.8600


 0470

REF 700-268 Qty: 1

.018 CERAMIC BRACKET, LOWER CUSPID LEFT, -11T, +5A / DIRECT BOND

LOT 123456



EC REP

mdf Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A


 Manufactured For
 Ortho Organizers, Inc
 1822 Aston Avenue
 Carlsbad, CA 92008-7306
 800.547.2000 760.448.8600


 0470

REF 700-367 Qty: 1

.022 CERAMIC BRACKET, LOWER CUSPID RIGHT, -11T, +5A / DIRECT BOND

LOT 123456



EC REP

mdf Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A


 Manufactured For
 Ortho Organizers, Inc
 1822 Aston Avenue
 Carlsbad, CA 92008-7306
 800.547.2000 760.448.8600


 0470

REF 700-368 Qty: 1

.022 CERAMIC BRACKET, LOWER CUSPID LEFT, -11T, +5A / DIRECT BOND

LOT 123456



EC REP

mdf Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A


 Manufactured For
 Ortho Organizers, Inc
 1822 Aston Avenue
 Carlsbad, CA 92008-7306
 800.547.2000 760.448.8600


 0470

REF 700-267HK Qty: 1

.018 CERAMIC BRACKET, LOWER CUSPID RIGHT, HOOK, -11T, +5A / DIRECT BOND

LOT 123456



EC REP

mdf Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A


 Manufactured For
 Ortho Organizers, Inc
 1822 Aston Avenue
 Carlsbad, CA 92008-7306
 800.547.2000 760.448.8600


 0470

REF 700-268HK Qty: 1

.018 CERAMIC BRACKET, LOWER CUSPID LEFT, HOOK, -11T, +5A / DIRECT BOND

LOT 123456



EC REP

mdf Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

Proposed Labeling

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 **0470**

REF 700-367HK **Qty:** 1

.022 CERAMIC BRACKET, LOWER CUSPID RIGHT,
HOOK, -11T, +5A / DIRECT BOND

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 **0470**

REF 700-288 **Qty:** 1

.018 CERAMIC BRACKET, LOWER BICUSPID LEFT, -17T,
0A / DIRECT BOND

LOT 123456



EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 **0470**

REF 700-368HK **Qty:** 1

.022 CERAMIC BRACKET, LOWER CUSPID LEFT, HOOK,
-11T, +5A / DIRECT BOND

LOT 123456



EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 **0470**

REF 700-387 **Qty:** 1

.022 CERAMIC BRACKET, LOWER BICUSPID RIGHT,
-17T, 0A / DIRECT BOND

LOT 123456



EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 **0470**

REF 700-287 **Qty:** 1

.018 CERAMIC BRACKET, LOWER BICUSPID RIGHT,
-17T, 0A / DIRECT BOND

LOT 123456



EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 **0470**

REF 700-388 **Qty:** 1

.022 CERAMIC BRACKET, LOWER BICUSPID LEFT, -17T,
0A / DIRECT BOND

LOT 123456



EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

LOT 123456



EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

Proposed Labeling

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc.
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-287HK Qty: 1

.018 CERAMIC BRACKET, LOWER BICUSPID RIGHT,
HOOK, -17T, 0A / DIRECT BOND

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc.
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-291 Qty: 1

.018 CERAMIC BRACKET, LOWER BICUSPID RIGHT,
-22T, 0A / DIRECT BOND

LOT 123456



 EC REP
mdf Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc.
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-288HK Qty: 1

.018 CERAMIC BRACKET, LOWER BICUSPID LEFT,
HOOK, -17T, 0A / DIRECT BOND

LOT 123456



 EC REP
mdf Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc.
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-388HK Qty: 1

.022 CERAMIC BRACKET, LOWER BICUSPID LEFT,
HOOK, -17T, 0A / DIRECT BOND

LOT 123456



 EC REP
mdf Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc.
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-387HK Qty: 1

.022 CERAMIC BRACKET, LOWER BICUSPID RIGHT,
HOOK, -17T, 0A / DIRECT BOND

LOT 123456



 EC REP
mdf Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc.
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-292 Qty: 1

.018 CERAMIC BRACKET, LOWER BICUSPID LEFT, -22T,
0A / DIRECT BOND

LOT 123456



 EC REP
mdf Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

LOT 123456



 EC REP
mdf Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

111

Proposed Labeling

 **Ortho Organizers**
 Made in USA

Manufactured For
 Ortho Organizers, Inc
 1822 Aston Avenue
 Carlsbad, CA 92008-7308
 800.547.2000 760.448.8600

 0470

REF 700-391

Qty: 1

.022 CERAMIC BRACKET, LOWER BICUSPID RIGHT,
-22T, 0A / DIRECT BOND

 **Ortho Organizers**
 Made in USA

Manufactured For
 Ortho Organizers, Inc
 1822 Aston Avenue
 Carlsbad, CA 92008-7308
 800.547.2000 760.448.8600

 0470

REF 700-292HK

Qty: 1

.018 CERAMIC BRACKET, LOWER BICUSPID LEFT,
HOOK, -22T, 0A / DIRECT BOND

LOT 123456



EC REP

mdI Europa GmbH
 Langenhagener Str. 71
 30855 Langenhagen, Germany
 F-Label Rev. A

 **Ortho Organizers**
 Made in USA

Manufactured For
 Ortho Organizers, Inc
 1822 Aston Avenue
 Carlsbad, CA 92008-7308
 800.547.2000 760.448.8600

 0470

REF 700-392

Qty: 1

.022 CERAMIC BRACKET, LOWER BICUSPID LEFT, -22T,
0A / DIRECT BOND

LOT 123456



EC REP

mdI Europa GmbH
 Langenhagener Str. 71
 30855 Langenhagen, Germany
 F-Label Rev. A

 **Ortho Organizers**
 Made in USA

Manufactured For
 Ortho Organizers, Inc
 1822 Aston Avenue
 Carlsbad, CA 92008-7308
 800.547.2000 760.448.8600

 0470

REF 700-391HK

Qty: 1

.022 CERAMIC BRACKET, LOWER BICUSPID RIGHT,
HOOK, -22T, 0A / DIRECT BOND

LOT 123456



EC REP

mdI Europa GmbH
 Langenhagener Str. 71
 30855 Langenhagen, Germany
 F-Label Rev. A

 **Ortho Organizers**
 Made in USA

Manufactured For
 Ortho Organizers, Inc
 1822 Aston Avenue
 Carlsbad, CA 92008-7308
 800.547.2000 760.448.8600

 0470

REF 700-291HK

Qty: 1

.018 CERAMIC BRACKET, LOWER BICUSPID RIGHT,
HOOK, -22T, 0A / DIRECT BOND

LOT 123456



EC REP

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 30855 Langenhagen, Germany
 F-Label Rev. A

