

K102803

510(k) Summary

FEB 17 2011

510(k) Submitter..... 3M Unitek Corp, 2724 S Peck Rd, Monrovia, CA 91016
Contact person..... L. Marlyn Scheff, Regulatory Affairs
Phone: (626) 574-4496
Date Summary was Prepared..... January 12, 2011
Device Name..... Clarity™ Advanced Ceramic Brackets
Common Name..... Orthodontic ceramic bracket
Recommended Classification..... Orthodontic ceramic bracket
(21 CFR 872.5470, Product Code: NJM)

Predicate Devices

K062345, Clarity™ SL Self-Ligating Ceramic Brackets
K944286, Clarity™ Metal-Reinforced Ceramic Brackets
K950992, InVu® Aesthetic Braces
K082974, Mystique® MB Clear Braces

Description of Device

Clarity Advanced Ceramic Brackets are intended to be bonded to teeth, upon which an orthodontic wire is used to move the teeth to new positions. Clarity Advanced Ceramic Brackets consist of a translucent alumina body and a glass-grit bonding base. The bracket is either uncoated or coated with a thin film of stabilized zirconia. The brackets incorporate a water-soluble color placement indicator system that marks archwire and vertical slots to aid in bracket positioning and color codes tie wing(s) to facilitate bracket identification.

Indications for Use

Clarity™ Advanced Ceramic Brackets are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth.

Substantial Equivalence

Both the non-clinical data and the biocompatibility evaluation indicate that Clarity™ Advanced Ceramic Brackets are safe and effective for their intended use in orthodontic treatment and perform as well or better than predicate devices. The table on the next page compares the new device with the predicate devices. Information provided in this 510(k) submission shows that Clarity™ Advanced Ceramic Brackets are substantially equivalent to the predicate devices in terms of intended use, indications for use, composition, device design, and performance. This 510(k) also includes data from bench testing to evaluate the performance of Clarity™ Advanced Ceramic Brackets compared to the predicate devices. The properties evaluated include bond strength, bracket strength, material friction, and debond strength.

Technological Characteristics

Clarity Advanced Ceramic Brackets are substantially equivalent in design features to the predicate devices.

Device Material

Clarity Advanced, Clarity SL, Clarity, InVu and Mystique MB brackets all have a bracket body made of ceramic, with Clarity Advanced, Clarity SL, and InVu brackets made of micro-fine ceramic. Clarity Advanced, Clarity SL, and Clarity have a glass-grit bonding base whereas InVu has a molded polymer bonding base and Mystique MB have a molded alumina bonding base. Clarity Advanced has a zirconia, or no coating, on the bracket and in the archwire slot, Clarity SL has a metal liner, or no liner, in the archwire slot, Clarity has a metal liner in the archwire slot, InVu has no liner or coating in the archwire slot, and Mystique MB has a silica coating in the archwire slot. Clarity Advanced has color slot & dot indicators whereas Clarity SL, Clarity, InVu have color dot indicators and Mystique MB has no color indicators.

Device Design

Clarity Advanced, Clarity SL, Clarity, InVu and Mystique MB brackets all have tying undercut spaces for orthodontic ligatures. Clarity Advanced, Clarity SL, Clarity and InVu brackets have true-twin tieings, i.e. four tieings, for versatile use with auxiliaries. Clarity Advanced, Clarity, and InVu brackets contain base flanges for bracket placement and adhesive flash cleanup. Clarity Advanced, Clarity SL and InVu brackets contain a molded ceramic bracket body with rounded corners and edges, which replaces the angular profile of machined ceramic brackets, and round hook on the distal-gingival tieings. Clarity Advanced, Clarity SL and Clarity brackets contain vertical slot and stress concentrator to facilitate debonding of the bracket from the tooth.

Nonclinical Performance Testing

The nonclinical performance testing analysis shows that Clarity Advanced Ceramic Brackets perform comparably to the predicate devices as follows:

1. The shear-peel bond strength test measures the force required to debond a bracket when a force is applied in the occlusal direction. The test results showed that the bond strengths of Clarity Advanced, Clarity SL and Clarity brackets are comparable and exceed the minimum bond strength to hold the bracket to the tooth.
2. The bracket strength test measures the torsional force to break a bracket when a rectangular archwire is twisted in the wire slot. The test results showed that the bracket strengths of Clarity Advanced Ceramic Brackets are comparable to Clarity Metal-Reinforced Ceramic Brackets and InVu Aesthetic Braces and exceed the minimum requirements.
3. The bracket material friction test measures the surface frictional forces of a stainless steel wire against a bracket surface. The test results showed that the zirconia-coated aluminum oxide surface exhibited lower coefficients of friction as compared to the uncoated aluminum oxide surface.

4. The squeeze debond test measures the forces applied to the sections left and right of the vertical slot in the Clarity Advanced, Clarity and Clarity SL brackets which cause the bracket to debond from the adhesive. The test results showed that squeeze debond moments for Clarity Advanced Ceramic Brackets are comparable to those for Clarity™ SL brackets and slightly lower for Clarity brackets.

In addition, a biocompatibility assessment was developed for Clarity Advanced Ceramic Brackets using standard risk assessment techniques and consideration of FDA and internationally recognized guidelines.

Clinical Performance Testing

No clinical performance testing was conducted on Clarity™ Advanced Ceramic Brackets.

Conclusion

The results from the nonclinical performance testing and the biocompatibility assessment demonstrate that Clarity Advanced Ceramic Brackets are safe and effective for their intended use and perform as well as predicate devices.



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

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

FEB 17 2011

Re: K102803
Trade/Device Name: Clarity™ Advanced Ceramic Brackets
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: January 26, 2011
Received: February 1, 2011

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. 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): K102803

Device Name: Clarity™ Advanced Ceramic Brackets

Indications for Use:

Clarity™ Advanced Ceramic Brackets are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth.

Prescription Use X
(Per 21 CFR 801 Subpart D)

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



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102803

3M Unitek
Orthodontic Products

2724 South Peck Road
Monrovia, CA 91016-5097
626 574 4000
www.3MUnitek.com

K 102803/A2

3M

FDA CDRH DMC

FEB 16 2011

~~RECEIVED~~

February 15, 2011

K-33

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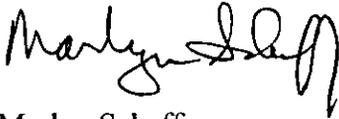
Attn: Sheena A. Green, M.S., Biomedical Engineer
Re: K102803, Clarity™ Advanced Aesthetic Brackets (now Clarity™ Advanced Ceramic Brackets)

Dear Ms Green:

This is to advise that 3M Unitek has changed the name of the device in our 510(k) submission K102803 from Clarity™ Advanced Aesthetic Brackets to Clarity™ Advanced Ceramic Brackets.

Please let me know if you require any additional information to complete the review of K102803 for Clarity™ Advanced Ceramic Brackets.

Sincerely,



Marlyn Scheff
3M Unitek
mscheff@mmm.com
☎ 626-574-4496

PLEASE ADD THE
ATTACHED INFORMATION
TO FILE:

2/18/11



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

FEB 17 2011

Re: K102803
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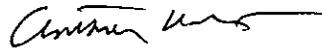
<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

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<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): K102803

Device Name: Clarity™ Advanced Ceramic Brackets

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Prescription Use X
(Per 21 CFR 801 Subpart D)

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



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102803

0003



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

December 23, 2010

3M UNITEK CORPORATION
2724 SOUTH PECK RD.
MONROVIA, CALIFORNIA 91016
UNITED STATES
ATTN: MARLYN L. SCHEFF

510k Number: K102803

Product: CLARITY ADVANCED AESTHETIC BRA

Extended Until: 02/02/2011

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). 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.

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

- 0056

FedEx

December 20, 2010



FDA CDRH DMC

DEC 21 2010

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

Received

Attention: Ms Marjorie Shulman, Consumer Safety Officer
Premarket Notification Section, Office of Device Evaluation

JK-14

RE: 510k Number K102803
Clarity Advanced Aesthetic Bracket

Dear Ms Shulman:

This is regarding your letter dated December 7, 2010, wherein the Office of Device Evaluation requests additional information on 3M Unitek's premarket notification, K102803. We are requesting an extension of 30 days from the January 7, 2011, due-date to provide the additional to the FDA.

Sincerely,

L. Marlyn Scheff
3M Unitek

☎ (626) 574-4496

Email: mscheff@mmm.com

0057



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

December 07, 2010

3M UNITEK CORPORATION
2724 SOUTH PECK RD.
MONROVIA, CALIFORNIA 91016
UNITED STATES
ATTN: MARLYN L. SCHEFF

510k Number: K102803

Product: CLARITY ADVANCED AESTHETIC BRA

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/MedicalDeviceProvisionsofFDAModer nizationAct/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.

0058

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 Mail Center 4 WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 28, 2010

3M UNITEK CORPORATION
2724 SOUTH PECK RD.
MONROVIA, CALIFORNIA 91016
UNITED STATES
ATTN: MARLYN L. SCHEFF

510k Number: K102803

Received: 9/28/2010

Product: CLARITY ADVANCED AESTHETIC BRA

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.

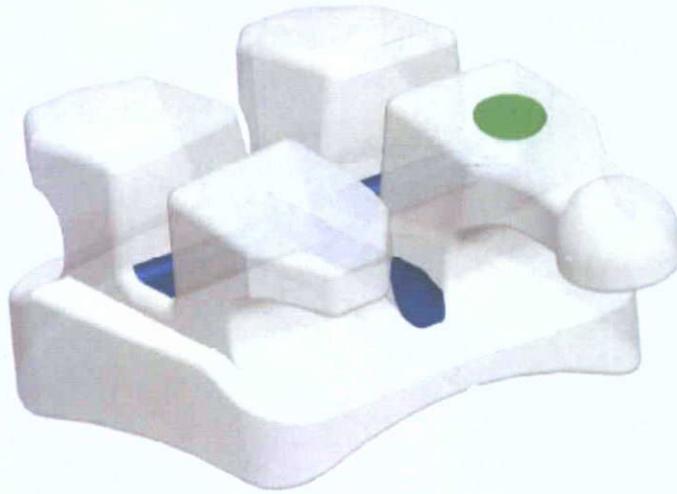
Sincerely,

510(k) Staff

Premarket Notification

for

Clarity™ Advanced Aesthetic Brackets



Submitted by:

3M Unitek Corporation
2724 South Peck Road
Monrovia, CA 91016

K47

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1. Medical Device User Fee Cover Sheet (Form FDA 3601)

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statistics.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade 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) 3M UNITEK CORP 2724 SOUTH PECK ROAD MONROVIA CA 910165097 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) ****6495		2. CONTACT NAME Jerold Horn 2.1 E-MAIL ADDRESS jshorn1@mmm.com 2.2 TELEPHONE NUMBER (include Area code) 626-523-9647 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 <u>3.2 Select one of the types below</u> <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		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)		

Form FDA 3601 (03/2007)

08-Jun-2010

2. CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		Form Approval OMB No. 9010-0120 Expiration Date: August 31, 2010 See OMB Statement on page 5.	
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET			
Date of Submission September 24, 2010	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)	
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
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
		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):	
		Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):	
Have you used or cited Standards in your submission? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, please complete Section I, Page 5)			
SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Company / Institution Name 3M Unitek Corporation		Establishment Registration Number (if known) 2020467	
Division Name (if applicable)		Phone Number (including area code) (626) 574-4496	
Street Address 2724 South Peck Road		FAX Number (including area code) (626) 574-4876	
City Monrovia	State / Province CA	ZIP/Postal Code 91016	Country USA
Contact Name L. Marlyn Scheff		Contact E-mail Address mscheff@mmm.com	
Contact Title Regulatory Affairs			
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/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<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"/> Reponse 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	NJM	2	DYW	3	4	5	6			
5	6	7	8	9	10	11	12			
Information on devices to which substantial equivalence is claimed (if known)										
510(k) Number		Trade or Proprietary or Model Name				Manufacturer				
1	K062305	1	Clarity™ SL Self-Ligating Appliance System (Clarity™ Modified Ceramic Brackets)				1	3M Unitek Corporation		
2	K944286	2	Clarity™ Metal-Reinforced Ceramic Brackets (Metal-Lined Transcend™ Ceramic Brackets)				2	3M Unitek Corporation		
3	K950992	3	InVu® Aesthetic Braces (Ceramaflex™ Ceramic Brackets)				3	TP Orthodontics Inc.		
4	K082974	4	Mystique® MB Clear Braces				4	Dentsply International		
5		5					5			
6		6					6			
SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS										
Common or usual name or classification										
Orthodontic ceramic bracket										
Trade or Proprietary or Model Name for This Device						Model Number				
1	Clarity™ Advanced Aesthetic Brackets					1				
2						2				
3						3				
4						4				
5						5				
FDA document numbers of all prior related submissions (regardless of outcome)										
1	2	3	4	5	6	7	8	9	10	
Data Included in Submission										
<input checked="" type="checkbox"/> Laboratory Testing <input type="checkbox"/> Animal Trials <input type="checkbox"/> Human Trials										
SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS										
Product Code NJM		C.F.R. Section (if applicable) 872.5470				Device Class				
Classification Panel Dental						<input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified				
Indications (from labeling) For use in orthodontic treatment.										

Note: Submission of this information does not effect the need to submit a 2891 or 2691a 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	FDA Establishment Identifier (FEI) Number 2020467	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name 3M Unitek Corporation		Establishment Registration Number 2020467	
Division Name (if applicable)		Phone Number (including area code) (626) 574-4496	
Street Address 2724 South Peck Road		FAX Number (including area code) (626) 574-4876	
City Monrovia		State / Province CA	ZIP/Postal Code 91016
Country USA			
Contact Name Jerold S. Horn	Contact Title Vice President, Quality & Regulatory	Contact E-mail Address jshorn1@mmm.com	
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Identifier (FEI) Number (b)(4) Trade Secret Process	<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name (b)		Establishment Registration Number (b)	
Division Name (if applicable)		Phone Number (including area code) (b)	
Street Address (b)		FAX Number (including area code) (b)	
City (b)		State / Province (b)	ZIP/Postal 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	FDA Establishment Identifier (FEI) Number (b)	<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name (b)		Establishment Registration Number (b)	
Division Name (if applicable)		Phone Number (including area code) (b)(4) Trade	
Street Address (b)(4) Trade		FAX Number (including area code) (b)	
City (b)		State / Province (b)	ZIP/Postal Code (b)
Country (b)			
Contact Name (b)(4) Trade	Contact Title (b)(4) Trade Secret	Contact E-mail Address (b)(4) Trade	

SECTION I UTILIZATION OF STANDARDS					
<p>Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.</p>					
1	Standards No. ISO 14971	Standards Organization ISO	Standards Title Medical devices - Application of risk management to medical devices	Version 2007	Date 9/12/2007
2	Standards No. ISO 10993-1	Standards Organization ISO	Standards Title Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process	Version 2009	Date 5/5/2010
3	Standards No. ISO 7405	Standards Organization ISO	Standards Title Dentistry -- Evaluation of biocompatibility of medical devices used in dentistry	Version 2008	Date 9/8/2009
4	Standards No. ISO 6872	Standards Organization ISO	Standards Title Dentistry - Ceramic materials	Version 2008	Date 9/8/2009
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date
<p>Please include any additional standards to be cited on a separate page.</p>					
<p>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:</p> <p style="text-align: center;">Department of Health and Human Services Food and Drug Administration Office of the Chief Information Officer (HFA-710) 5600 Fisher Lane Rockville, Maryland 20857</p> <p>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.</p>					

3M Unitek

K102803

3. 510(k) Cover Letter

**3M Unitek Corporation
Orthodontic Products**

2724 South Peck Road
Monrovia, CA 91016-5097
636 574 4000

3M

September 24, 2010

FDA CDRH DMC
SEP 28 2010
Received

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Subject: 510(k) Notification for Clarity™ Advanced Aesthetic Brackets

Dear Sir/Madam,

Enclosed are the original and two copies of the Premarket Notification 510(k) submission for Clarity™ Advanced Aesthetic Brackets in accordance with 21 CFR 807.87. The next page contains the administrative information, basis for the submission, and design and use of Clarity™ Advanced Aesthetic Brackets.

If there are any questions concerning this submission, please contact me by phone at (626) 574-4496, FAX at (626) 574-4876, or e-mail at mscheff@mmm.com

Sincerely,



L. Marlyn Scheff
Regulatory Affairs

3M Unitek

3.1 Administrative Information:

User Fee Payment ID Number..... (b)(4) B

Type of 510(k) submission..... Traditional

Device type (common name)..... Orthodontic ceramic bracket

510(k) Submitter..... 3M Unitek Corporation
2724 South Peck Road
Monrovia, CA 91016-5097
Owner/ Operator No.: 2110898
Establishment Registration No.: 2020467

Contact person..... L. Marlyn Scheff
Regulatory Affairs
Phone: (626) 574-4496
Fax: (626) 574-4876
mscheff@mmm.com

Additional Contact persons..... Kathleen F. Bacon
Global Regulatory Affairs Mgr.
Phone: (626) 574-4212
Fax: (626) 574-4894
kbacon@mmm.com

Jerold S. Horn
Vice President, Quality and Regulatory
Phone: (626) 574-4462
Fax: (626) 574-4894
jshorn1@mmm.com

Preference for Continued Confidentiality: 3M Company requests that all trade secret and confidential commercial information contained in this submission be maintained as confidential by the Agency and not disclosed publicly, consistent with 21 CFR 20.61.

Recommended classification regulation..... 21 CFR 872.3750
Class..... II
Panel..... Dental
Product code..... NJM

3.2 Basis for Submission: Modification of a legally marketed device

3.3 Design and Use of Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	√	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		√
Does the device contain components derived from a tissue or other biologic source?		√
Is the device provided sterile?		√
Is the device intended for single use?	√	
Is the device a reprocessed single use device?		√
If yes, does this device type require reprocessed validation data?	N/A	N/A
Does the device contain a drug?		√
Does the device contain a biologic?		√
Does the device use software?		√
Does the submission include clinical information?		√
Is the device implanted?		√

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: Clarity™ Advanced Aesthetic Brackets

Indications for Use:

Clarity™ Advanced Aesthetic Brackets are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth.

Prescription Use X
(Per 21 CFR 801 Subpart D)

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

5. 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Submitter..... 3M Unitek Corporation, 2724 South Peck Road,
Monrovia, CA 91016-5097

Contact person.....L. Marlyn Scheff, Regulatory Affairs
Phone: (626) 574-4496
Fax: (626) 574-4876
mscheff@mmm.com

Date Summary was Prepared..... September 24, 2010
Device Name..... Clarity™ Advanced Aesthetic Brackets
Common Name..... Orthodontic ceramic bracket
Recommended Classification..... Orthodontic plastic bracket
(21 CFR 872.5470, Product Code: NJM)

Predicate Devices:

Clarity™ SL Self-Ligating Ceramic Brackets, Clarity™ Metal-Reinforced Ceramic Brackets. InVu® Aesthetic Braces. Mystique® MB Clear Braces

Description of Device:

Clarity™ Advanced Aesthetic Brackets are intended to be bonded to teeth, upon which an orthodontic wire is used to move the teeth to new positions. Clarity™ Advanced Aesthetic Brackets consist of a translucent alumina body and a glass-grit bonding base. The bracket is either uncoated or coated with a thin film of stabilized zirconia. The brackets incorporate a water-soluble color placement indicator system that marks archwire and vertical slots to aid in bracket positioning and color codes tie wing(s) to facilitate bracket identification.

Indications for Use:

Clarity™ Advanced Aesthetic Brackets are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth.

Substantial Equivalence:

Information provided in this 510(k) submission shows that Clarity™ Advanced Aesthetic Brackets are substantially equivalent to the predicate devices in terms of intended use, indications for use, composition, device design, and performance. A biocompatibility assessment was developed for Clarity™ Advanced Aesthetic Brackets using standard risk assessment techniques and consideration of FDA and internationally recognized guidelines. The conclusion of the assessment is that Clarity™ Advanced Aesthetic Brackets are safe for the intended use. This 510(k) also includes data from bench testing to evaluate the performance of Clarity™ Advanced Aesthetic Brackets compared to the predicate devices. The properties evaluated include bond strength, bracket strength, material friction, and debond strength.

7. Class III Summary and Certification

Not applicable. Subject medical device is not a Class III device.

8. Financial Certification or Disclosure Statement

Not applicable. This submission does not contain information from clinical studies.

9. Declaration of Conformity and Summary Reports

9.1 Declaration of Conformity

Not applicable. This is not an Abbreviated 510(k) submission.

9.2 Summary Reports

Please see Form 3654, Standard Data Reports, beginning on the next page. Since these standards do not include pass/fail criteria, summaries describing the extent of conformance are provided in the following sections:

Section	Standard
11.5	ISO 14971: 2007 Medical devices – Application of risk management to medical devices
15	ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
15	ISO 7405:2008 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
15	ISO 6872:2008, Dentistry - Ceramic materials

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s <i>(To be filled in by applicant)</i>	
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).	
TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	
STANDARD TITLE ¹ ISO 14971:2007 Medical Devices - Application of Risk Management to Medical Devices	
Please answer the following questions Yes No	
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number ³	# 5-311
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input type="checkbox"/> <input checked="" type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	<input type="checkbox"/> <input checked="" type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report those exclusions in the summary report table.	<input type="checkbox"/> <input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510(k)?	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Title of guidance: _____	
<p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority (21 U.S.C. 360d), www.fda.gov/cdrh/rdmt/prog.html</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or</p>	<p>certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.</p> <p>⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁶ The online search for CDHR Guidance Documents can be found at www.fda.gov/cdrh/guidance.html</p>

Form FDA 3654 for ISO 14971 (page 2 of 2)

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 14971:2007 Medical Devices - Application of Risk Management to Medical Devices		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>Paperwork Reduction Act Statement</p> <p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p><i>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.</i></p>		

9.2.1 Form FDA 3654 for ISO 10993 (page 1 of 3)

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s (To be filled in by applicant)	
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).	
TYPE OF 510(k) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	
STANDARD TITLE ¹ ISO 10993-1:2003 Biological evaluation of medical devices-Part 1: Evaluation and testing	
Please answer the following questions	
Is this standard recognized by FDA? ²	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
FDA Recognition number ³	# 2-98
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input type="checkbox"/> <input checked="" type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input type="checkbox"/> <input checked="" type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	<input type="checkbox"/> <input checked="" type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	<input type="checkbox"/> <input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510(k)?	<input checked="" type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
Title of guidance: G95-1, Use of international standard ISO 10993...	
¹ The formatting convention for the title is: [SDO] (numeric identifier) [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/instdprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or	certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993-1:2003 Biological evaluation of medical devices-Part 1: Evaluation and testing		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 3.8	SECTION TITLE General principles applying to biological evaluation of medical devices	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED* assessed based on relevant experience for the same and equivalent materials in commercially available products		
DESCRIPTION clinical complaint history for the same alumina material in commercially available products		
JUSTIFICATION states to consider "other information", other non-clinical tests, and post-market experience		
SECTION NUMBER 6	SECTION TITLE Selection of biological evaluation tests	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED* No biological evaluation tests conducted		
DESCRIPTION Based on complaint history for same alumina material in commercial products, and published test results for alumina and zirconia		
JUSTIFICATION Section 6 states that such evaluation may result in conclusion that no testing is needed		
SECTION NUMBER A.2, subclause 3.6	SECTION TITLE Rationale for specific clauses, Annex A	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED* No biological evaluation tests conducted		
DESCRIPTION Assessed established use of alumina & zirconia in devices, published test results, and complaint history		
JUSTIFICATION States that testing may not be needed if the material has history of use in same role as the device under design		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>Paperwork Reduction Act Statement</p> <p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p style="text-align: center;"><i>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.</i></p>		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993-1:2003 Biological evaluation of medical devices-Part 1: Evaluation and testing		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Annex B	SECTION TITLE Flow chart to aid in ensuring a systemic approach to biological evaluation...	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Final assessment was completed without biological evaluation tests		
DESCRIPTION Material is same as in existing commercially available devices, with same properties as to manufacturing and body contact		
JUSTIFICATION Per flow chart, material characterization can be sufficient for assessment without need for biological evaluation tests		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, or similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>Paperwork Reduction Act Statement</p> <p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p><i>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.</i></p>		

9.2.2 Form FDA 3654 for ISO 7405 (page 1 of 2)

Form Approved: OMB No. 0910-0120; Expiration Date 8/31/10

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s <i>(To be filled in by applicant)</i>		
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).		
TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ ISO 7405: 2008 (E) Dentistry-Evaluation of Biocompatibility of Medical Devices used in Dentistry		
Please answer the following questions Yes No		
Is this standard recognized by FDA ² ?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
FDA Recognition number ³		# 4-179
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Does this standard include acceptance criteria?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Were deviations or adaptations made beyond what is specified in the FDA SIS?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
If yes, was the guidance document followed in preparation of this 510k?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Title of guidance: <u>Guidance for Industry and FDA Staff: Dental Handpieces-Premarket Notification [510(k)] Submissions</u>		
<small> ¹ The formatting convention for the title is: [SDO] (numeric identifier) [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/sidsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cddocs/cf/Standards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cddocs/cf/Standards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html </small>		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 7405: 2008 (E) Dentistry-Evaluation of Biocompatibility of Medical Devices used in Dentistry		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 5.1	SECTION TITLE Biological Evaluation Process--General	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED* Conducted structured biological evaluation according to ISO 10993-1		
DESCRIPTION Reviewed data sets concerning biological properties of the device material and concluded that data were complete		
JUSTIFICATION Section indicates that further testing is needed only when data sets are incomplete		
SECTION NUMBER 5.4	SECTION TITLE Biological Evaluation Process--Type of Tests	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED* No tests conducted		
DESCRIPTION Reviewed data sets and concluded that data were complete		
JUSTIFICATION Section references Annex A which lists test methods to be considered, but states that tests are not necessarily required.		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>Paperwork Reduction Act Statement</p> <p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p style="text-align: center;"><i>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.</i></p>		

9.2.3 Form FDA 3654 for ISO 6872 (page 1 of 3)

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s (To be filled in by applicant)	
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).	
TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	
STANDARD TITLE ¹ ISO 6872:2008 Dentistry - Ceramic materials	
Please answer the following questions	
Is this standard recognized by FDA ² ?	Yes No <input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number ³	# 8-10
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input type="checkbox"/> <input checked="" type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input checked="" type="checkbox"/> <input type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	<input checked="" type="checkbox"/> <input type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510(k)?	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Title of guidance: _____	
<p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or</p>	<p>certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.</p> <p>⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html</p>

Form FDA 3654 for ISO 6872 (page 2 of 3)

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 6872:2008 Dentistry - Ceramic materials		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 7.6	SECTION TITLE Chemical Solubility	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED* see attached file		
DESCRIPTION		
JUSTIFICATION Scope of standard does not include ceramic materials used in orthodontic appliances.		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>Paperwork Reduction Act Statement</p> <p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p style="text-align: center;"><i>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.</i></p>		

Form FDA 3654 for ISO 6872 (page 3 of 3)
Attached file to section 7.6, Chemical Solubility

The scope of ISO 6872:2008 is for the requirements of dental ceramic materials for fixed all-ceramic and metal-ceramic restorations and prostheses and is not intended for ceramic materials used in orthodontic treatment; however, (b)(4)Trade Secret Process (b) as guidance for our (b)(4)Trade Secret and (b)(4)Trade (4)Trade S t P.

The ceramic materials described in this 510(k) are (b)(4)Trade (b) and optionally (b) with a (b)(4)Trade to (b)(4)Trade Secret Process as compared to the (b) aluminum oxide samples. The (b)(4)Trade Secret and (b) dimensions (4)Trade described in ISO 6872:2008 are (b)(4)Trade Secret we ran a (b)(4)Trade Secret where a (b)(4)Trade with a (b)(4)Trade of (b) was used with the (b) applied to (b) A (b) was determined and is significantly (b) the (b)(4)Trade listed in table 1 of the standard for all categories of fixed prostheses dental (4)Tra Secret ceramics.

10 Executive Summary

10.1 Description of Device

Clarity™ Advanced Aesthetic Brackets are intended to be bonded to teeth, upon which an orthodontic wire is used to move the teeth to new positions. Clarity™ Advanced Aesthetic Brackets consist of a translucent alumina body and a (b) [REDACTED] bonding base. The bracket is either uncoated or the bracket top surface is coated with a (b)(4)Trade Secret Process [REDACTED].

The brackets incorporate a water-soluble color placement indicator system that marks archwire and vertical slots to facilitate bracket positioning and color codes tie wing(s) to facilitate bracket identification.

10.2 Device Comparison Table

Table 1, Device Comparison, on the following page compares the differences and similarities between Clarity™ Advanced Aesthetic Brackets and the legally marketed predicate devices.

Clarity™ Advanced Aesthetic Brackets are substantially equivalent to the predicate devices in terms of indications for use, intended use, composition, device design and performance. Please see section 12 for the substantial equivalence discussion.

Table 1 Device Comparison

#	Device Name	Clarity™ Advanced Aesthetic Brackets Coated	Clarity™ Advanced Aesthetic Brackets Uncoated	Clarity™ SL Self-Ligating Ceramic Brackets With metal liner	Clarity™ SL Self-Ligating Ceramic Brackets Without metal liner	Clarity™ Metal-Reinforced Ceramic Brackets	InVu® Aesthetic Braces	Mystique® MB Clear Braces
1a	Premarket Notification	New Device	New Device	K062345	K062345	K944286	K950992	K082974
1b	Intended Use	√	√	√	√	√	√	√
2		(b)(4)Trade Secret Process						
2a								
2b								
2c								
2d								
3								
3a								
3b								
3c								
3d								
3e								
3f								
3g								
3h								
4	Performance	√	√	√	√	√	√	√
	Please see Section 12.2.4							
	Bench Test Data							
	Comparison with SE							
	Devices							

¹ Mystique MB Clear Braces contain removable color tubes in the archwire slot. The tubes are removed immediately after bracketing bonding.

10.3 Summary of Performance Testing

The following summarizes the performance tests that were done:

(b)(4)Trade Bond Strength

The (b)(4)Trade bond strength test measures the force required to debond a bracket from the tooth when (b)(4)Trade Secret Process. The (b)(4)Trade is (b)(4)Trade Secret on a (b)(4)Trade Secret Process of a bonded bracket. The test data shows that Clarity™ Advanced Aesthetic Brackets provide acceptable bond strength to hold the brackets to the teeth.

Bracket Strength

The bracket strength test measures the (b)(4)Trade Secret Process when a (b)(4)Trade Secret is (b)(4)Trade in the wire slot. The (b)(4)Trade the bracket is recorded while (b)(4)Trade the wire in the bracket wire slot. The test data showed that Clarity™ Advanced Aesthetic Brackets provide acceptable (b)(4)Trade strength.

Bracket Material Friction

The bracket material (b)(4)Trade Secret the (b)(4)Trade Secret occurs as a stainless steel (b)(4)Trade Secret Process material (b)(4)Trade were measured along the (b)(4)Trade direction during the test. The test showed a (b)(4)Trade for (b)(4)Trade material as (b)(4)Trade to the (b)(4)Trade aluminum oxide material, which is comparable to Clarity™ SL (b)(4)Trade bracket material.

Squeeze Debond Strength

The squeeze debond strength test measures the force required to debond a bracket from the tooth after orthodontic treatment is completed. A (b)(4)Trade Secret (b)(4)Trade Secret Process by (b)(4)Trade to the (b)(4)Trade (b)(4)Trade the bracket, (b)(4)Trade the (b)(4)Trade to (b)(4)Trade one (b)(4)Trade. The (b)(4)Trade the (b)(4)Trade Secret causes the base to debond from the adhesive as the bracket (b)(4)Trade along the (b)(4)Trade Secret in the (b)(4)Trade. The test data showed the force required to debond Clarity™ Advanced Aesthetic Brackets is comparable to Clarity™ and Clarity™ SL brackets.