 **Ortho Organizers**
 Made in USA

Manufactured For
 Ortho Organizers, Inc
 1822 Aston Avenue
 Carlsbad, CA 92008-7308
 800.547.2000 760.448.8600

 0470

REF 700-392HK

Qty: 1

.022 CERAMIC BRACKET, LOWER BICUSPID LEFT,
HOOK, -22T, 0A / DIRECT BOND

LOT 123456



EC REP

mdI Europa GmbH
 Langenhagener Str. 71
 30855 Langenhagen, Germany
 F-Label Rev. A

LOT 123456



EC REP

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 Langenhagener Str. 71
 30855 Langenhagen, Germany
 F-Label Rev. A

Proposed Labeling

 **ORTHO**
Organizers
Made in USA

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Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-307

Qty: 1

.022 CERAMIC BRACKET, UPPER CENTRAL RIGHT,
+17T, +4A / DIRECT BOND

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-324

Qty: 1

.022 CERAMIC BRACKET, UPPER LATERAL LEFT, +10T,
+8A / DIRECT BOND

LOT 123456



 **EC REP**
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

LOT 123456



 **EC REP**
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-308

Qty: 1

.022 CERAMIC BRACKET, UPPER CENTRAL LEFT, +17T,
+4A / DIRECT BOND

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-339HK

Qty: 1

.022 CERAMIC BRACKET, UPPER CUSPID RIGHT,
HOOK, -7T, +8A / DIRECT BOND

LOT 123456



 **EC REP**
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

LOT 123456



 **EC REP**
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-323

Qty: 1

.022 CERAMIC BRACKET, UPPER LATERAL RIGHT,
+10T, +8A / DIRECT BOND

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-340HK

Qty: 1

.022 CERAMIC BRACKET, UPPER CUSPID LEFT, HOOK,
-7T, +8A / DIRECT BOND

LOT 123456



 **EC REP**
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

LOT 123456



 **EC REP**
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

113

Proposed Labeling

 **ORTHOTH**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-357HK Qty: 1

.022 CERAMIC BRACKET, UPPER BICUSPID RIGHT,
HOOK, -7T, 0A / DIRECT BOND

 **ORTHOTH**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-332 Qty: 1

.022 CERAMIC BRACKET, LOWER ANTERIOR LEFT, -6T,
0A / DIRECT BOND

LOT 123456



 EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

 **ORTHOTH**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-358HK Qty: 1

.022 CERAMIC BRACKET, UPPER BICUSPID LEFT,
HOOK, -7T, 0A / DIRECT BOND

LOT 123456



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30855 Langenhagen, Germany
F-Label Rev. A

 **ORTHOTH**
Organizers
Made in USA

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Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-371HK Qty: 1

.022 CERAMIC BRACKET, LOWER CUSPID RIGHT,
HOOK, -6T, +3A / DIRECT BOND

LOT 123456



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F-Label Rev. A

 **ORTHOTH**
Organizers
Made in USA

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1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-331 Qty: 1

.022 CERAMIC BRACKET, LOWER ANTERIOR RIGHT,
-6T, 0A / DIRECT BOND

LOT 123456



 EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

 **ORTHOTH**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7306
800.547.2000 760.448.8600

 0470

REF 700-372HK Qty: 1

.022 CERAMIC BRACKET, LOWER CUSPID LEFT, HOOK,
-6T, +3A / DIRECT BOND

LOT 123456



 EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

LOT 123456



 EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev. A

114

Proposed Labeling

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7308
800.547.2800 760.448.8800

 **CE**
0470

REF 700-385HK **Qty:** 1

.022 CERAMIC BRACKET, LOWER BICUSPID RIGHT,
HOOK, -12T, 0A / DIRECT BOND

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7308
800.547.2800 760.448.8800

 **CE**
0470

REF 700-386HK **Qty:** 1

.022 CERAMIC BRACKET, LOWER BICUSPID LEFT,
HOOK, -12T, 0A / DIRECT BOND

LOT 123456



EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

LOT 123456



EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

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Organizers
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Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7308
800.547.2800 760.448.8800

 **CE**
0470

REF 700-387HK **Qty:** 1

.022 CERAMIC BRACKET, LOWER BICUSPID RIGHT,
HOOK, -17T, 0A / DIRECT BOND

 **ORTHO**
Organizers
Made in USA

Manufactured For
Ortho Organizers, Inc
1822 Aston Avenue
Carlsbad, CA 92008-7308
800.547.2800 760.448.8800

 **CE**
0470

REF 700-388HK **Qty:** 1

.022 CERAMIC BRACKET, LOWER BICUSPID LEFT,
HOOK, -17T, 0A / DIRECT BOND

LOT 123456



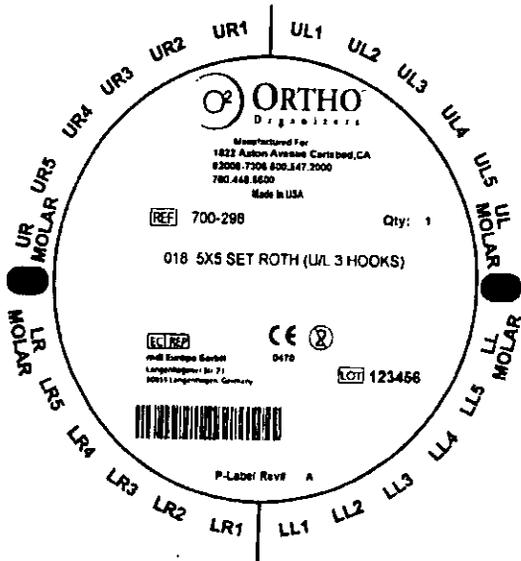
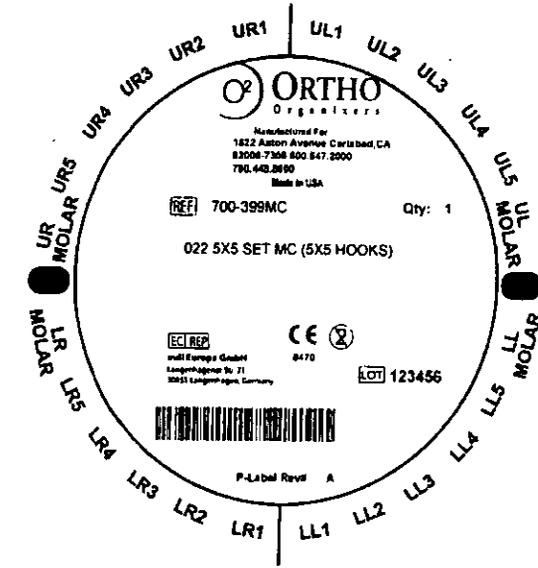
EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

LOT 123456

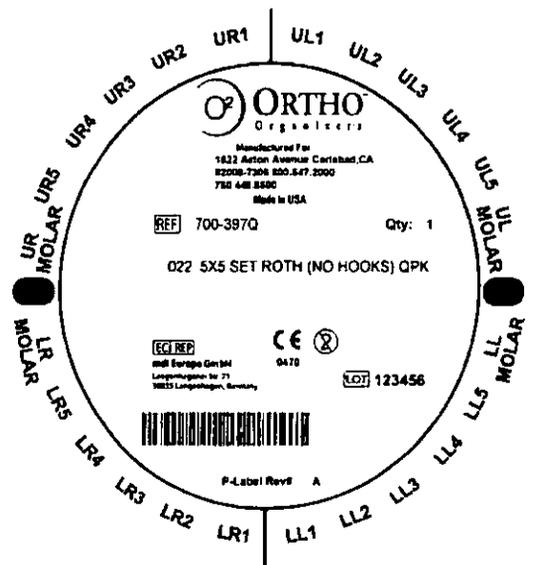
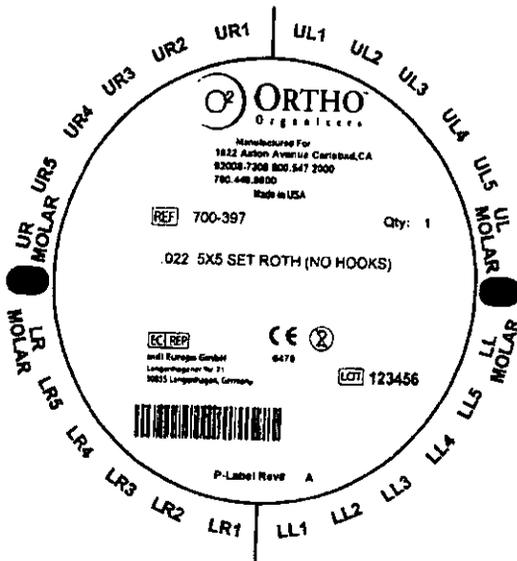
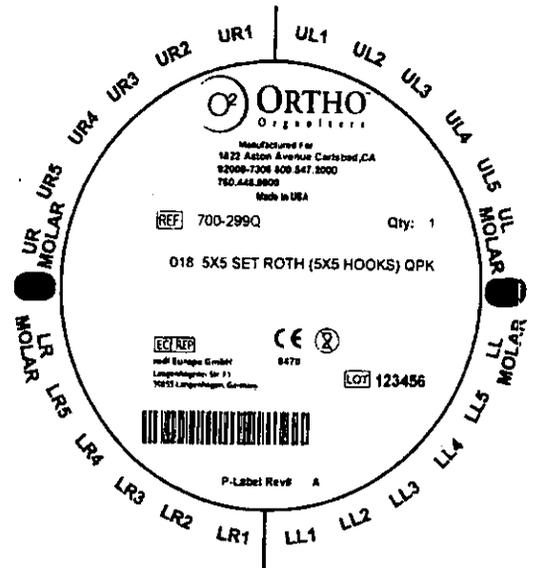
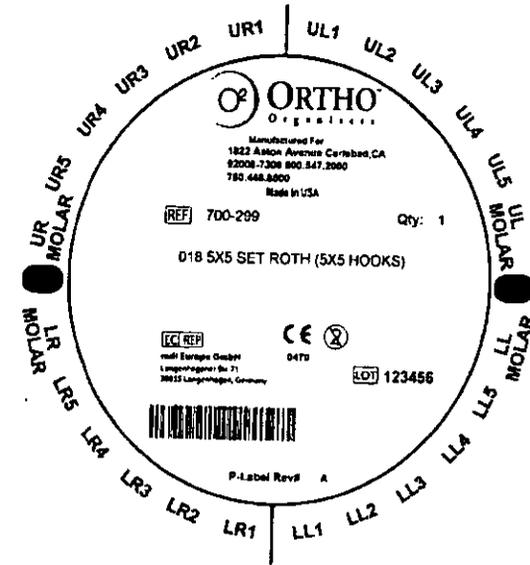


EC REP
mdl Europa GmbH
Langenhagener Str. 71
30855 Langenhagen, Germany
F-Label Rev# A

Proposed Labeling

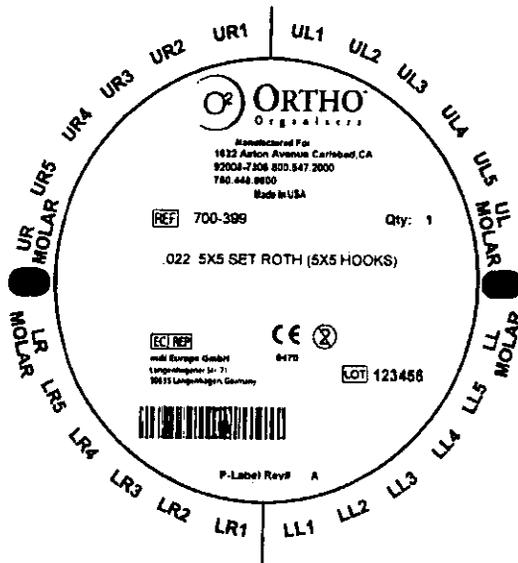


Proposed Labeling



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Proposed Labeling



14. Sterilization/Shelf Life
(Not Applicable)

15. Biocompatibility

Biocompatibility

Ortho Organizers Ceramic Brackets are manufactured from Aluminum Oxide materials that have been well characterized chemically and physically in the published literature and have a long history of safe use in Orthodontics. To verify that the Ortho Organizers Ceramic Brackets are biocompatible a MEM Elution Test for cytotoxicity was performed. Testing results showed a grade 0 reactivity response indicating the test article is not cytotoxic. A record of these results is included on the following pages.