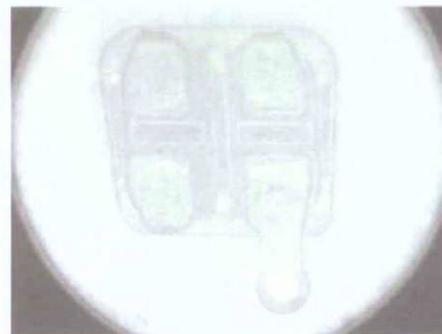
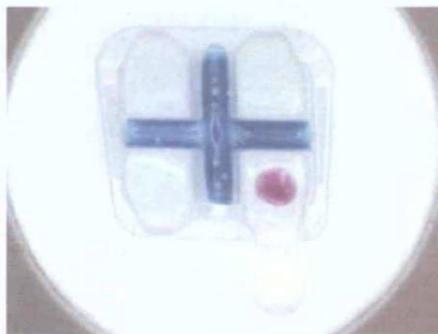
11 Device Description

11.1 General Description

Clarity™ Advanced Aesthetic Brackets are bonded to teeth, upon which an orthodontic wire is used to move the teeth to new positions. Clarity™ Advanced Aesthetic Brackets consist of a translucent alumina (aluminum oxide) body and a (b) (4)Trade Secret bonding base formed by polycrystalline (b) (4)Trade Secret matrix. The bracket is either (b) (4)Trade Secret or the bracket (b) (4)Trade Secret is (b) (4)Trade Secret with a (b) (4)Trade Secret of (b) (4)Trade Secret. Clarity™ Advanced Aesthetic Brackets contain a vertical slot extending in an occlusal-lingual direction through the center of the body and a stress concentrator in the base. The vertical slot and stress concentrator facilitate debonding of the bracket from the tooth. Clarity™ Advanced Aesthetic Brackets incorporate a water-soluble color placement indicator system that marks archwire and vertical slots to aid in bracket positioning and color-codes the tie wing(s) to facilitate bracket identification.

Clarity™ Advanced Aesthetic Brackets are a modification of the predicate device, Clarity Modified Ceramic Brackets, which is currently marketed under the trade name Clarity SL Self-Ligating Ceramic Brackets. The modifications include removal of the two nickel-titanium clips, replacement of the metal archwire slot liner with either an uncoated surface, or a thin film of stabilized zirconia, and the addition of a water-soluble color system that aids the orthodontist in positioning the bracket on the tooth.

The photographs below show Clarity™ Advanced Aesthetic Brackets with and without the water-soluble color indicator.



11.2 Material Composition

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The components of Clarity™ Advanced Aesthetic Brackets and their functions are listed in Table 2 below.

Table 2 Clarity™ Advanced Aesthetic Bracket Components

#	Component	Chemical Name	CAS#
2a	Bracket Body	Aluminum oxide (b)(4)Trade Secret with (b)(4)T P	(b)(4)Trade Secret Process
2b	Bonding Base	Alumina oxide (b)(4)T d matrix	
2C	Water-soluble Indicator	Color Indicators	see Table 2-1, p.35

(2a) **Bracket body:** The bracket body guides tooth movement via an archwire. The bracket body consists of translucent polycrystalline alumina (aluminum oxide). The aluminum oxide meets the chemical composition requirements of American Society for Testing and Materials (ASTM) standard F603-00, High Purity Dense Aluminum Oxide for Medical Application. In the Clarity™ Advanced coated bracket, the top of the bracket body is treated with a (b)(4)Trade Secret Process (b)(4)T

(2b) **Base:** The bracket base bonds the bracket body to tooth. The bracket base is (b)(4)Trade Secret, which (b)(4)Trade and (b)(4)Trade, which (b)(4)T a (b)(4)T (b)(4)Trade for (b)(4)Trade Secret. The (b)(4)T contains (b)(4)T the following chemicals. (b)(4)T

Chemical Name (formula)	CAS Number
(b)(4)T	(b)(4)T
Aluminum oxide (Al ₂ O ₃)	1344-28-1
(b)(4)Trade Secret Process	

(2c) **Water-soluble indicator:** The color indicators are composed of color additives (b)(4)Trade and a water soluble (b)(4)Trade Secret Process (b)(4)Trade Secret Process

(b)(4)T The color indicators are (b)(4)T to the brackets (b)(4)Trade Secret by (b)(4)T a solution of water-soluble indicators in a (b)(4)Trade Secret Process (b)(4)T d

and then (b)(4)Trade Secret in a (b)(4)Trade Secret Process (b)(4)Trade Secret Process (b) and (b)(4)Trade Secret. All (b) and (b)(4)Trade Secret in the color indicators are approved for use in foods, cosmetics and/or medical devices. The chemical compositions of the color indicators (b)(4)Trade Secret (b)(4)Trade are shown in Table 2.1 on the following page. The estimated amount of color indicators used in the orthodontic treatment is approximately (b)(4) mg/patient.

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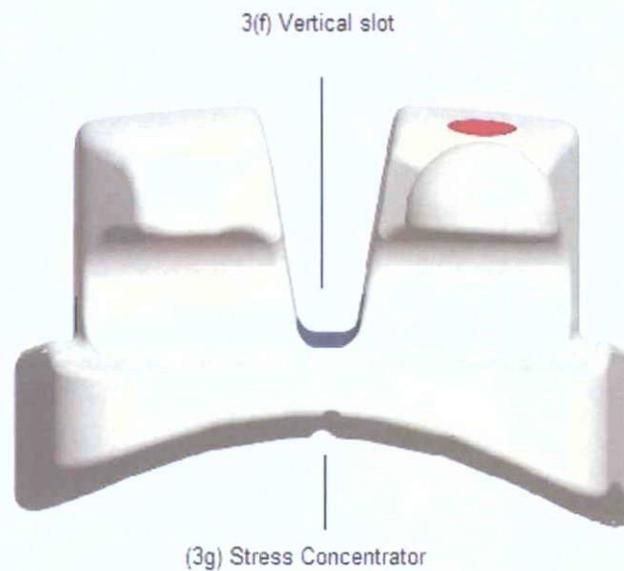
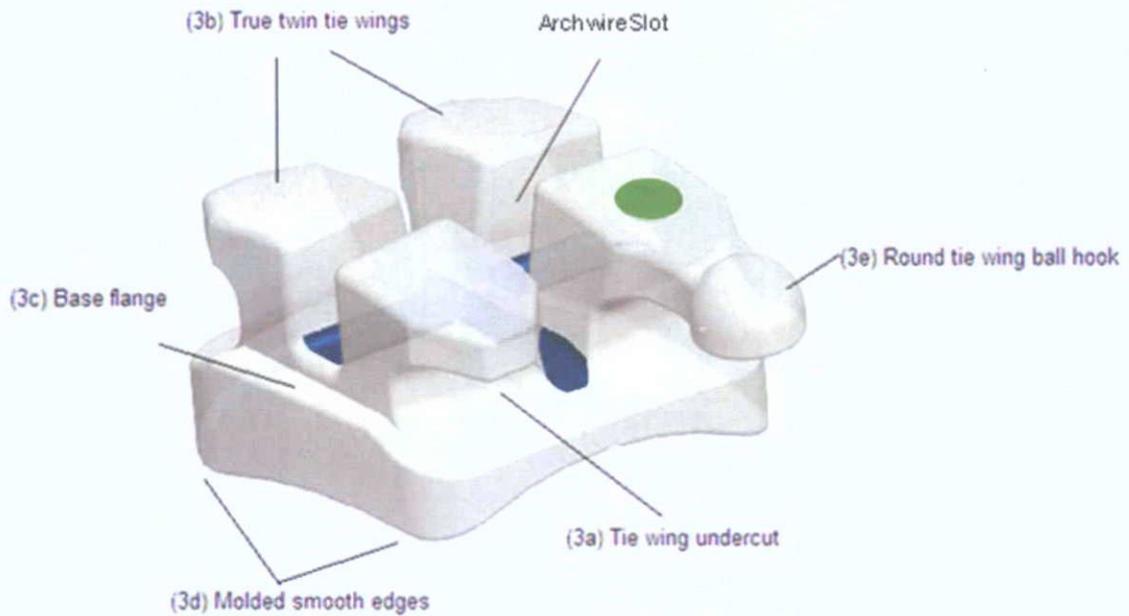
(b)
(4)Trade Secret Process

Table 3 Composition of Water-Soluble Indicators Used in Clarity™ Advanced Aesthetic Brackets

#	Chemical Name	CAS #	21 CFR # or USP #	Relative Weight %									
				Black	Blue	Bright Red	Orange	Yellow	Green	Purple	Pink	Brown	Light Blue
(b)(4)Trade Secret Process													

11.3 Design Features

The diagrams below illustrate the design features of Clarity™ Advanced Aesthetic Brackets. Clarity™ Advanced Aesthetic Brackets may be marketed in 3M™ Unitek™ APCT™ Adhesive Coated Appliance System, in which the bracket is supplied with a pre-applied adhesive, i.e. APCT™ II Adhesive or APCT™ PLUS Adhesive. Please see Section 12.2.3 for additional details related to the design features.



11.4 Performance Specifications

Table 4 below describes the device design and the specifications for Clarity™ Advanced Aesthetic Brackets. These design specifications were set to ensure that Clarity™ Advanced Aesthetic Brackets have sufficient physical properties to perform as orthodontic ceramic bracket; namely, acceptable bond strength, bracket strength, bracket material (b) (4)Trade Secret Process, and bracket debonding. Please see Section 12.4 for additional details related to the test method. Please see the sections indicated in Table 4 for the test results.

Table 4 Performance Specifications

Performance	Specification	Test Results
(b)(4)Trade Secret Process		
Bracket material wear	comparable to SE devices	page 43
Squeeze debond strength	comparable to SE devices	page 45

11.5 Risk Management

The risk to health for Clarity™ Advanced Aesthetic Brackets was evaluated using a process which is compliant with ISO 14971, Application of Risk Management to Medical Devices. Although the risk of enamel damage is very unlikely, information is provided in the instructions-for-use to assure proper use of the brackets.

Identified Risk	Risk Mitigation Measure
Enamel damage	Instructions-for-use provide warnings for the use of the brackets and the procedure for debonding the brackets.

12 Substantial Equivalence Discussion

Substantial equivalence of Clarity™ Advanced Aesthetic Brackets and the predicate devices is supported by a comparison of the following: (1) intended use, (2) material composition, (3) device design and (4) performance tests. The comparisons can be found in the following sections and tables:

Section	Table	Title
12.2.1	1	Intended Use Comparison with SE Devices
12.2.2	1	Material Composition Comparison with SE Devices
12.2.3	1	Device Design Comparison with SE Devices
12.2.4	5	Performance Comparison with SE Devices

12.1 identity of Substantially Equivalent (SE) Devices

510(k) #	Trade Name	Manufacturer
K062345	Clarity™ SL Self-Ligating Ceramic Brackets	3M Unitek Corp.
K944286	Clarity™ Metal-Reinforced Ceramic Brackets	3M Unitek Corp.
K950992	InVu® Aesthetic Braces	TP Orthodontics Inc.
K082974	Mystique® MB Clear Braces	Dentsply International

12.2 Comparison with Substantially Equivalent (SE) Devices

12.2.1 Intended Use Comparison with SE Devices

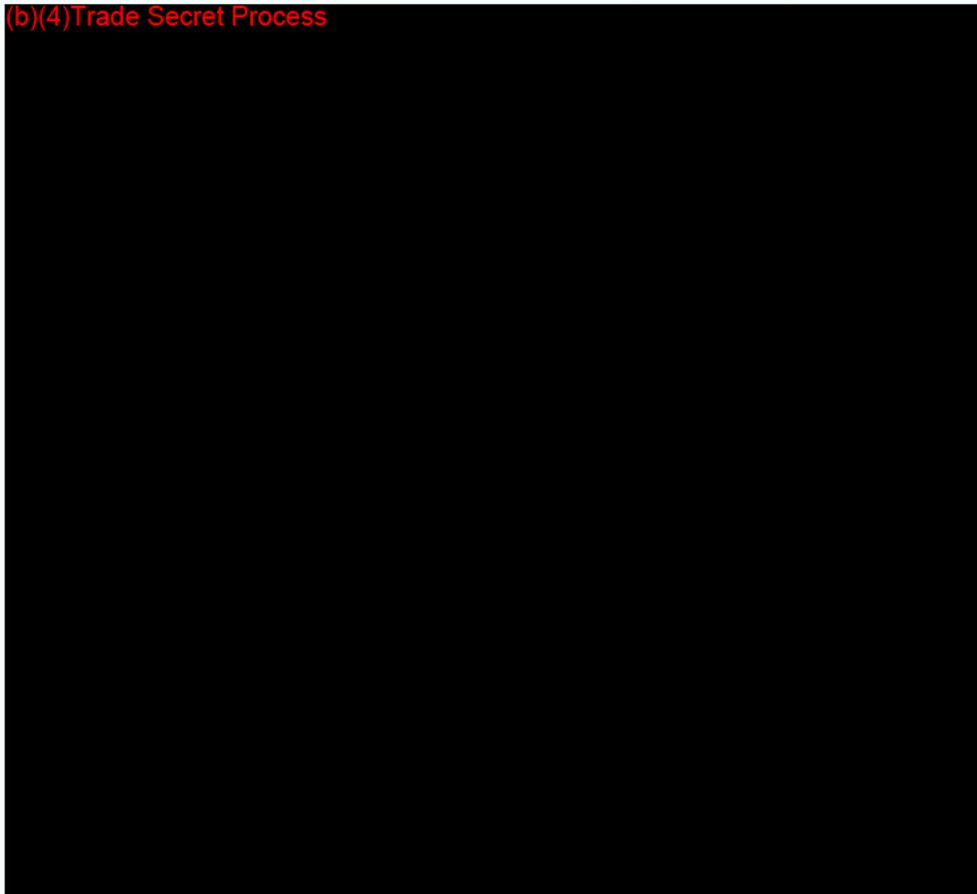
Clarity™ Advanced Aesthetic Brackets are substantially equivalent in the intended use of orthodontic treatment to the predicate devices Clarity™ SL Self-Ligating Ceramic Brackets, Clarity™ Metal-Reinforced Ceramic Brackets, InVu® Aesthetic Braces and Mystique® MB Clear Braces.

12.2.2 Material Composition Comparison with SE Devices

Clarity™ Advanced Aesthetic Brackets are substantially equivalent to the predicate devices in composition, i.e. all have ceramic bracket bodies made from translucent alumina (aluminum oxide).

Alumina materials are comprised of (b)(4)Trade Secret Process (Figure 1). Clarity™ Advanced, Clarity™ SL and InVu® brackets are molded from (b)(4)Trade Secret Process (#2a, Table 1). The (b)(4)Trade Secret Process of a ceramic

material (b) as the (b)(4)Trade Secret Process. Figure 2 shows the (b)(4)Trade Secret Process and (b)(4)Trade Secret materials.

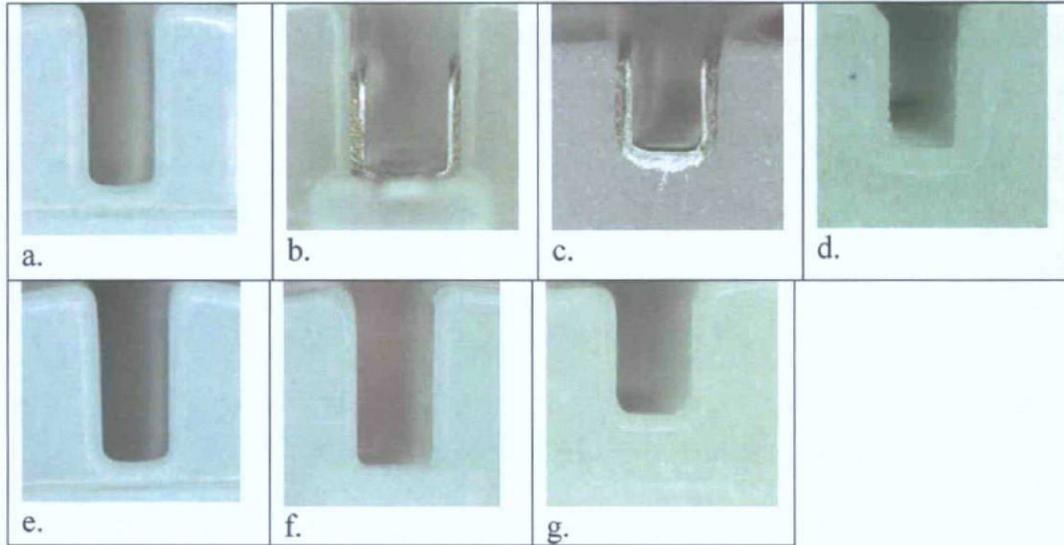


The bonding surface on the bracket bases of Clarity™ Advanced, Clarity™ SL and Clarity™ Ceramic Brackets is formed by (b)(4)Trade Secret (#2b, Table 1) as shown in Figure 3 below.



All of the predicate devices have an archwire slot which enables the bracket to slide along on the archwire. The archwire slots of Clarity™ Advanced (with coating), Clarity™ SL (with liner), Clarity™, and Mystique® MB contain a liner or coating. Clarity™ Advanced (b)(4)Trade, Clarity™ SL (b)(4)Trade and InVu® brackets do not contain a (b)(4)Trade. (see #2c, Table 1)

Figure 4 Photographs of the (b)(4)Trade of a. Clarity™ Advanced (b)(4)Trade, Clarity™ SL, c. Clarity™, d. Mystique® MB, e. Clarity™ Advanced (b)(4)Trade, Clarity™ SL (b)(4)Trade and g. InVu®



All Clarity™ Advanced Aesthetic Brackets and the predicate devices (b)(4)Trade color slots and/or color dots on the bracket tie wing(s) to (b)(4)Trade bracket (b)(4)Trade positioning on the tooth (#2d, table 1).

12.2.3 Device Design Comparison with SE Devices

Clarity™ Advanced Aesthetic Brackets are substantially equivalent in design features to the predicate devices listed in table 1, i.e., Clarity™ SL Self-Ligating Ceramic Brackets, Clarity™ Metal-Reinforced Ceramic Brackets, InVu® Aesthetic Braces and Mystique® MB Clear Braces.

Tiewing (b) [REDACTED]

Clarity™ Advanced, Clarity SL, Clarity, InVu and Mystique MB brackets all have tiewing (b)(4)Trade Secret [REDACTED] for (b)(4)Trade Secret [REDACTED] (#3a, table 1).

True-twin Tiewings

Clarity™ Advanced Aesthetic Brackets, Clarity™ SL, Clarity™ and InVu® brackets have true-twin tiewings, i.e. four tiewings, for versatile use with auxiliaries (#3b, Table 1).

(b)(4)Trade Secret [REDACTED]

Clarity™ Advanced, Clarity™, and InVu® brackets (b)(4)Trade Secret [REDACTED] for bracket (b) [REDACTED] and adhesive (b)(4)Trade Secret [REDACTED] (#3c, table 1).

(b) [REDACTED] Ceramic

Clarity™ Advanced, Clarity™ SL and InVu® brackets contain a (b) [REDACTED] ceramic bracket body with (b)(4)Trade Secret [REDACTED] and (b) [REDACTED] (#3d, table 1), which replaces the (b)(4)Trade Secret [REDACTED] of (b) [REDACTED] ceramic brackets, and (b)(4)Trade Secret [REDACTED] on the distal-lingival tiewings (#3e, Table 1).

(b)(4)Trade Secret Process [REDACTED]

Clarity™ Advanced, Clarity™ SL and Clarity™ brackets (b)(4)Trade Secret [REDACTED] (#3f, table 1) and (b)(4)Trade Secret [REDACTED] (#3g, table 1) to facilitate debonding of the bracket from the tooth.

Pre-coated Adhesive

Clarity™ Advanced, Clarity™ SL and Clarity™ brackets are marketed with or without a pre-coated adhesive, i.e. 3M Unitek APCT™ II (K911271) Adhesive or APCT™ PLUS (K020394) Adhesive. InVu® brackets are marketed with or without Read-Base® Pre-Applied Adhesive (#3h, table 1). The pre-coated adhesive (b) [REDACTED] a (b)(4)Trade Secret [REDACTED] of adhesive on the bracket.

12.2.4 Performance Comparison with SE Devices

Table 5 Performance Comparison with Predicate Devices

Pg	Device Name	Clarity™ Advanced Aesthetic Brackets	Clarity™ SL Self-Ligating Ceramic Brackets	Clarity™ Metal-Reinforced Ceramic Brackets	InVu® Aesthetic Braces
	Performance	(b)(4) Trade Secret Process			
41	(b) Bond strength				
42	Bracket Strength				
43	Bracket Material (b)				
45	Squeeze Debond Strength				

The discussion for the performance comparisons is contained on the pages listed in table 5 above.

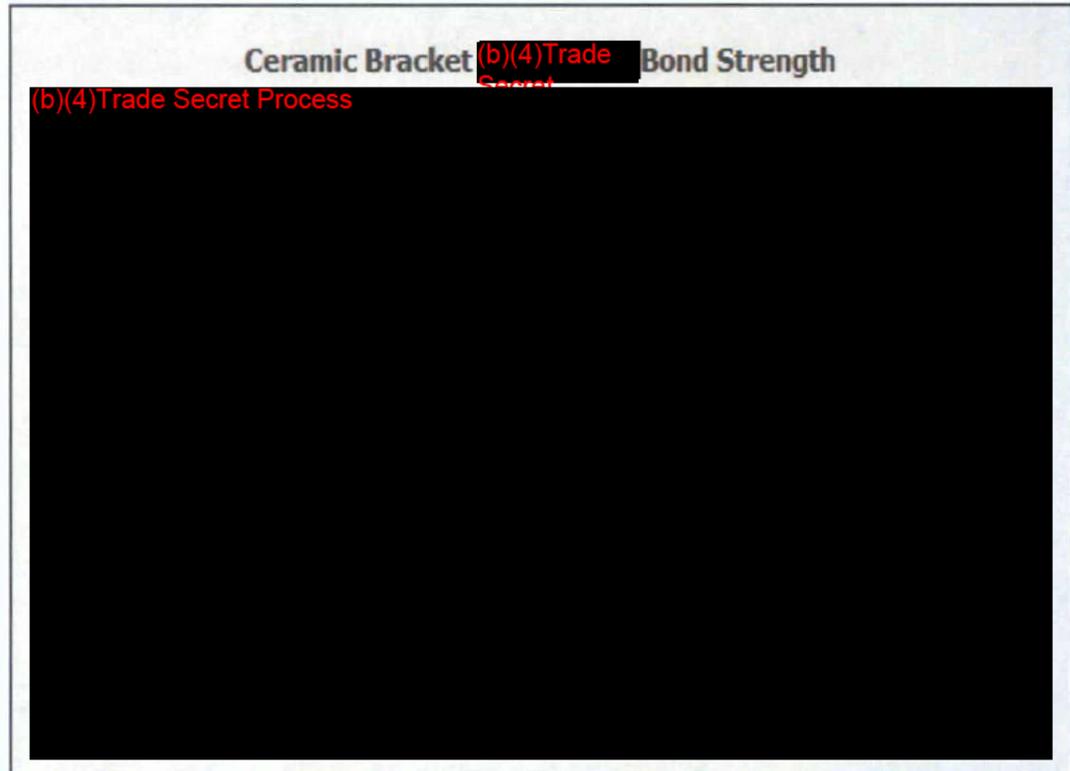
(b)(4)Trade Secret Bond Strength

The (b)(4)Trade Secret bond strength test measures the (b)(4)Trade Secret a bracket when a (b)(4)Trade Secret Process Clarity™ Advanced Aesthetic Brackets are compared to Clarity™ SL Self Ligating Ceramic Brackets and Clarity™ Metal-Reinforced Ceramic brackets.

(b)(4)Trade Secret brackets of (b)(4)Trade Secret type were bonded to test substrates. All brackets were bonded per manufacturer's instructions using Transbond™ XT Light Cure Adhesive. Bond strength was tested by fixing the test substrate in a (b)(4)Trade Secret test (b)(4)Trade Secret a (b)(4)Trade Secret Process at a (b)(4)Trade Secret (b)(4)Trade Secret and recording the (b)(4)Trade Secret (b)(4)Trade Secret

Figure 5 below shows that the bond strengths of Clarity™ Advanced, Clarity™ SL and Clarity™ brackets are comparable and exceed the minimum bond strength (i.e. (b)(4)Trade Secret) to hold the bracket to the tooth.

Figure 5 (b)(4)Trade Secret Bond Strength



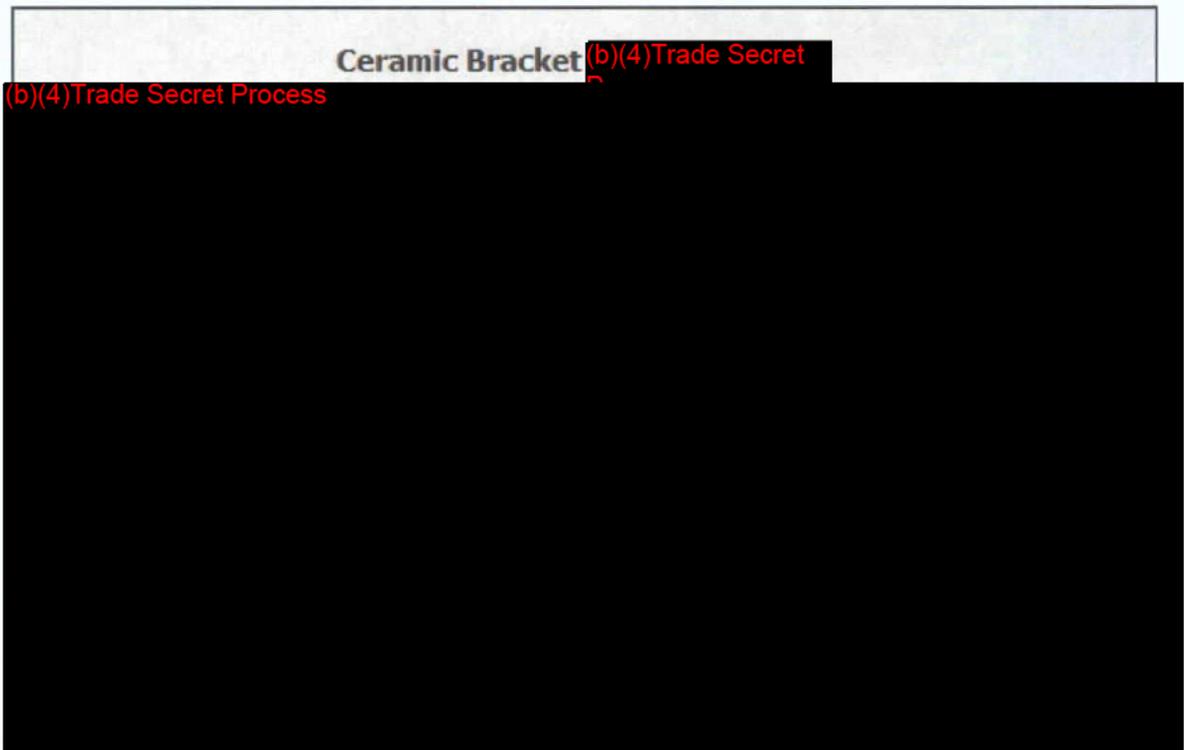
Bracket Strength

The bracket strength test measures the (b) force to break a bracket when a (b)(4)Trade Secret is (b) in the wire slot. Clarity™ Advanced Aesthetic Brackets are compared to Clarity™ Metal-Reinforced Ceramic Brackets and InVu® Aesthetic Braces.

(b)(4)Trade Secret brackets for cuspid tooth of each type were bonded to test substrates. All brackets were bonded per manufacturer's instructions using Transbond™ XT Light Cure Adhesive. Bracket strength was tested by engaging a (b)(4)Trade Secret Process (b) Length (b)(4)Trade Secret Process to the mechanical testing machine) to the (b)(4)Trade Secret, the (b) the bracket (b) and recording the (b). The force (b)(4)Trade Secret bracket is (b)(4)Trade Secret (4)Trade Secret

Figure 6 below shows that the bracket strengths of Clarity™ Advanced Aesthetic Brackets, Clarity™, and InVu® brackets are statistically the same. The average strength value of all bracket types exceeds the minimum strength (i.e. (b)(4)Trade Secret) to withstand (b) forces. (4)Trade

Figure 6 Bracket (b)(4)Trade Secret



¹ R.J. Nikolai, *Bioengineering Analysis of Orthodontic Mechanics*, Lee & Fibiger, Philadelphia, 1985, p.304

Bracket Material (b) (4)Trade

In this section, the (b) (4)Trade of the aesthetic bracket material are tested. The material applied to (b) (4)Trade Clarity™ Advanced Aesthetic Brackets, (b) (4)Trade (b) (4)Trade is compared to the (b) (4)Trade aluminum oxide substrate material. Testing was conducted in (b) (4)Trade Secret Process Test Method for (b) (4)Trade Secret Process This test (b) (4)Trade Secret Process during the test.

Testing was performed in accordance with Procedure A, Unlubricated Wear Testing at Room Temperature. The ball specimen is made from (b) (4)Trade stainless steel. The (b) (4)Trade sample is (b) (4)Trade Secret Process (b) (4)Trade used in the Clarity™ SL Self-Ligating Ceramic Brackets and in Clarity™ Advanced Aesthetic Brackets. (b) (4)Trade samples that are (b) (4)Trade Secret coating are compared to the uncoated (b) (4)Trade aluminum oxide samples. The test method was (b) (4)Trade to simulate the (b) (4)Trade and conditions that a (b) (4)Trade Secret can exert against a bracket (b) (4)Trade are as follows:

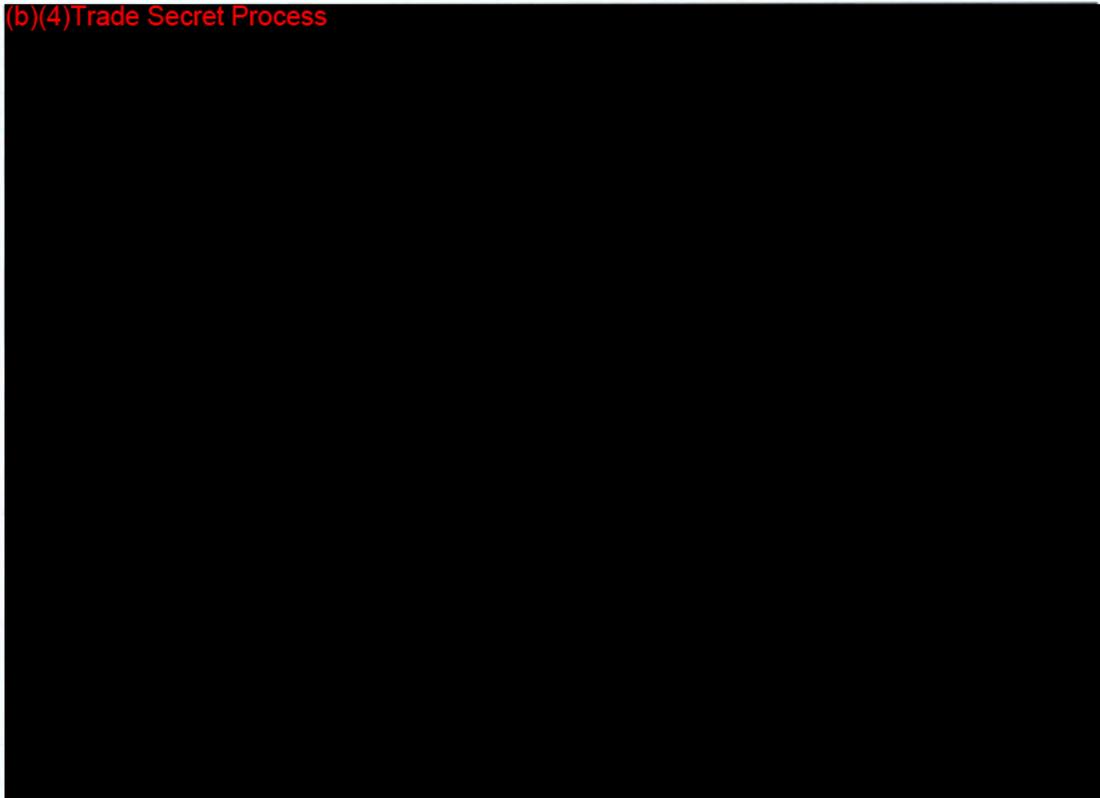
- 1) The (b) (4)Trade Secret Process
- 2) The normal (b) (4)Trade
- 3) The (b) (4)Trade Secret Process
- 4) The (b) (4)Trade Secret Process
- 5) The test d (b) (4)Trade Secret Process

(b) (4)Trade samples and (b) (4)Trade samples were tested. Each (b) (4)Trade sample was tested with (b) (4)Trade readings per sample. Frictional forces were measured along the sliding direction during the test. The dimensionless coefficient of friction (μ) was calculated as: $\mu = \text{frictional force} / \text{normal force}$. Each sample was observed under a microscope at (b) (4)Trade and (b) (4)Trade magnification after testing.