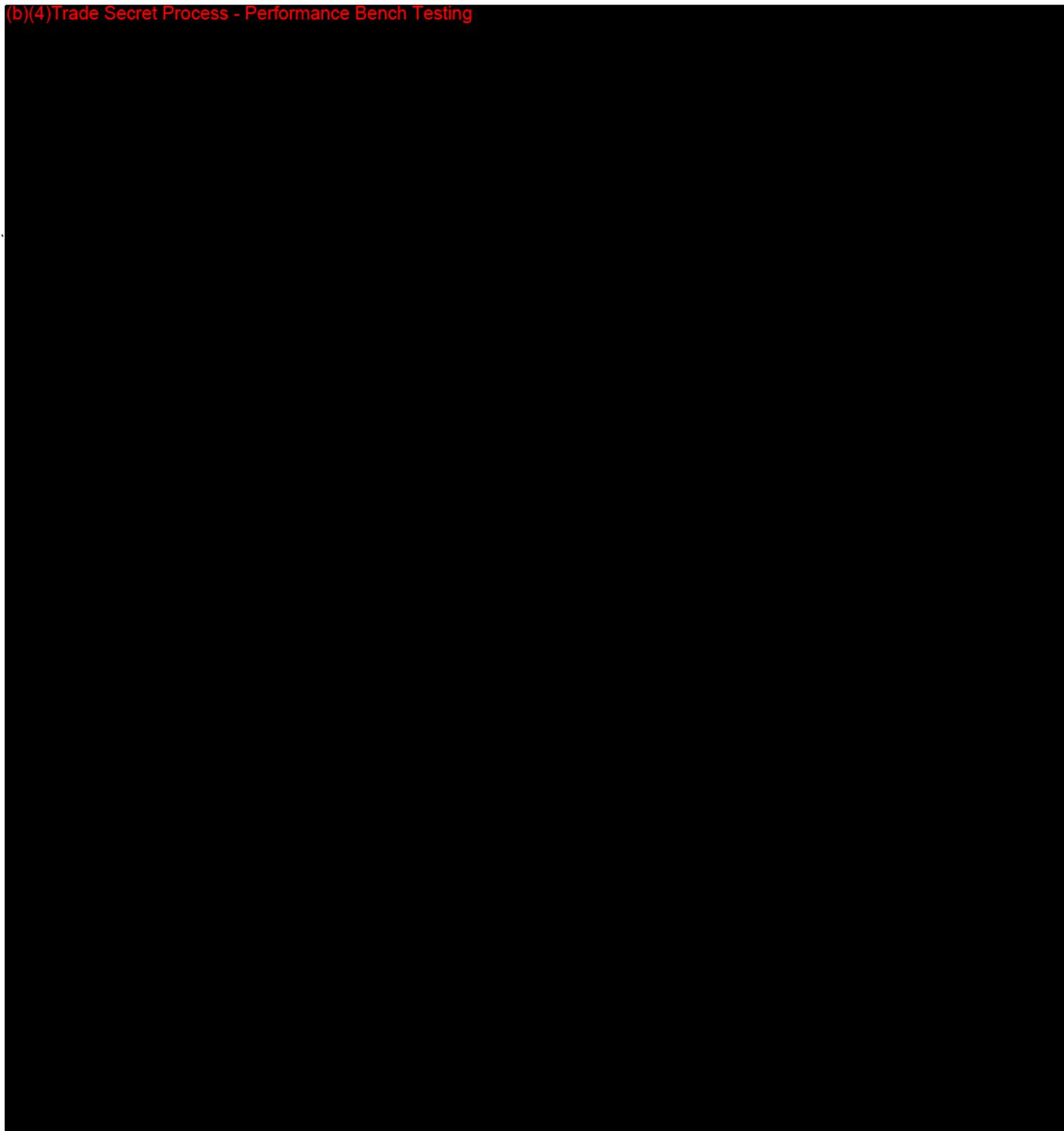
16. Software
(Not Applicable)

17. Electromagnetic Compatibility/Electrical Safety
(Not Applicable)

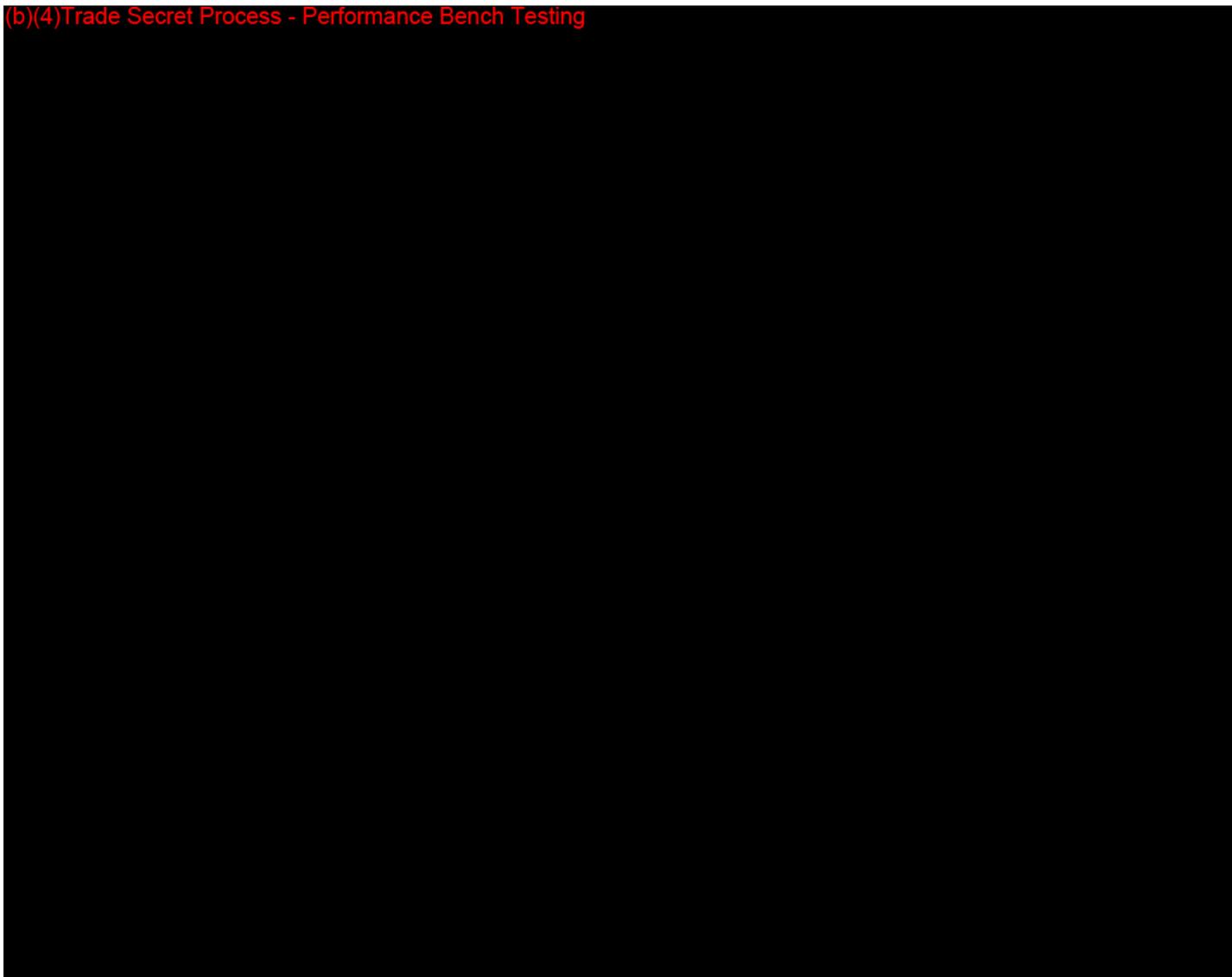
18. Performance Testing-Bench

Performance Testing (Bench)

(b)(4) Trade Secret Process - Performance Bench Testing

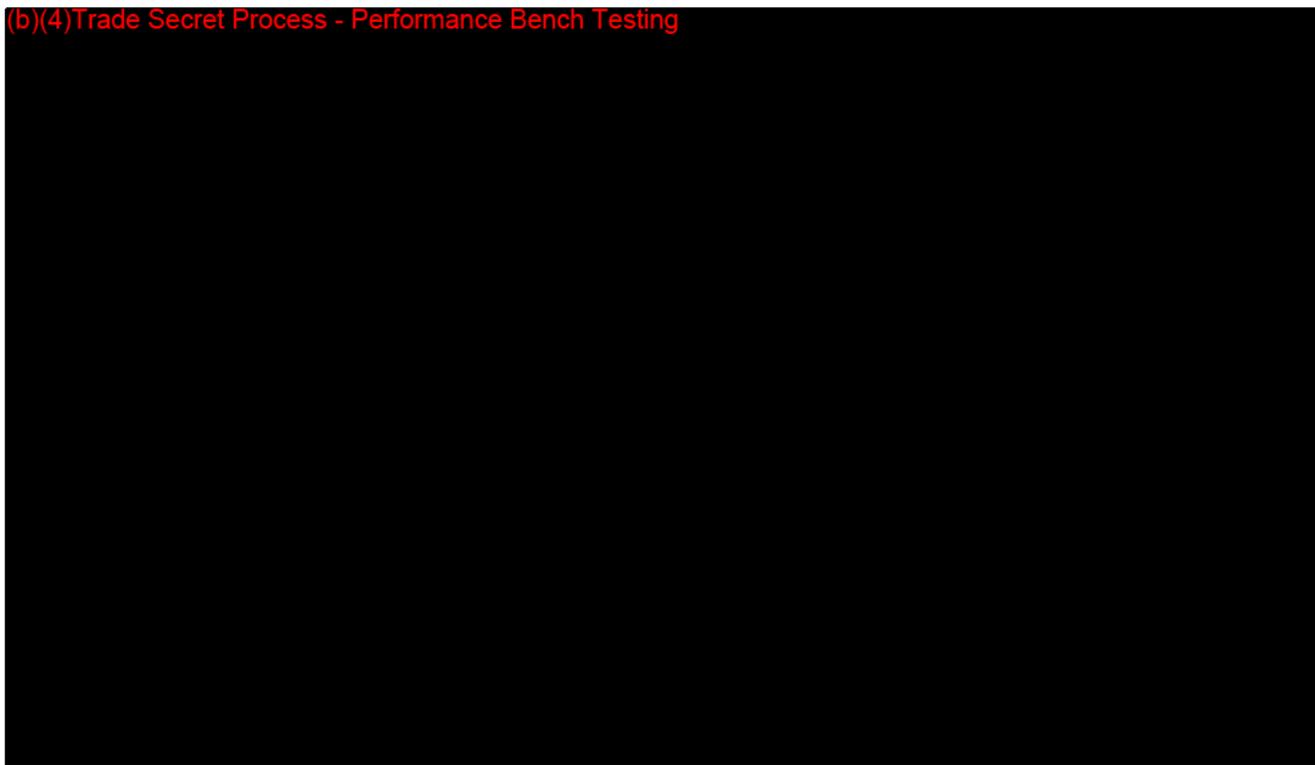


(b)(4) Trade Secret Process - Performance Bench Testing



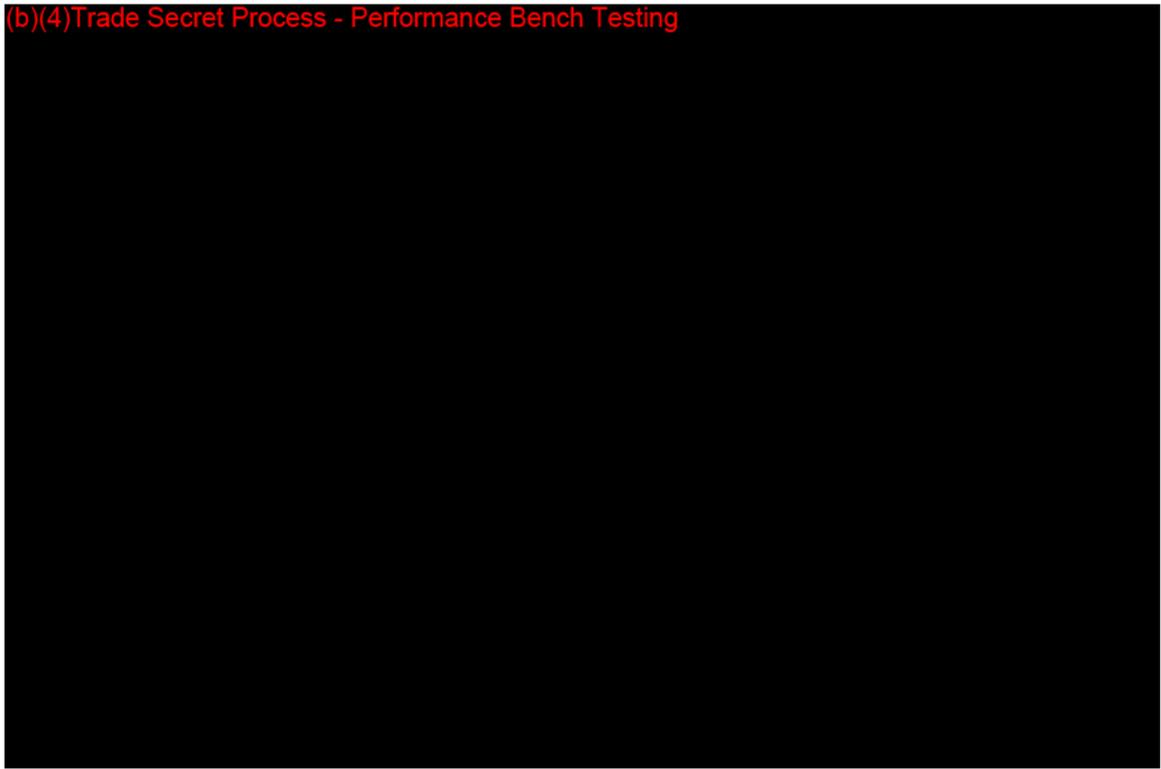
Bond Strength
Test Results

(b)(4)Trade Secret Process - Performance Bench Testing



(b) [redacted] Test Result
(4) Trade

(b)(4) Trade Secret Process - Performance Bench Testing



(b)(4) Trade Secret Process - Performance Bench
Testing



19. Performance Testing-Animal
(Not Applicable)

**20. Performance Testing-Clinical
(Not Applicable)**

21. FORM FDA 3654
(Not Applicable)

22. Kit Certification
(Not Applicable)



COVER SHEET MEMORANDUM

From: Reviewer Name Michael E. Adjodha
 Subject: 510(k) Number K110335/S11
 To: The Record