In a linear-reciprocating, (b) (4)Trade Secret test with (b) (4)Trade Secret on (b) (4)Trade, the (b) (4)Trade aluminum oxide material exhibited (b) (4)Trade coefficients of friction as compared to the (b) (4)Trade aluminum oxide material, as shown in Figure 7.

Figure 7 Coefficient of Friction of (b) [redacted] aluminum oxide (Al_2O_3) and (b) [redacted]
[redacted] (4)Trade (4)Trade

(b)(4)Trade Secret Process



Squeeze Debond Strength

In the Clarity™ Advanced, Clarity™ and Clarity™ SL brackets, each bracket has a vertical slot which separates the (b)(4)Trade Secret of the bracket. During squeeze debonding, the force applied to the (b)(4)Trade Secret causes the (b) sections to (b) one another. The motion of the bracket sections causes the base to debond from the adhesive as the bracket splits along the (b)(4)Trade Secret in the base.

A (b)(4)Trade Secret between the points of contact of the two debonding tool tips (simulated in the mechanical squeeze debond testing apparatus; see Figure 8). The (b)(4)Trade Secret from this (b)(4)Trade Secret Process. The measured (b)(4)Trade Secret Process the squeeze (b)(4)Trade Secret Process.

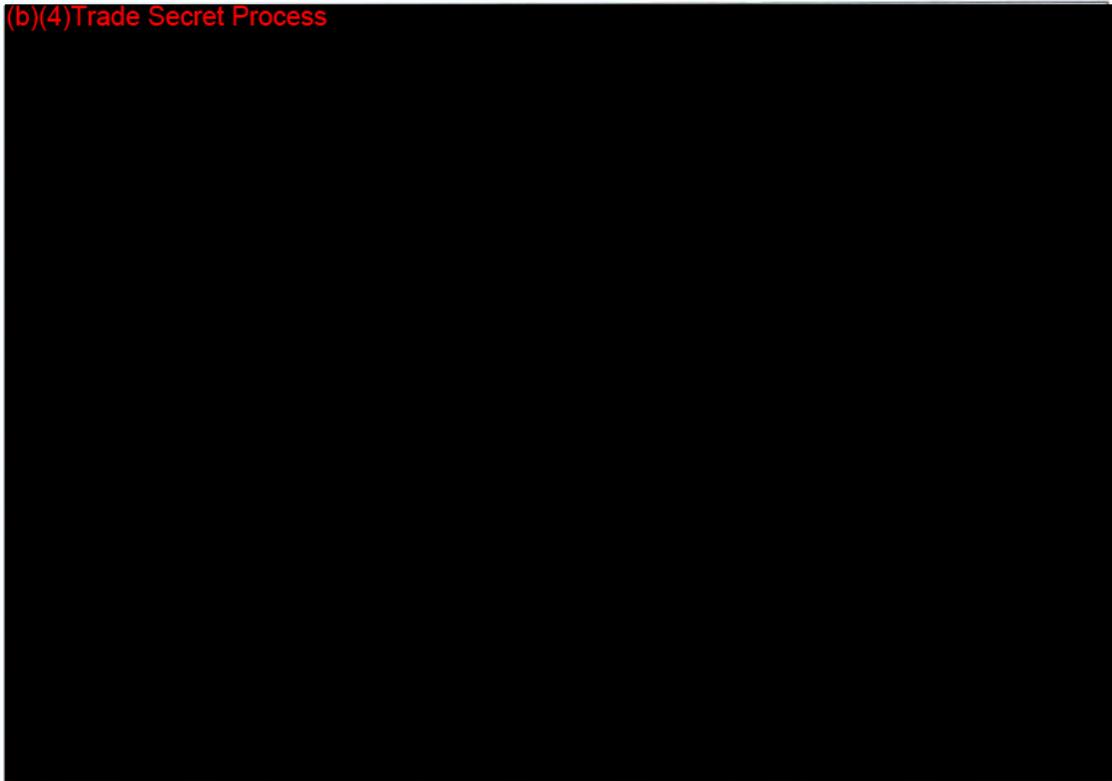
(b)(4)Trade Secret brackets of each of the (b) bracket types were bonded to substrates in accordance with manufacturer's instructions using Transbond XT, and were subsequently debonded with a squeeze debond testing apparatus connected to a (b) (b)(4)Trade Secret. The squeeze debond moment is then (b) from the (b) d force.

Figure 8 Squeeze debond test (b) with Clarity™ Advanced Aesthetic Bracket (4)T d



The squeeze debond (b) for the Clarity™ Advanced, Clarity™ and Clarity™ SL brackets are shown in Figure 9. The results for Clarity™ Advanced Aesthetic Brackets are similar to those for Clarity™ SL brackets and slightly (b) than the result for Clarity™. (4)T d

Figure 9 Squeeze debond (b)(4)Trade by (b)(4)Trade squeeze debond test (b)(4)Trade



13 Proposed Labeling

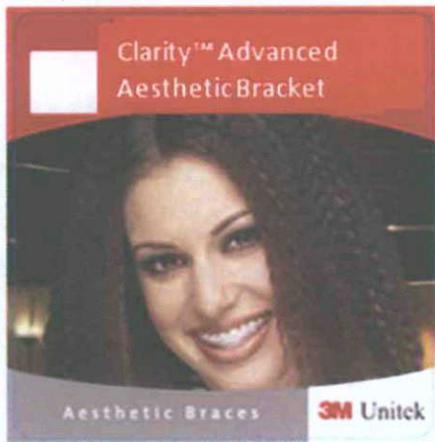
13.1 Proposed Claims

- (a) Clarity™ Advanced Aesthetic Brackets feature better aesthetics when compared to ceramic brackets with metal liners.
- (b) Clarity™ Advanced Aesthetic Brackets use a finer grain ceramic material that improves strength when compared to the leading polycrystalline ceramic brackets.
- (c) Clarity™ Advanced Aesthetic Brackets (b) feature a (b)(4)Trade (b) that (b)(4)Trade (4)T d S t (4)T d S t P
- (d) Clarity™ Advanced Aesthetic Brackets feature a stress concentrator in the base that allows mesial-distal squeeze debonding.
- (e) Clarity™ Advanced Aesthetic Brackets feature a glass-grit bonding base for bond strength similar to Clarity™ Metal-Reinforced Ceramic Brackets and Clarity™ SL Self-Ligating Ceramic Brackets.

13.2 Package Labels

Clarity™ Advanced Aesthetic Brackets will be packaged in a plastic case with foam insert. The proposed package labeling is shown below and on the next page.

13.2.1 Proposed Case Label for Loose Brackets



Clarity™ Advanced
Aesthetic Bracket

REF | AESTHETIC CERAMIC BRACKET

REF | Sample

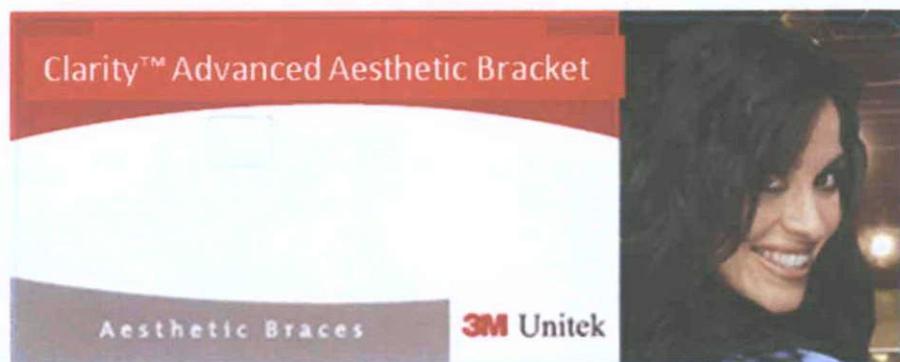
13.2.2 Proposed Case Label for Bracket Kits

Clarity™ Advanced Aesthetic Bracket

U/L DxD
.022(0,68 mm) 1 CASE KIT
MBT™ RX, NO HOOKS
MADE IN U.S.A. **LOT** BM7LN
REF SAMPLE **GS1-128**



(01)09652221101693(30)1(10)BM7LN



13.3 Proposed Instructions for Use

The proposed instructions for use are presented on the next page.

13.4 Promotional materials

No advertisements are proposed at this time.

14 Sterilization and Shelf Life

14.1 Sterilization

Not applicable. Clarity™ Advanced Aesthetic Brackets are not labeled or otherwise represented as sterile, nor is it intended to be sterilized by the user.

14.2 Shelf Life

Shelf life is not applicable.

Clarity™ Advanced Aesthetic Brackets



Instructions For Use

Warnings

- Due to the hardness of ceramic brackets, bonding brackets in occlusion should be avoided to prevent wearing of enamel surfaces during all phases of treatment.
- Instruct patients not to chew or bite on hard substances such as hard candy, ice, carrots, etc. Careful and thorough patient instruction is a key to avoiding appliance or enamel damage.
- Bonding of ceramic brackets to compromised teeth (i.e., with large restorations, peg laterals or preexisting conditions) can increase the risk of tooth damage.
- Bonding to porcelain crowns or facings may cause chipping or breakage of the crown or facing during treatment or debonding.
- Debonding of Clarity™ Advanced Aesthetic brackets can be done using a Unitek™ Self-Ligating Bracket Debonding Instrument, REF 804-170. No other existing ceramic debonding instrument is recommended to debond Clarity™ Advanced Aesthetic brackets. Doing so may result in fractured tie-wings or tooth damage.

Cautions

If a bracket fractures during treatment or debonding, use a diamond burr to carefully remove the ceramic fragments. Failure to follow the correct debonding procedure may lead to tooth damage.

Note

Clarity™ Advanced Aesthetic brackets are for single use only. Due to its vertical debonding slot design, these brackets collapse during debonding and cannot be reused or recycled.

Bracket Identification and Bracket Position

- Clarity™ Advanced Aesthetic brackets are identifiable by a color coded recessed distal gingival dot.
- Vertical and horizontal indicators are water soluble and it is recommended that the patient rinse after bonding but before the placement of the archwire.

Bracket Bonding

Remove adhesive flash at bonding to minimize staining of the adhesive and reduce the risk of bracket breakage during the debonding procedure. Clarity™ Advanced Aesthetic brackets feature mechanical retention on the bonding base. No special primers or pretreatments are necessary. Clarity™ Advanced Aesthetic brackets can be used with traditional direct or indirect bonding methods. No change in bonding technique is necessary. For bonding procedures please follow the adhesive manufacturer's recommendations. When placing Clarity™ Advanced Aesthetic brackets, it is suggested that the bracket be placed in a sliding motion, occlusal to gingival, forcing excess adhesive to the incisal edge of the bracket for easier clean-up. Care must be taken when cleaning up adhesive flash so as not to disturb the final positioning before adhesive curing.

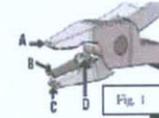
Debonding Procedure

Note

Clarity™ Advanced Aesthetic brackets may be debonded either with the archwire engaged in the archwire slots or with the archwire removed.

Using the Unitek™ Self-Ligating Bracket Debonding Instrument, Figure 1, (PN 804-170) to debond the Clarity™ Advanced Aesthetic bracket:

- 1) Remove adhesive flash around base of bracket to be debonded. Note: Failure to remove flash around bracket base, especially on the mesial-distal sides, may result in incomplete debonding.
- 2) Place the Nitinol Insert of the debonding instrument vertically into the center of the bracket, perpendicular to the archwire slot. Be sure that the ledges of the instrument are symmetrically positioned against the labial surfaces of the bracket. (Figure 2)



Instrument Descriptor (Fig 1):

- A. Archwire Slot
- B. Nitinol Insert
- C. Bracket Gripping Shelf
- D. Screw holding Nitinol Insert in place

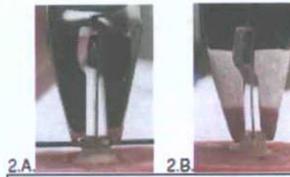


Figure 2. Squeeze Debond positioning.
2.A. with archwire and elastic ligature.
2.B. with no archwire.

- 3) Squeeze instrument handles until the Clarity™ Advanced Aesthetic bracket collapses. Gently rock the bracket in the mesial or distal direction to completely separate the bracket from the enamel. (Figure 3)

NOTE: Maintain the hold on the bracket to keep the 2 parts in the instrument tips.



Figure 3. Squeeze debonded bracket.
3.A. with archwire and elastic ligature.
3.B. with no archwire.

Bracket Rebonding Procedure

In the case of a spontaneous bond failure, it may be necessary to rebond a bracket. The following steps are recommended:

1. Carefully inspect the bracket for any damage. Brackets that have fractured through the vertical debonding slot cannot be rebonded and must be replaced. If a tie-wing is cracked, replace the bracket.
2. Remove any excess adhesive. Extra care must be taken to prevent chipping or breaking of the bracket. Use a hand scaler to remove any excess flash from around the edges of the bracket. Do not use a burr. Do not attempt to scrape adhesive from the base of the bracket or attempt to micro-etch the adhesive as this may damage the bracket's bonding surface.
3. If the bracket has been contaminated (e.g., moisture), rinse the bracket in isopropyl alcohol and allow to dry.
4. Prepare the tooth surface and bond the bracket using the procedure as described by the adhesive manufacturer.

Warranty and Limited Remedy

3M Unitek warrants that this Product is free from defects in materials and manufacturer. 3M Unitek's sole obligation and customer's sole remedy in the event of a claimed defect shall be limited to replacement of merchandise or refund of the purchase price. ALL IMPLIED WARRANTIES, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OR USE ARE DISCLAIMED.

Limitation of Liability

Except where prohibited by law, 3M Unitek will not be liable for any loss or damages arising from this Product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability. This limitation does not apply to third party personal injury claims

15 Biocompatibility

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3M Unitek
Orthodontic Products

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Monterey, CA 91016-5097
626 574 4000
www.3MUnitek.com



Biocompatibility Statement
3M™ Unitek™ Aesthetic Ligated Brackets

A Diplomate of the American Board of Toxicology has assessed the safety of this product. Standard risk assessment techniques and consideration of internationally recognized guidelines were used in this evaluation.

Aesthetic Ligated Brackets are safe for their intended use based on the following considerations:

- 1) (b)(4)Trade Secret Process
- 2) (b)(4)Trade Secret Process
- 3) Favorable clinical (b)(4)Trade Secret, Clarity SL brackets; and
- 4) (b)(4)Trade Secret Process in artificial joints, dentistry and orthodontia.

The biocompatibility assessment for this product was conducted in accordance with the following standards:

- 1) Testing guidelines outlined in the FDA General Program Memorandum G95.
- 2) ISO 10993-1:2009(E) Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process; in addition, relevant detailed guidance in ISO Standards 10993-3:2003 (Tests for genotoxicity, carcinogenicity and reproductive toxicity), 10993-5:2009 (Tests for in vitro cytotoxicity), 10993-10:2002/Amd 1:2006 (Tests for irritation and delayed-type hypersensitivity); and 10993-11:2006 (Tests for systemic toxicity) was considered;
- 3) ISO 7405: 2008 (E) Dentistry - Evaluation of Biocompatibility of Medical Devices used in Dentistry;
- 4) Japan: PFSB Medical Device No 0831002: August 31, 2007 (as translated (b)(4)T February 1, 2008); and
- 5) Standard Operating Procedure (b)(4)T.

In accordance with the combined guidance found in ISO 10993 and ISO 7405, the endpoints below must be considered in the biocompatibility evaluation of this product. The following summary describes the information that was used in the evaluation of each endpoint and in support of the overall conclusion that the product is safe for its intended use.

Cytotoxicity

The product shows (b)(4)T levels of (b)(4)Trade Secret in ISO 10993- and ISO 6872-compliant extraction tests;

Biocompatibility Statement 3M™ Unitek™ Aesthetic Ligated Brackets

(b)(4)Trade Secret Process
[Redacted]

Sensitization

The product shows (b)(4)Trade Secret Process
(b)(4)Trade Secret Process in ISO 10993- and ISO 6872-compliant (b)(4)Trade
(b)(4)Trade Secret Process
(b)(4)Trade Secret Process product.

Irritation/Intracutaneous Reactivity

The product shows (b)(4)Trade Secret Process
[Redacted]
product.

Acute Systemic Toxicity

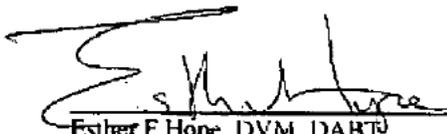
The product shows (b)(4)Trade Secret Process
[Redacted]

Repeated-Dose Systemic Toxicity

The product shows (b)(4)Trade Secret Process
[Redacted] ceramic materials in
medical devices.

Genotoxicity

The product shows (b)(4)Trade Secret Process
(b)(4)Trade Secret Process in ISO 10993- and ISO 6872-compliant extraction tests;
the (b)(4)Trade Secret indicates that (b)(4)Trade Secret Process
(b)(4)Trade Secret Process ceramic materials in medical devices

 25 Jun 2010
Date

Esther F. Hope, DVM, DABT
Advanced Toxicology Specialist
Toxicology Assessment and Compliance Assurance Section
3M Medical Department

Note: The brand name for 3M™ Unitek™ Aesthetic Brackets is Clarity™ Advanced Aesthetic Brackets.

16 Software

Not applicable. Clarity™ Advanced Aesthetic Brackets do not contain software.

17 Electromagnetic Compatibility and Electrical Safety

Not applicable. Clarity™ Advanced Aesthetic Brackets are not an electrical device.

18 Performance Testing – Bench

Please see Bench Test Data Comparison with S/E Devices in section 12.2.4.

19 Performance Testing – Animal

Not applicable. This submission does not contain animal performance testing.

20 Performance Testing – Clinical

Not applicable. This submission does not contain clinical performance testing.



COVER SHEET MEMORANDUM

From: Reviewer Name Sheena A. Green
Subject: 510(k) Number K102803/S1
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/O_5631/Screening%20Checklist%20202%2007.doc)
 - Hold (Additional Information or Telephone Hold).
 - Final Decision (SE, 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	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 type="checkbox"/>	<input checked="" 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 checked="" type="checkbox"/>	<input type="checkbox"/>
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/O_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)		<input checked="" type="checkbox"/>	<input 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 checked="" 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 type="checkbox"/>	<input checked="" type="checkbox"/>
Neonate/Newborn (Birth to 28 days)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Infant (29 days - < 2 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Child (2 years - < 12 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Adolescent (12 years - < 18 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.)		<input type="checkbox"/>	<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: 21 CFR 872.5470
Class: II
Product Code: NJM
(If unclassified, see 510(k) Staff)

Additional Product Codes: _____
Review: Susan Renner (Branch Chief) DEB (Branch Code) 2/16/11 (Date)
Final Review: Antonia (Division Director) 2/17/11 (Date)



DEPARTMENT OF HEALTH AND HUMAN SERVICES M E M O R A N D U M

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue, WO66
Silver Spring, MD 20993

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

510(k) Memorandum

TO: The Record

FROM: Sheena A. Green
ODE/DAGID/DEDB

DATE: February 15, 2011

SUBJECT: *Clarity™ Advanced Ceramic Brackets* (K102803/S001)

CONTACT: Ms. Marlyn L. Scheff
Regulatory Affairs
3M Unitek Corporation
Monrovia, CA 91016
Phone: (626)574-4496
Fax: (626)574-4876
Email: mscheff@mmm.com

RECOMMENDATION: Substantially Equivalent (SE)

I. Purpose and Submission Summary

- ❖ **Purpose:** 3M Unitek, Corporation of Monrovia, CA has submitted a pre-market submission (510(k)) to obtain marketing clearance in the U.S. for the *Clarity™ Advanced Ceramic Brackets*. The device is intended for use in orthodontic treatment.
- ❖ **Review Summary:** The proposed device is an orthodontic ceramic bracket intended for use in orthodontic treatment. Many similar devices have been cleared under the product code NJM as Orthodontic plastic bracket (21 CFR.872.5470). The sponsor claims substantial equivalence to the following:

510(k) Numbers	Device Names	Manufacturers
K062305	Clarity™ Modified Ceramic Brackets	3M Unitek Corporation

K944286	Metal-Lined Transcent™ Ceramic Brackets	3M Unitek Corporation
K950992	Ceramaflex™ Ceramic Brackets	TP Orthodontics Inc.
K082974	Mystique® MB Clear Braces	Dentsply International

The submission purports conformity to the following standards and/or guidance documents:

- ISO 14791:2007 Medical Devices - Application of risk management to medical devices
- ISO 10993-1:2009 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process
- ISO 7405:2008 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
- ISO 6872:2008 Dentistry - Ceramic Materials
- ASTM F603-00 High Purity Dense Aluminum Oxide for Medical Application
- ASTM G133-05 Standard Test for Linearly Reciprocating Ball-on Flat Sliding Wear

II. Administrative Requirements

	Yes	No	N/
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 #3654		X	
Clinical Trials Form		X	

	YES	NO	N/A
510(k) Statement: I certify that, in my capacity as (the position held in company by person required to submit the premarket notification, preferably the official correspondent in the firm), of (company name), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and		X	

	YES	NO	N/A
effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.			
OR			
510(k) Summary labeled as a 510(k) Summary	X		
Submitter's name, address, phone number, and contact person	X		
Date the summary was prepared	X		
The name of the device/trade name/common name/classification name	X		
An identification of the legally marketed Predicate	X		
Description of the subject device including functions, scientific concepts on which the device is based, physical and performance characteristics including design and material composition	X		
Statement of intended use, disease/condition, use population, if intended use not same as predicate, why differences are not critical and do not affect safety and effectiveness when used as labeled.	X		
Summary of technological characteristics and if different from those of predicate, how characteristics compare to those of predicate	X		
If performance data is submitted; description of nonclinical and clinical test data used to support SE decision. For clinical data, adverse events and complications observed relevant to SE decision.	X		
Conclusions drawn from clinical and nonclinical data indicating that the new device is safe and effective for its intended use and performs as well or better than predicate device.	X		
The 510(k) Summary is on a separate section of the document on a separate page not shares with any other section of 510(k)	X		
Any other information reasonably deemed necessary by the agency			X

III. Device Description

	Yes	No	N/
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	

	Yes	No	N/
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?			

The Clarity™ Advanced Ceramic Brackets consist of a translucent alumina body and a (b) (4) Trade Secret bonding base formed by polycrystalline alumina (b) (4) Trade Secret matrix. The device is provided in either (b) (4) Trade Secret or the bracket (b) (4) Trade Secret is coated with a (b) (4) Trade Secret Process. The Clarity™ Advanced Ceramic Bracket contains a vertical slot extending in an occlusal-lingual direction through the center of the body and a (b) (4) Trade Secret in the base. The vertical slot and (b) (4) Trade Secret facilitate debonding of the bracket from the tooth. In addition, the bracket incorporates a water-soluble color placement indicator system on the tie-wings to facilitate positioning of the bracket on the tooth. The color indicators are composed of color (b) (4) Trade Secret and a water soluble (b) (4) Trade Secret Process. The (b) (4) Trade Secret Process by applying a solution of (b) (4) Trade Secret in a (b) (4) Trade Secret and then the (b) (4) Trade Secret in a (b) (4) Trade Secret so that only the (b) (4) Trade Secret on the bracket. The sponsor states that the (b) (4) Trade Secret (b) (4) Trade Secret; however it was not clear from the original submission what the (b) (4) Trade Secret for the colorants used in the device was (See December 2, 2010 correspondence (Deficiency #3)). In S001 (See February 1, 2011 Correspondence), the sponsor stated that the colorants are all (b) (4) Trade Secret which is acceptable because this means that the colored indicators are water soluble which is consistent with the (b) (4) Trade Secret of the predicate.

The components of the Clarity™ Advanced Ceramic Brackets and their functions are listed in the Table below.

Component	Function
Bracket Body	Bonded to the teeth to guide the (b) (4) Trade Secret of the teeth via an archwire
Bonding Base	(b) (4) Trade Secret and alumina grit to create a (b) (4) Trade Secret surface for (b) (4) Trade Secret
Water-soluble indicator	(b) (4) Trade Secret facilitate positioning of brackets on teeth

The Table below shows the chemical composition of the Clarity™ Advanced Ceramic Brackets. In the original submission, the sponsor did not provide the percentage of components below that makes up device (See December 2, 2010 correspondence (Deficiency #2)). A revised chemical composition chart was provided in S001.

Component	Composition	CAS #	Weight %
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Bracket Body	Aluminum oxide	1344-28-1	(b) (4)TT
(b) (4)Trade Surface Coating	(b)(4)Trade Secret (b)(4)Trade Secret	(b) (4)Trade Secret	(b) (4)TT
Bonding Base	Alumina oxide (b)(4)Trade Secret matrix	1344-28-1	(b) (4)TT
Water-soluble indicator	Color indicators	See Table 3 in original submission	(b) (4)TT

Bracket Body:

The bracket body is (b) (4)Trade Secret from translucent (b)(4)Trade Secret polycrystalline alumina (aluminum oxide). The aluminum oxide meets the chemical composition requirements of American Society for Testing and Materials (ASTM) standard F603-00, High Purity Dense Aluminum Oxide for Medical Application.

Bonding Base:

Glass matrix and polycrystalline alumina grit form the (b) (4)Trade Secret bonding base of the bracket. The main component of the (b) (4)Trade Secret matrix is (b)(4)Trade Secret with (b) (4)Trade Secret

Water-soluble indicator:

This system facilitates placement of brackets on teeth via the location of one or two colored dots on the bracket tie wings. The (b)(4)Trade Secret of the colored dots (b)(4)Trade Secret during the manufacturing process, so that only the (b)(4)Trade Secret Process and color additive remain on the bracket. Table 3 on page 33 in the original submission lists the colorants used, the (b)(4)Trade Secret Process of the (b)(4)Trade Secret, their (b)(4)Trade Secret, and their (b) (4)Trade Secret. In addition, the (b)(4)Trade Secret Process is found in Table 3.

IV. Indications for Use

"Clarity™ Advanced Ceramic Brackets are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth."

V. Predicate Device Comparison

The sponsor claims substantial equivalence to *Clarity™ Modified Ceramic Brackets* (K062305), *Metal-Lined Transcent™ Ceramic Brackets* (K944286), *Ceramaflex™ Ceramic Brackets* (K950992), and *Mystique® MB Clear Braces* (K082974).

The *Clarity™ Advanced Ceramic Brackets* are similar in composition to the predicate devices. All devices have ceramic bracket bodies made from translucent alumina (aluminum oxide). Alumina materials are comprised of (b)(4)Trade Secret called (b) (4)Trade Secret. *Clarity™ Advanced Ceramic Brackets*, *Clarity™ Modified Ceramic Brackets*, and *Ceramaflex™ Ceramic Brackets* are (b) (4)Trade Secret from (b)(4)Trade Secret

(b)(4)Trade Secret The bonding surface on the Clarity™ Advanced Ceramic Brackets, Clarity™ Modified Ceramic Brackets, and Metal-Lined Transcent™ Ceramic Brackets is formed by glass and alumina grit.

All the predicates have an archwire slot which enables the bracket to slide along on the archwire. The archwire slots of Clarity™ Advanced Ceramic Brackets (b)(4)Trade Secret Clarity™ Modified Ceramic Brackets (b)(4)Trade Secret Metal-Lined Transcent™ Ceramic Brackets, and Mystique® MB Clear Braces contain a liner or coating. Clarity™ Advanced Ceramic Brackets (b)(4)Trade Secret Clarity™ Modified Ceramic Brackets (b)(4)Trade Secret and Ceramaflex™ Ceramic Brackets do (b)(4)Trade Secret Process (b)(4)Trade Secret

The design of the Clarity™ Advanced Ceramic Brackets and its predicates are identical in design. Each bracket includes a tie wing undercut, true twin tie-wings, (b)(4)Trade Secret edges, round tie-wing ball hook, vertical slot, (b)(4)Trade Secret, and adhesive pre-coated. In addition, all Clarity™ Modified Ceramic Brackets and the predicate devices contain color slots and/or color dots on the bracket tie wings to facilitate bracket positioning of the tooth. However, the (b) used in the water-soluble indicator system (b) In the predicate, Clarity™ Modified Ceramic Brackets, the (b) used is (b)(4)Trade Secret Process (b)(4)Trade Secret. For the Clarity™ Advanced Ceramic Brackets it is (b)(4)Trade Secret Process (b)(4)Trade Secret Process (b)(4)Trade Secret Process. Originally, the reviewer was not aware of this type of (b) and there was a (b)(4)Trade Secret Process (b) in this device (see biocompatibility section).

VI. Labeling

Labeling as been provided which includes device package label, instructions for use, and proposed claims. The package label for the device includes the device name, usage status, company's name, ref number, and lot number. The label in the original submission did not include the required "Rx only" logo or prescription statement as required by 21 CFR 801.109 (See December 2, 2010 Correspondence (Deficiency #5)). A revised device label was provided in S001 that included the above missing information which makes the device label acceptable.

The draft of the instructions for use provided in the original submission include warnings, cautions, bracket bonding and debonding procedures, warranty info, and limitation of liability info. The indications for use statement for the device were not found in the instructions in the original submission (See December 2, 2010 Correspondence (Deficiency #4)). In S001, the sponsor provided revised instructions for use that included identical indications.

The sponsor made the following proposed claims for their device. The data provided in the submission adequately supports each claim.

- a. "Clarity™ Advanced Aesthetic Brackets feature a better aesthetics when

- compared to ceramic brackets with metal liners.”
- b. “Clarity™ Advanced Aesthetic Brackets use a finer grain ceramic material that improves strength when compared to the leading polycrystalline ceramic brackets.”
 - c. “Clarity™ Advanced Aesthetic Brackets (b)(4)Trade Secret Process [REDACTED]”
 - d. “Clarity™ Advanced Aesthetic Brackets feature a glass-grit bonding base for bond strength similar to Clarity™ Metal-Reinforced Ceramic Brackets and Clarity™ SL Self-Ligating Ceramic Brackets.”

VII. Sterilization/Shelf Life/Reuse

Typically these types of devices are not labeled or otherwise represented as sterile, nor are they intended to be sterilized by the end user. The Clarity™ Advanced Ceramic Brackets are indicated for single use.

VIII. Biocompatibility

Clarity™ Advanced Ceramic Brackets consists of the bracket Body, Bonding base, and Water-soluble Indicator System. The Bracket Body is made from (b)(4)Trade Secret [REDACTED] polycrystalline alumina (aluminum oxide) that meets the chemical composition requirements of American Society for Testing and Materials (ASTM) standard F603-00, High Purity Dense Aluminum Oxide for Medical Application. The bonding base is made mainly from (b)(4)Trade [REDACTED] combined with (b) [REDACTED] and include (b)(4)Trade Secret [REDACTED]. The water-soluble indicator (b)(4)Trade Secret Process [REDACTED] and colorants.