- Please list CTS decision code SE
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%20202%2007.doc)
 - Hold (Additional Information or Telephone Hold).
 - Final Decision SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NT NSE for new technology
- NI NSE for new intended use
- NP NSE for lack of performance data
- NN NSE raises new types of safety and effectiveness questions
- NC NSE call for PMAs
- NS NSE no response
- NH NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary /510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement.	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, does firm include Class III Summary?	Must be present for a Final Decision	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/CO-MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this device intended for pediatric use only?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this device include an Animal Tissue Source?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
All Pediatric Patients age<=21		<input checked="" type="checkbox"/>	<input type="checkbox"/>

Neonate/Newborn (Birth to 28 days)	✓
Infant (29 days -< 2 years old)	✓
Child (2 years -< 12 years old)	✓
Adolescent (12 years -< 18 years old)	✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)	✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)	✓
Nanotechnology	✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	✓
Contact OC.	✓

Regulation Number 21CFR 872.5470 Class* II Product Code NJM
 (*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: Simon Runover (Branch Chief) DEP3 (Branch Code) 5/18/11 (Date)

Final Review: [Signature] (Division Director) 5/19/11 (Date)



Food and Drug Administration
CDRH/Office of Device Evaluation
10903 New Hampshire Avenue, Bldg.66
Silver Spring, MD 20993

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

K110335

Date: 17 May 2011
To: The Record
Office/Division/Branch: ODE/DAGID/DEDB
From: Michael E. Adjodha, M.ChE., Chemical Engineer
510(k) Submitter: Ortho Organizers, Inc., Carlsbad, CA
Device Name: Ceramic Brackets
Contact: Mr. Foster Boop
Phone: 760-448-8600
Fax: 760-448-8613
Email: foster.boop@orthoorganizers.com

Purpose and Submission Summary

The 510(k) Submitter would like to introduce *Ceramic Brackets* into interstate commerce.

Ceramic Brackets are orthodontic brackets that are intended to be bonded to tooth surfaces and interfaced with archwires for correction of malocclusions.

Ceramic Brackets is substantially equivalent (SE) to legally marketed ceramic orthodontic brackets because the information submitted by Ortho Organizers, Inc., demonstrates that the device has the same indication and technological characteristics as legally marketed ceramic orthodontic brackets.

Administrative Requirements

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

Indications for Use

Ceramic Brackets are orthodontic brackets that are intended to be bonded to tooth surfaces and interfaced with archwires for correction of malocclusions.

The indication of *Ceramic Brackets* does not differ from that of legally marketed orthodontic brackets.

Device Description/Formulation

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

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

Ceramic Brackets will be supplied in solid preformed shapes, featuring a variety of designs under Roth and MBT prescriptions. Available styles and geometries of the various styles and configurations are included in the submission.

Ceramic Brackets achieves its intended purpose by serving as a platform upon which an archwire is placed to apply forces to effect the orthodontic movement of teeth.

The formulation *Ceramic Brackets* is composed of (b)(4)Trade Secret Process [Redacted]

The technical and performance specifications of *Ceramic Brackets* include the following:

Physical Property	<i>Ceramic Brackets</i>
(b)(4)Trade Secret Process	[Redacted]

Contact History/Deficiencies

By an email on April 8, 2011, the reviewer contacted the submitter to request the identity of the color additives used in *Ceramic Brackets*. The submitter responded to this request by a letter on May 5, 2011. No other deficiencies have been identified.

Labeling

The proposed labeling of *Ceramic Brackets* has been provided. As professional use devices, these devices are exempt from providing adequate directions for use (Part 801), as they are intended only for use by trained practitioners of orthodontics. No unsubstantiated claims are made.

Sterilization/Shelf Life/Reuse:

Ceramic Brackets will be provided non-sterile and is not intended to be sterilized before use.

Biocompatibility

Ceramic Brackets is composed of (b)(4)Trade Secret Process Dental ceramics of this type are known to be biocompatible for its intended use. Biocompatibility testing is not required. Nevertheless, the submitter conducted the following tests in accordance with the recognized consensus standard ISO 10993-5:

- Cytotoxicity - MEM elution - 0 reactivity grade

Ceramic Brackets was found to be non-cytotoxic, according to the test above.

Software

Ceramic Brackets contains no software. A software analysis is not applicable.

Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Ceramic Brackets is not an electrical or mechanical device. Therefore, mechanical safety, electrical safety, EMC, and thermal safety are not applicable.

Performance Testing - Bench

Engineering test results are provided above in the device description/formulation section.

Performance Testing - Animal

Animal test results were not provided for *Ceramic Brackets*, neither are they recommended for a conventional formulation such as this.

Performance Testing - Clinical

Human test results were not provided for *Ceramic Brackets*, neither are they recommended for a conventional formulation such as this.

Device Comparison

Predicate Device: *Transcend and Clarity* (K062305) from 3M Unitek.

Physical Property	<i>Ceramic Brackets</i>	<i>Transcend and Clarity</i> (K062305)
Torque (°)	(b)(4) Trade Secret Process	
Angulation (°)		
Maxillary Bond Strength (lbf)		
Mandibular Bond Strength (lbf)		
Tie Wing Crush Strength (lbf)		
Hook Strength (lbf)		

Ceramic Brackets is comparable to other legally marketed ceramic orthodontic brackets on the market such as *Transcend and Clarity* (K062305) of 3M Unitek. These devices are essentially identical in intended use and alumina composition and feature similar bracket designs. The difference in *Ceramic Brackets* lies primarily in the particular shape and configuration of the brackets offered. These modifications do not appear to affect the effectiveness of the brackets as the bond strength of *Ceramic Brackets* is equivalent to that of the predicate device and is sufficient for its intended use.

No new technology has been introduced in *Ceramic Brackets* that would affect its safety or effectiveness. *Ceramic Brackets* appears to be a minor change in the styling of a legally marketed device.

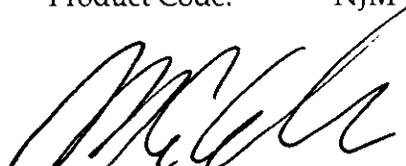
Substantial Equivalence Discussion¹

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

Recommendation

Ceramic Brackets is substantially equivalent to legally marketed ceramic orthodontic brackets under the following classification regulation:

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


 Michael E. Adjodha, M.ChE., Chemical Engineer
 Reviewer

5/17/2011
 Date


 Susan Runner, DDS, MA
 Branch Chief

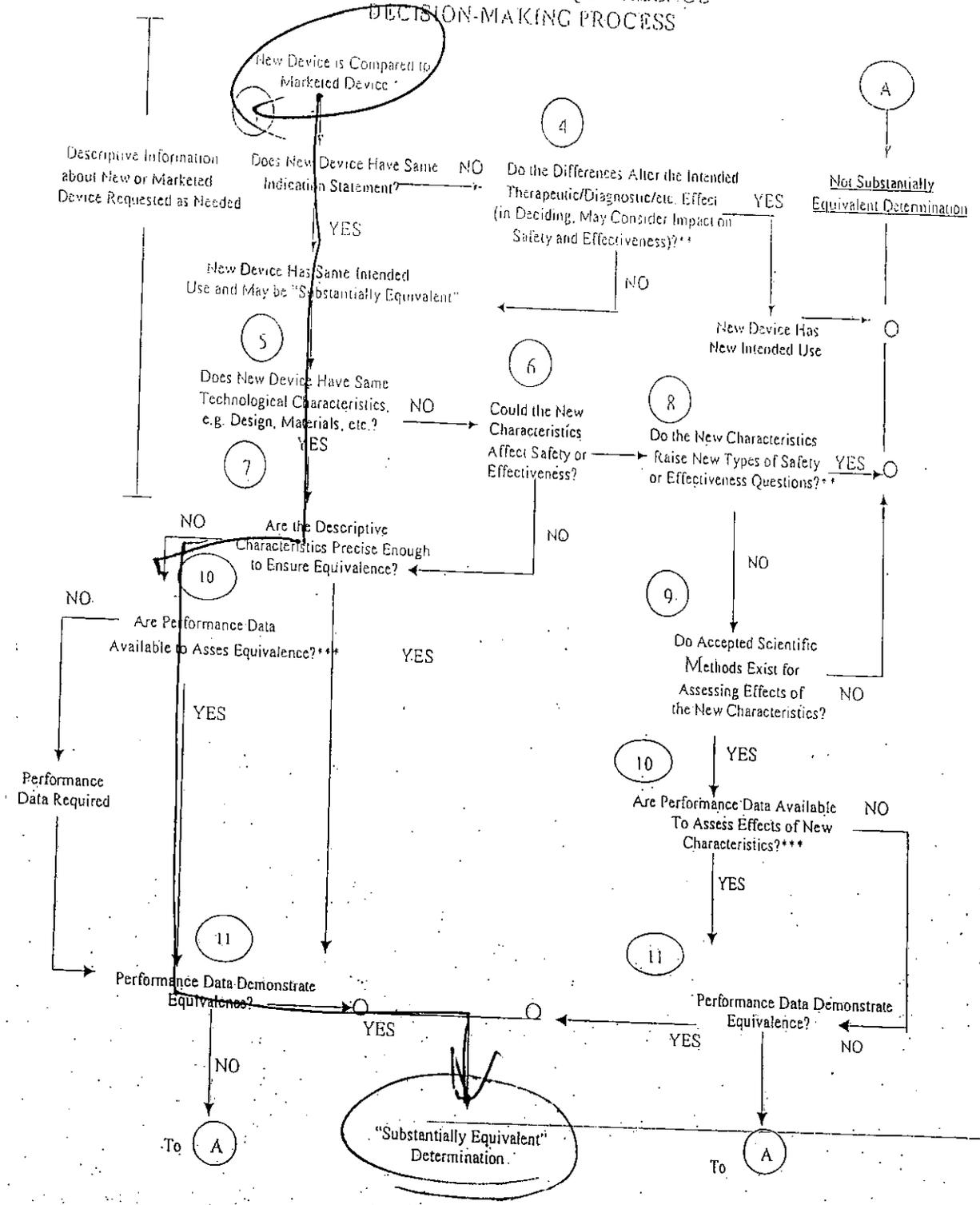
5/18/11
 Date

¹ Note: See http://croom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

² No. Engineering performance data needed.

³ Yes. Engineering performance is equivalent to legally marketed ceramic orthodontic brackets.

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



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

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

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

Adjodha, Michael E

From: Boop, Foster [mailto:Foster.Boop@orthoorganizers.com]
Sent: Tuesday, May 03, 2011 1:23 PM
To: Adjodha, Michael E
Subject: RE: Ceramic Brackets (K110335)
Attachments: Additional Information K110335.pdf

Dear Mr. Adjodha,
Attached is information regarding the color additives to be used for the color coding of ceramic brackets.
Sincerely,
Foster Boop

From: Adjodha, Michael E [mailto:Michael.Adjodha@fda.hhs.gov]
Sent: Tuesday, April 19, 2011 4:01 AM
To: Boop, Foster
Subject: RE: Ceramic Brackets (K110335)

Mr. Boop,

I am placing your submission on hold until the issue of the identity of the color additive used is resolved. To reactivate your submission, please provide the information requested first by email then, after confirmation, by mail.

Please contact me if you have any questions or concerns.

Michael Adjodha

Michael E. Adjodha, M.ChE.
Chemical Engineer
Food and Drug Administration
Center for Devices and Radiological Health
Dental Devices Branch
10903 New Hampshire Avenue
WO66-2606
Silver Spring, MD 20993-0002
E-mail: michael.adjodha@fda.hhs.gov
Phone: 301-796-6276

From: Boop, Foster [mailto:Foster.Boop@orthoorganizers.com]
Sent: Friday, April 08, 2011 1:21 PM
To: Adjodha, Michael E
Subject: RE: Ceramic Brackets (K110335)

Dear Mr. Adjodha,
The purpose of color coding is for orientation and identification of the bracket. Diagram #1 within the submission provides an image of a color coded bracket. (b) [REDACTED]
[REDACTED]
Sincerely,
Foster Boop (4)Trad

From: Adjodha, Michael E [mailto:Michael.Adjodha@fda.hhs.gov]
Sent: Friday, April 08, 2011 8:56 AM
To: Boop, Foster
Subject: RE: Ceramic Brackets (K110335)

Mr. Boop,

Thank you for your quick response. Can you tell me what then is the "color coded indicator for bracket identification" on page 35 of your submission?

Thank you,
Michael Adjodha

From: Boop, Foster [mailto:Foster.Boop@orthoorganizers.com]
Sent: Friday, April 08, 2011 11:52 AM
To: Adjodha, Michael E
Subject: RE: Ceramic Brackets (K110335)

Dear Mr. Adjodha,
[REDACTED] (b) [REDACTED]
Sincerely,
Foster Boop
Director, Regulatory Affairs & Quality Assurance
Ortho Organizers, Inc.

From: Adjodha, Michael E [mailto:Michael.Adjodha@fda.hhs.gov]
Sent: Friday, April 08, 2011 8:12 AM

To: Boop, Foster
Subject: Ceramic Brackets (K110335)
Importance: High

Dear Mr. Boop,

I am currently reviewing your 510(k) submission for Ceramic Brackets (K110335). In order to complete my review, I would like to request the following information:

- The chemical identity and percentages of all color additives included in the formulation.

Thank you for your attention to this. Please contact me if you have any questions or concerns.