The sponsor provided a biocompatibility statement in the submission that states that biocompatibility testing has been performed on their “Aesthetic Ligated Brackets” according to ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11, and ISO 7405. The tests performed were Cytotoxicity, Sensitization, Irritation/Intracutaneous Reactivity, Acute Systemic Toxicity, Repeated-Dose Systemic Toxicity, and Genotoxicity. The biocompatibility statement states that the product (b)(4)Trade Secret Process [REDACTED] for cytotoxicity, sensitization, irritation, intracutaneous reactivity, acute systemic toxicity, repeated-exposure systemic toxicity, and genotoxicity. It was not clear what the term (b)(4)Trade Secret [REDACTED] means. The actual biocompatibility reports were (b)(4)Trade Secret [REDACTED] of the original submission and the sponsor was asked to provide them (See December 2, 2010 Correspondence (Deficiency #1)). Initially, there was a (b) [REDACTED] in the use of the water-soluble indicator system of this device. The (b)(4)Trade Secret Process [REDACTED] (b)(4)Trade Secret Process [REDACTED] along with the colorants will be released in the patient’s mouth. The sponsor states that the (b) [REDACTED] is approximately (b)(4)Trade Secret [REDACTED]. (It was (b)(4)Trade Secret [REDACTED] the above chemicals (b)(4)Trade Secret [REDACTED] and colorants) (b)(4)Trade Secret Process [REDACTED] are biocompatible.

In response to the (b)(4)Trade Secret Process, the sponsor provided a complete list of the (b)(4)Trade Secret used in this device. Each colorant was previously used in the predicate device K062305 and is (b)(4)Trade Secret. The (b)(4)Trade Secret used as part of the color indicator system in this device is (b)(4)Trade Secret. The reviewer was not aware of this type of (b)(4)Trade Secret (and the main biocompatibility (b)(4)Trade Secret was for this type of (b)(4)Trade Secret. In S001, the sponsor identified a (b)(4)Trade Secret (in which (b)(4)Trade Secret was utilized in dental applications; such predicate is 3M Sustel Dental System (K770500). In addition, (b)(4)Trade Secret approved for use in several food and drug applications (21 CFR 172.210 and 21 CFR 173.55. Similarly, (b)(4)Trade Secret Process food (b)(4)Trade Secret adhesives (21 CFR 175.105, 21 CFR 175.125, 21 CFR 176.170, and 21 CFR 176.180) and is a pharmaceutical excipient (United States Pharmacopeia, USP 32-NF 27). Because the (b)(4)Trade Secret colorants and (b)(4)Trade Secret that make up the (b)(4)Trade Secret system has been approved for several food, drug, and (b)(4)Trade Secret Process that (b)(4)Trade Secret Process are safe for human use. Therefore additional (b)(4)Trade Secret Process

IX. Software

The operating principle of this device does not rely upon software; therefore this section does not apply to this 510(k).

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

This device does not include electronic components; therefore this section is not required for this 510(k).

XI. Performance Testing - Bench

The sponsor conducted the following tests to demonstrate that Clarity™ Advanced Aesthetic Brackets are substantially equivalent to the predicate devices: (b)(4)Trade Secret bond strength, Squeeze Debond Strength test, (b)(4)Trade Secret test, and (b)(4)Trade Secret test. All tests were conducted using a (b)(4)Trade Secret Process

In detail, the Shear-peel Bond Strength test measures the occlusal force required to debond a bracket. The test data showed that Clarity™ Advanced Ceramic Brackets are substantially equivalent to the predicate devices in shear-peel bond strength. The (b)(4)Trade Secret test measures the (b)(4)Trade Secret to debond a bracket using an instrument. The test data showed that the Clarity™ Advanced Ceramic Brackets are substantially equivalent to the predicate device in (b)(4)Trade Secret. The (b)(4)Trade Secret test (b)(4)Trade Secret Process between the (b)(4)Trade Secret Process. The test data showed that the Clarity™ Advanced Ceramic Brackets are substantially equivalent to the predicate devices with a (b)(4)Trade Secret mechanism in (b)(4)Trade Secret. The Bracket (b)(4)Trade Secret measures the (b)(4)Trade Secret Process bracket when a (b)(4)Trade Secret is (b)(4)Trade Secret in the (b)(4)Trade Secret. The results of the test show that the (b)(4)Trade Secret Clarity™ Advanced Ceramic Brackets and its predicates are statistically the same.

XII. Performance Testing – Animal

No animal testing has not been provided to evaluate the performance of this device.

XIII. Performance Testing – Clinical

No clinical testing has not been provided to evaluate the performance of this device.

XIV. Substantial Equivalence Discussion

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

¹The indications for this device and the predicates are not identical; however they are similar in that each device is used for orthodontic treatment.

²The differences in the (b) used in the color indicator systems (b)(4)Trade Secret Process (because the (b) used in this system has been previously cleared for use in similar dental applications.

⁵The technological characteristics in the original submission were (b). Such information as complete identification of the components of the color indicator system and the (b)(4)Trade for the colorants were not provided.

XV. Contact History

➤ *December 2, 2010: The deficiencies below were provided to the sponsor via e-mail and they were also notified that the file was placed on telephone hold as of this date.*

1. You provided a biocompatibility statement in your original submission that states that biocompatibility evaluation was performed on your Aesthetic Ligated Brackets. Was biocompatibility testing conducted on the Clarity™ Advanced Aesthetic Brackets? Is the Aesthetic Ligated Brackets the same as the Clarity™ Advanced

Aesthetic Brackets? In addition, please provide the actual test reports for the biocompatibility testing performed on your device.

2. Please provide the (b)(4)Trade Secret of each component that make up your device, e.g. colorants.
3. One (b)(4)Trade Secret device is the "color indicator" that includes the (b)(4)Trade Secret or (b)(4)Trade Secret. Please provide a predicate that utilizes the above (b)(4)Trade Secret with similar intended uses. In addition, please provide information on the release (b)(4)Trade Secret for the colorants used in your device? How long does it take the colorants to be all released?
4. It is required that the instructions for use manual include the indications for use statement. The instructions for use manual you provided do not include your device indications. Please revise your instructions for use to include your indications for use statement. Please note that the indications found on the IFU form, 510(k) summary, and instructions for use must be identical.
5. The draft label provided for your device does not include the required "Rx only" logo or prescription statement required by 21 CFR 801.109. Please revise your device label accordingly.
6. It is required that Standard data report forms 3654 are provided for all standards your device **claims conformity or referenced** in your submission for any sterilization, materials, or testing. Please submit these missing standard data report forms for standards referenced such as ASTM F603-00, ISO 10993-5 etc. These forms can be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>
7. FDA conducts a comprehensive review of the 510(k) Summary in accordance with 21 CFR 807.92 and the Required Elements for 510(k) Statements in accordance with 21 CFR 807.93. Based on our assessment of your 510(k) Summary found on pages 14 of your original submission, FDA believes that your Summary does not meet the regulation. Please revise your 510(k) summary to include the following information:

- Revised predicate device section that also includes the 510(k) numbers of the predicate devices listed
- Summary of technological characteristics and if different from those of predicate, how characteristics compare to those of predicate
- Description of nonclinical data used to support Substantial equivalence (SE) claim.
- Description of clinical data used to support Substantial equivalence (SE) claim, if any.
- Conclusions drawn from clinical and nonclinical data indicating that the new device is safe and effective for its intended use and performs as well or better than predicate device.

➤ February 1, 2010: The sponsor provided responses to the above issues with the following responses through DMC:

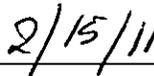
1. **Adequate Response:** The sponsor identified a predicate in which (b) has been utilized. In addition, the sponsor provided information that indicates that the components used in the color indicator system (b)(4)Trade Secret.
2. **Adequate Response:** The sponsor provided a revised table that shows the percentage of each component that makes up this device.
3. **Adequate Response:** The sponsor identified the (b)(4)Trade Secret for this device as (b) which is consistent with the predicate's.
4. **Adequate Response:** The instructions for use manual, 510(k) summary, and IFU form have been revised to include the identical indications.
5. **Adequate Response:** The device label has been revised appropriately.
6. **Adequate Response:** The missing standard data report forms have been provided.
7. **Adequate Response:** The revised 510(k) summary is in accordance with 21 CFR 807.92.

➤ February 15, 2011: The sponsor noted in their responses above that they wish to change the name of the device from Clarity™ Advanced Aesthetic Brackets to Clarity™ Advanced Ceramic Brackets. The reviewer contacted the sponsor via e-mail and requested that an official signed letter be sent to the Agency through DMC indicating the device name change.

XVII. Recommendation:

After review of K102803 and K102803/S001, I recommend that the *Clarity™ Advanced Ceramic Brackets* be cleared for marketing.

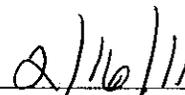




Reviewer
Sheena A. Green
Biomedical Engineer

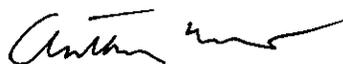
Date

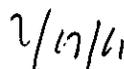




Branch Reviewer
M. Susan Runner, D.D.S., M.A.
Branch Chief Dental Devices

Date





3M Unitek
Orthodontic Products

2724 South Peck Road
Monrovia, CA 91016-5097
626 574 4000
www.3MUnitek.com



February 15, 2011

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

Attn: Sheena A. Green, M.S., Biomedical Engineer
Re: K102803, Clarity™ Advanced Aesthetic Brackets (now Clarity™ Advanced Ceramic Brackets)

Dear Ms Green:

This is to advise that 3M Unitek has changed the name of the device in our 510(k) submission K102803 from Clarity™ Advanced Aesthetic Brackets to Clarity™ Advanced Ceramic Brackets.

Please let me know if you require any additional information to complete the review of K102803 for Clarity™ Advanced Ceramic Brackets.

Sincerely,

A handwritten signature in black ink, appearing to read 'Marlyn Scheff'.

Marlyn Scheff
3M Unitek
mscheff@mmm.com
☎ 626-574-4496

0019

Green, Sheena

From: mscheff@mmm.com
Sent: Tuesday, February 15, 2011 12:37 PM
To: Green, Sheena
Cc: jshorn1@mmm.com; kbacon@mmm.com
Subject: RE: K102803: CLARITY ADVANCED AESTHETIC BRACKETS (2-15-2011)
Attachments: ATT9GXDQ.pdf

Dear Sheena:

The attached letter officially indicates that 3M Unitek has changed the name of the device in our 510(k) submission K102803 from Clarity™ Advanced Aesthetic Brackets to Clarity™ Advanced Ceramic Brackets. We will send the letter today via FedEx to the FDA's Document Mail Center.

Please let me know if you need any additional information to facilitate your review of K102803.
(See attached file: Document.pdf)

Best regards,
 Marlyn
 L. Marlyn Scheff
 Regulatory Affairs
 3M Unitek, 2724 South Peck Road, Monrovia, California 91016
 Location 53/001, mail station 132
 Tel: (626) 574-4496
 Fax: (626) 574-4876

"Green, Sheena" ---02/15/2011 08:04:22 AM---Dear Marlyn, Thank you for your recent responses to the Agency in reference to your file K102803. I

From: "Green, Sheena" <Sheena.Green@fda.hhs.gov>
To: "mscheff@mmm.com" <mscheff@mmm.com>
Date: 02/15/2011 08:04 AM
Subject: RE: K102803: CLARITY ADVANCED AESTHETIC BRACKETS (2-15-2011)

Dear Marlyn,

Thank you for your recent responses to the Agency in reference to your file K102803. It is noted in your responses that you have changed the name of your device from Clarity Advanced Aesthetic Brackets to Clarity Advanced Ceramic Brackets. For our records, please submit an official signed letter to the Agency through the Document Mail Center (DMC) indicating that you wish to make changes to your device name. In addition, please be sure to reference the 510(k) number above in your letter.

Best Regards,
 Sheena

— 0020

2/15/2011

From: mscheff@mmm.com [mailto:mscheff@mmm.com]
Sent: Wednesday, January 26, 2011 7:00 PM
To: Green, Sheena
Cc: jshorn1@mmm.com; kbacon@mmm.com
Subject: Re: K102803: CLARITY ADVANCED AESTHETIC BRACKETS (12-2-2010)

Dear Ms Green:

Attached below is our proposed response to your request for additional information on K102803. If you have time this week, we would very much appreciate your feedback on the adequacy of our response before we mail it to the FDA on Monday, January 31.

(See attached file: Document.pdf)

Best regards,
L. Marlyn Scheff
Regulatory Affairs
3M Unitek, 2724 South Peck Road, Monrovia, California 91016
Location 53/001, mail station 132
Tel: (626) 574-4496
Fax: (626) 574-4876

"Green, Sheena" ---12/02/2010 03:05:53 PM---Dear Ms. Scheff, I reviewed your submission Clarity Advanced Aesthetic Brackets (K102803) and found
From: "Green, Sheena" <Sheena.Green@fda.hhs.gov>
To: "mscheff@mmm.com" <mscheff@mmm.com>
Date: 12/02/2010 03:05 PM
Subject: K102803: CLARITY ADVANCED AESTHETIC BRACKETS (12-2-2010)

Dear Ms. Scheff,

I reviewed your submission *Clarity Advanced Aesthetic Brackets (K102803)* and found that the following issues must be addressed before review can continue. **Please note that your file will be placed on hold as of this date until the following issues below are adequately addressed. Please confirm receipt of this e-mail with a reply.**

Additional Information requested:

1. You provided a biocompatibility statement in your original submission that states that biocompatibility evaluation was performed on your Aesthetic Ligated Brackets. Was biocompatibility testing conducted on the Clarity™ Advanced Aesthetic Brackets? Is the Aesthetic Ligated Brackets the same as the Clarity™ Advanced Aesthetic Brackets? In addition, please provide the actual test reports for the biocompatibility testing performed on your device.
2. Please provide the percentage of each component that make up your device, e.g. colorants.
3. One feature of your device is the "color indicator" that includes the (b)(4)Trade Secret Process. Please provide a predicate that (b) the above (b) with similar intended uses. In addition, please provide information on the (b)(4)Trade for the colorants used in your device? How long does it take the colorants to be all released?

0021

2/15/2011

Green, Sheena

From: Green, Sheena
Sent: Tuesday, February 15, 2011 12:18 PM
To: Shulman, Marjorie G.; Jones, Edwena
Subject: Device Name change - K102803

Dear Marjorie,

The sponsor for K102803 has informed me in their recent supplement that they wish to change the name of their device from Clarity™ Advanced Aesthetic Brackets to Clarity™ Advanced Ceramic Brackets. Can you please make this change in CTS for this file? I have also asked that the sponsor submit to us an official letter indicating the change in device name for our records.

Thanks,
Sheena

Sheena A. Green, M.S.

Biomedical Engineer
U.S. Food & Drug Administration
ODE/CDRH/DAGID
Dental Devices Branch
10903 New Hampshire Avenue
W066 - 2545
Silver Spring, MD 20993
Ph: (301) 796-6279
Fax: (301) 847-8109
sheena.green@fda.hhs.gov

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by email or telephone. This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: Green, Sheena
Sent: Monday, December 06, 2010 3:22 PM
To: 'mscheff@mmm.com'
Subject: RE: *Confidential: K102803: CLARITY ADVANCED AESTHETIC BRACKETS (12-6-2010)
 Dear Ms. Scheff,

Thank you for your notification. I believe the hold letter sent out by the Document Mail Center states that you have 30 days to provide adequate responses to the deficiencies found in your submission. If for some reason you are unable to provide your responses within the 30 days you have the option of requesting additional time by providing a signed official letter to the Document Mail Center requesting an extension on your file. Please be sure to reference the 510(k) number K102803 on the letter. If you have any other questions please feel free to contact me.