Sincerely,
Michael Adjodha

Michael E. Adjodha, M.ChE.
Chemical Engineer
Food and Drug Administration
Center for Devices and Radiological Health
Dental Devices Branch
10903 New Hampshire Avenue
WO66-2606
Silver Spring, MD 20993-0002
E-mail: michael.adjodha@fda.hhs.gov
Phone: 301-796-6276

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COVER SHEET MEMORANDUM

From: Reviewer Name

Michael E. Adyodha

Subject: 510(k) Number

K110335

To: The Record

~~ADY~~ TH (See memo 4/19/11)

Please list CTS decision code

- Refused to accept (Note: this is considered the first review cycle. See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/O_5631/Screening%20Checklist%202007.doc)
- Hold (Additional Information or Telephone Hold)
- Final Decision (SE with Limitations, NSE, Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):

	YES	NO
Indications for Use Page		
510(k) Summary / 510(k) Statement	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, does firm include Class III Summary?		<input checked="" type="checkbox"/>
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		<input checked="" type="checkbox"/>
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/O_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)		<input checked="" type="checkbox"/>
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		<input checked="" type="checkbox"/>
Is this device intended for pediatric use only?		<input checked="" type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)		<input checked="" type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)?		<input checked="" type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)		<input checked="" type="checkbox"/>
Does this device include an Animal Tissue Source?		<input type="checkbox"/>
All Pediatric Patients age <= 21		<input checked="" type="checkbox"/>
Neonate/Newborn (Birth to 28 days)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Infant (29 days - < 2 years old)		<input checked="" type="checkbox"/>
Child (2 years - < 12 years old)		<input checked="" type="checkbox"/>
Adolescent (12 years - < 18 years old)		<input checked="" type="checkbox"/>
Transitional Adolescent A (18 - < 24 years old) Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)		<input checked="" type="checkbox"/>

Transitional Adolescent B (18 <= 21. No special considerations compared to adults => 21 years old) ✓
Nanotechnology ✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>) Contact OC ✓

Regulation Number 21CFR Class II Product Code NJM
872.5470 (If unclassified, see 510(k) Staff)

Additional Product Codes: _____
Review: R. Bdz for Susan Ranne DED3 4/13/11 (RSB)
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)
04-19-2011

Adjodha, Michael E

From: Adjodha, Michael E
Sent: Tuesday, April 19, 2011 7:01 AM
To: 'Boop, Foster'
Subject: RE: Ceramic Brackets (K110335)

Mr. Boop,

I am placing your submission on hold until the issue of the identity of the color additive used is resolved. To reactivate your submission, please provide the information requested first by email then, after confirmation, by mail.

Please contact me if you have any questions or concerns.

Michael Adjodha

Michael E. Adjodha, M.ChE.
Chemical Engineer
Food and Drug Administration
Center for Devices and Radiological Health
Dental Devices Branch
10903 New Hampshire Avenue
WO66-2606
Silver Spring, MD 20993-0002
E-mail: michael.adjodha@fda.hhs.gov
Phone: 301-796-6276

From: Boop, Foster [mailto:Foster.Boop@orthoorganizers.com]
Sent: Friday, April 08, 2011 1:21 PM
To: Adjodha, Michael E
Subject: RE: Ceramic Brackets (K110335)

Dear Mr. Adjodha,

The purpose of color coding is for orientation and identification of the bracket. Diagram #1 within the submission provides an image of a color coded bracket. (b)

Sincerely,
Foster Boop

(4)Trade

From: Adjodha, Michael E [mailto:Michael.Adjodha@fda.hhs.gov]
Sent: Friday, April 08, 2011 8:56 AM
To: Boop, Foster
Subject: RE: Ceramic Brackets (K110335)

Mr. Boop,

Thank you for your quick response. Can you tell me what then is the "color coded indicator for bracket identification" on page 35 of your submission?

Thank you,
Michael Adjodha

From: Boop, Foster [mailto:Foster.Boop@orthoorganizers.com]
Sent: Friday, April 08, 2011 11:52 AM
To: Adjodha, Michael E
Subject: RE: Ceramic Brackets (K110335)

Dear Mr. Adjodha,

Sincerely,
Foster Boop
Director, Regulatory Affairs & Quality Assurance
Ortho Organizers, Inc.

From: Adjodha, Michael E [mailto:Michael.Adjodha@fda.hhs.gov]
Sent: Friday, April 08, 2011 8:12 AM
To: Boop, Foster
Subject: Ceramic Brackets (K110335)
Importance: High

Dear Mr. Boop,

I am currently reviewing your 510(k) submission for Ceramic Brackets (K110335). In order to complete my review, I would like to request the following information:

- The chemical identity and percentages of all color additives included in the formulation.

Thank you for your attention to this. Please contact me if you have any questions or concerns.

Sincerely,
Michael Adjodha

Michael E. Adjodha, M.ChE.
Chemical Engineer
Food and Drug Administration
Center for Devices and Radiological Health
Dental Devices Branch
10903 New Hampshire Avenue
WO66-2606
Silver Spring, MD 20993-0002
E-mail: michael.adjodha@fda.hhs.gov
Phone: 301-796-6276

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

May 11, 2011

ORTHO ORGANIZERS, INC.
1822 ASTON AVENUE
CARLSBAD, CALIFORNIA 92008-7603
ATTN: FOSTER BOOP

510k Number: K110335

Product: CERAMIC BRACKETS

The additional information you have submitted has been received.

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

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

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

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

Sincerely,

510(k) Staff



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

May 5, 2011

FDA CDRH DMC

MAY 10 2011

RE: Additional Information 510(k) Number: K110335

Received

Dear Sir or Madam,

Ortho Organizers is submitting additional information in duplicate in response to a request regarding the chemical identity and percentages of all color additives included in the formulation for the color code indicator for bracket identification.

Ortho Organizers considers its intent to market this device as confidential commercial information and requests that this additional information presented herein be treated as confidential commercial information in accordance with 21 CFR 807.95.

Sincerely,

Foster Boop
Director of Regulatory Affairs and Quality Assurance
Ortho Organizers

K53



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

May 3, 2011

RE: Additional Information 510(k) Number: K110335

Dear Michael Adjodha,

Ortho Organizers is submitting additional information in response to a request noted in e-mail correspondence regarding the chemical identity and percentages of all color additives included in the formulation for the color code indicator for bracket identification.

The color code indicators contain the following material and percentages of color additives.

Chemical Composition of Color ID marks for Ceramic Brackets					
	(b)(4)Trade Secret Process				
Color	Percentage	%	%	%	%
Pink	(b)(4)Trade Secret Process				
Red					
Yellow					
Blue					
Green					
Black					
	* listed in 21 CFR 172.820				
	** listed in 21 CFR Part 74				

Sincerely,

Foster Boop
 Director of Regulatory Affairs and Quality Assurance
 Ortho Organizers