Best Regards,
 Sheena

From: mscheff@mmm.com [mailto:mscheff@mmm.com]
Sent: Monday, December 06, 2010 2:44 PM
To: Green, Sheena
Subject: *Confidential: K102803: CLARITY ADVANCED AESTHETIC BRACKETS (12-2-2010)

Dear Ms Green:

Thank you for your email below. We will provide a response for each of the issues you have listed. Please let us know the deadline, if any, for our response to you on this 510(k) submission..

Regards,
 L. Marlyn Scheff
 Regulatory Affairs
 3M Unitek, 2724 South Peck Road, Monrovia, California 91016
 Location 53/001, mail station 132
 Tel: (626) 574-4496
 Fax: (626) 574-4876

"Green, Sheena" ---12/02/2010 03:05:53 PM---Dear Ms. Scheff. I reviewed your submission Clarity Advanced Aesthetic Brackets (K102803) and found

From: "Green, Sheena" <Sheena.Green@fda.hhs.gov>
To: "mscheff@mmm.com" <mscheff@mmm.com>
Date: 12/02/2010 03:05 PM
Subject: K102803: CLARITY ADVANCED AESTHETIC BRACKETS (12-2-2010)

Dear Ms. Scheff,

I reviewed your submission *Clarity Advanced Aesthetic Brackets (K102803)* and found that the following issues must be addressed before review can continue. Please note that your file will be placed on hold as of this date until the following issues below are adequately addressed. Please confirm receipt of this e-mail with a reply.

Additional Information requested:

0023

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2. Please provide the percentage of each component that make up your device, e.g. colorants.

3. One feature of your device is the "color indicator" that includes the (b)(4)Trade Secret Process. Please provide a predicate that (b) the above (b) with similar intended uses. In addition, please provide information on the (b)(4)Trade for the colorants used in your device? How long does it take the colorants to be all released?

4. It is required that the instructions for use manual include the indications for use statement. The instructions for use manual you provided do not include your device indications. Please revise your instructions for use to include your indications for use statement. Please note that the indications found on the IFU form, 510(k) summary, and instructions for use must be identical.

5. The draft label provided for your device does not include the required "Rx only" logo or prescription statement required by 21 CFR 801.109. Please revise your device label accordingly.

6. It is required that Standard data report forms 3654 are provided for all standards your device claims conformity or referenced in your submission for any sterilization, materials, or testing. Please submit these missing standard data report forms for standards referenced such as ASTM F603-00, ISO 10993-5 etc. These forms can be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>

7. FDA conducts a comprehensive review of the 510(k) Summary in accordance with 21 CFR 807.92 and the Required Elements for 510(k) Statements in accordance with 21 CFR 807.93. Based on our assessment of your 510(k) Summary found on pages 14 of your original submission, FDA believes that your Summary does not meet the regulation. Please revise your 510(k) summary to include the following information:

- Revised predicate device section that also includes the 510(k) numbers of the predicate devices listed
- Summary of technological characteristics and if different from those of predicate, how characteristics compare to those of predicate
- Description of nonclinical data used to support Substantial equivalence (SE) claim.
- Description of clinical data used to support Substantial equivalence (SE) claim, if any.
- Conclusions drawn from clinical and nonclinical data indicating that the new device is safe and effective for its intended use and performs as well or better than predicate device.

Best Regards,
Sheena

Sheena A. Green, M.S.
Biomedical Engineer
U.S. Food & Drug Administration
Office of Device Evaluation
Dental Devices Branch

0024

10903 New Hampshire Avenue
WO66, RM 2545
Silver Spring, MD 20993
Ph: (301) 796-6279
Fax: (301) 847-8109

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-- 0025

Subject: *Confidential: K102803: CLARITY ADVANCED AESTHETIC BRACKETS (12-2-2010)

Dear Ms Green:

Thank you for your email below. We will provide a response for each of the issues you have listed. Please let us know the deadline, if any, for our response to you on this 510(k) submission..

Regards,.

L. Marlyn Scheff
Regulatory Affairs
3M Unitek, 2724 South Peck Road, Monrovia, California 91016
Location 53/001, mail station 132
Tel: (626) 574-4496
Fax: (626) 574-4876

"Green, Sheena" ---12/02/2010 03:05:53 PM---Dear Ms. Scheff, I reviewed your submission Clarity Advanced Aesthetic Brackets (K102803) and found

From: "Green, Sheena" <Sheena.Green@fda.hhs.gov>
To: "mscheff@mmm.com" <mscheff@mmm.com>
Date: 12/02/2010 03:05 PM
Subject: K102803: CLARITY ADVANCED AESTHETIC BRACKETS (12-2-2010)

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5. The draft label provided for your device does not include the required "Rx only" logo or prescription statement required by 21 CFR 801.109. Please revise your device label accordingly.
6. It is required that Standard data report forms 3654 are provided for all standards your device claims 0026

From: mscheff@mmm.com
Sent: Monday, January 31, 2011 1:28 PM
To: Green, Sheena
Subject: *Confidential: K102803: CLARITY ADVANCED Ceramic Brackets

Dear Ms Green:

Just a note to let you know that I have mailed today via FedEx our response for the additional information you requested for K102803 to the following address:

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

The letter should arrive at the FDA Document Mail Center tomorrow, February 1st.

Regards,
L. Marlyn Scheff
Regulatory Affairs
3M Unitek, 2724 South Peck Road, Monrovia, California 91016
Location 53/001, mail station 132
Tel: (626) 574-4496
Fax: (626) 574-4876

"Green, Sheena" ---12/06/2010 12:22:24 PM---Dear Ms. Scheff, Thank you for your notification. I believe the hold letter sent out by the Document

From: "Green, Sheena" <Sheena.Green@fda.hhs.gov>
To: "mscheff@mmm.com" <mscheff@mmm.com>
Date: 12/06/2010 12:22 PM
Subject: RE: *Confidential: K102803: CLARITY ADVANCED AESTHETIC BRACKETS (12-6-2010)

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Best Regards,
Sheena

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Sent: Monday, December 06, 2010 2:44 PM
To: Green, Sheena

0027

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Additional Information requested:

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 - Summary of technological characteristics and if different from those of predicate, how characteristics compare to those of predicate
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 - Description of clinical data used to support Substantial equivalence (SE) claim, if any.
 - Conclusions drawn from clinical and nonclinical data indicating that the new device is safe and effective for its intended use and performs as well or better than predicate device.

Best Regards,
Sheena

Sheena A. Green, M.S.

- 0028

Biomedical Engineer
U.S. Food & Drug Administration
Office of Device Evaluation
Dental Devices Branch
10903 New Hampshire Avenue
WO66, RM 2545
Silver Spring, MD 20993
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- 0029

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referenced in your submission for any sterilization, materials, or testing. Please submit these missing standard data report

forms for standards referenced such as ASTM F603-00, ISO 10993-5 etc. These forms can be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>

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Sheena A. Green, M.S.

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- 0030

From: Green, Sheena
Sent: Tuesday, February 15, 2011 11:04 AM
To: 'mscheff@mmm.com'
Subject: RE: K102803: CLARITY ADVANCED AESTHETIC BRACKETS (2-15-2011)

Dear Marlyn,

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Best Regards,
 Sheena

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To: Green, Sheena
Cc: jshorn1@mmm.com; kbacon@mmm.com
Subject: Re: K102803: CLARITY ADVANCED AESTHETIC BRACKETS (12-2-2010)

Dear Ms Green:

Attached below is our proposed response to your request for additional information on K102803. If you have time this week, we would very much appreciate your feedback on the adequacy of our response before we mail it to the FDA on Monday, January 31.

(See attached file: Document.pdf)

Best regards,
 L. Marlyn Scheff
 Regulatory Affairs
 3M Unitek, 2724 South Peck Road, Monrovia, California 91016
 Location 53/001, mail station 132
 Tel: (626) 574-4496
 Fax: (626) 574-4876

"Green, Sheena" ---12/02/2010 03:05:53 PM---Dear Ms. Scheff, I reviewed your submission Clarity Advanced Aesthetic Brackets (K102803) and found

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To: "mscheff@mmm.com" <mscheff@mmm.com>
Date: 12/02/2010 03:05 PM
Subject: K102803: CLARITY ADVANCED AESTHETIC BRACKETS (12-2-2010)

Dear Ms. Scheff,

I reviewed your submission *Clarity Advanced Aesthetic Brackets (K102803)* and found that the following issues

— 0031



COVER SHEET MEMORANDUM

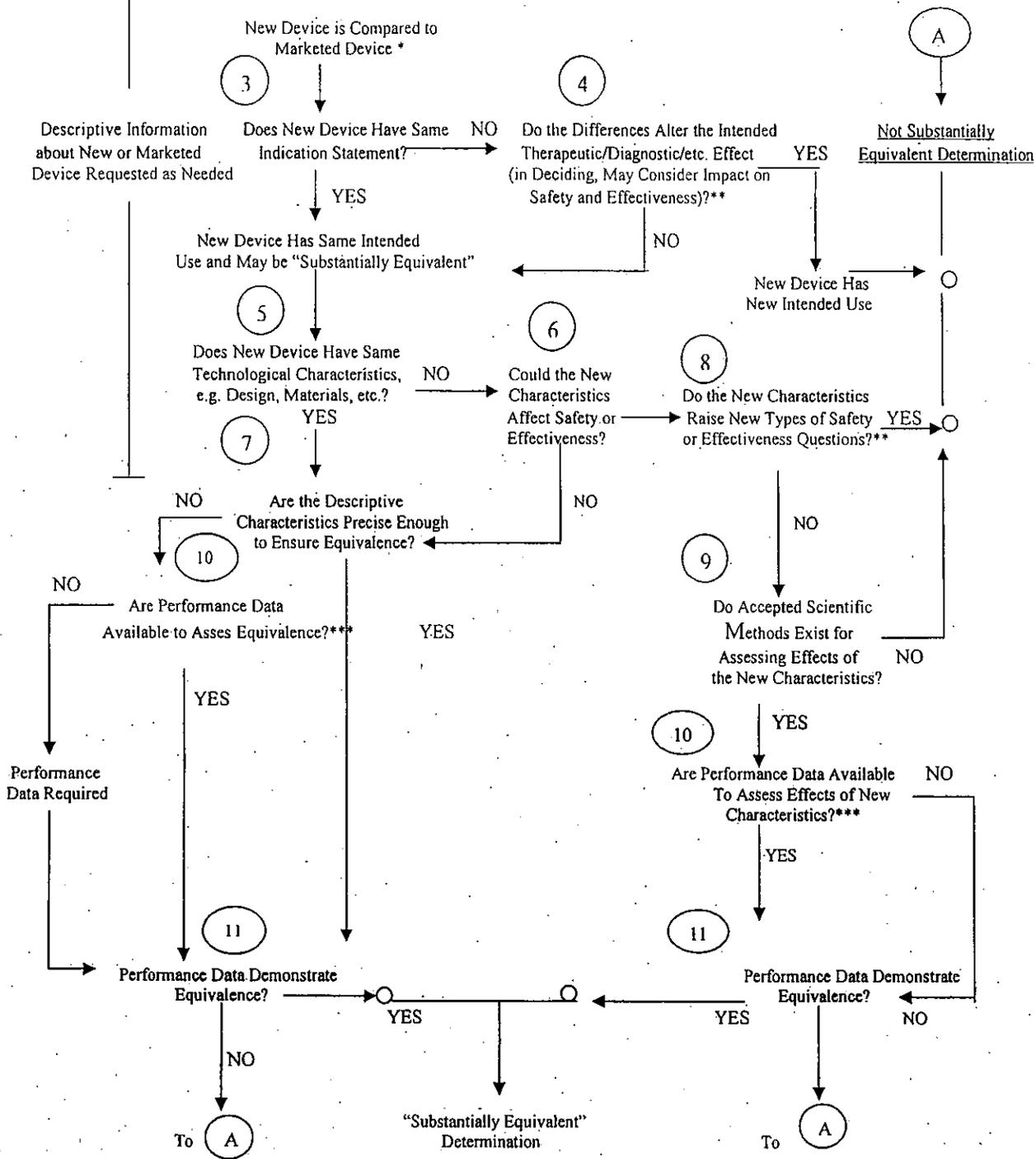
From: Reviewer Name Sheena A. Green
Subject: 510(k) Number K102803
To: The Record

Please list CTS decision code TH

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc).
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? 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.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age <=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

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



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

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

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

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

Regulation Number

Class*

Product Code

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

Additional Product Codes:

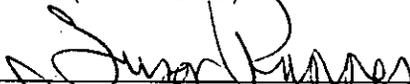
Review:


(Branch Chief)

DEB
(Branch Code)

12/3/10
(Date)

Final Review:


(Division Director)

12/3/10
(Date)



DEPARTMENT OF HEALTH AND HUMAN SERVICES M E M O R A N D U M

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue, WO66
Silver Spring, MD 20993

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

510(k) Memorandum

TO: The Record

FROM: Sheena A. Green
ODE/DAGID/DEDB

DATE: December 2, 2010

SUBJECT: *Clarity Advanced Aesthetic Brackets* (K102803)

CONTACT: Ms. Marlyn L. Scheff
Regulatory Affairs
3M Unitek Corporation
Monrovia, CA 91016
Phone: (626)574-4496
Fax: (626)574-4876
Email: mscheff@mmm.com

RECOMMENDATION: Telephone Hold (TH)

I. Purpose and Submission Summary

- ❖ **Purpose:** 3M Unitek, Corporation of Monrovia, CA has submitted a pre-market submission (510(k)) to obtain marketing clearance in the U.S. for the *Clarity Advanced Aesthetic Brackets*. The device is intended for use in orthodontic treatment.
- ❖ **Review Summary:** The proposed device is an orthodontic ceramic bracket intended for use in orthodontic treatment. Many similar devices have been cleared under the product code NJM as Orthodontic plastic bracket (21 CFR.872.5470). The sponsor claims substantial equivalence to the following:

510(k) Numbers	Device Names	Manufacturers
K062305	Clarity™ Modified Ceramic Brackets	3M Unitek Corporation

K944286	Metal-Lined Transcent™ Ceramic Brackets	3M Unitek Corporation
K950992	Ceramaflex™ Ceramic Brackets	TP Orthodontics Inc.
K082974	Mystique® MB Clear Braces	Dentsply International

The submission purports conformity to the following standards and/or guidance documents:

- o ISO 14791:2007 Medical Devices - Application of risk management to medical devices
- o ISO 10993-1:2009 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process
- o ISO 7405:2008 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
- o ISO 6872:2008 Dentistry - Ceramic Materials

II. Administrative Requirements

	Yes	No	N/
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) <u>Summary</u> or 510(k) Statement	X		
Standards Form #3654		X	
Clinical Trials Form		X	

	YES	NO	N/A
510(k) Statement: I certify that, in my capacity as (the position held in company by person required to submit the premarket notification, preferably the official correspondent in the firm), of (company name), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.		X	
<u>OR</u>			

	YES	NO	N/A
510(k) Summary labeled as a 510(k) Summary	X		
Submitter's name, address, phone number, and contact person	X		
Date the summary was prepared	X		
The name of the device/trade name/common name/classification name	X		
An identification of the legally marketed Predicate	X		
Description of the subject device including functions, scientific concepts on which the device is based, physical and performance characteristics including design and material composition	X		
Statement of intended use, disease/condition, use population, if intended use not same as predicate, why differences are not critical and do not affect safety and effectiveness when used as labeled.	X		
Summary of technological characteristics and if different from those of predicate, how characteristics compare to those of predicate		X	
If performance data is submitted; description of nonclinical and clinical test data used to support SE decision. For clinical data, adverse events and complications observed relevant to SE decision.		X	
Conclusions drawn from clinical and nonclinical data indicating that the new device is safe and effective for its intended use and performs as well or better than predicate device.		X	
The 510(k) Summary is on a separate section of the document on a separate page not shares with any other section of 510(k)	X		
Any other information reasonably deemed necessary by the agency			X

III. Device Description

	Yes	No	N/
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 Clarity™ Advanced Aesthetics Brackets consist of a translucent alumina body and a (b) (4) bonding base formed by polycrystalline alumina (b)(4)Trade matrix. The (4) d S tP

device is provided in either (b)(4)Trade Secret or the bracket top surface is coated with a (b)(4)Trade Secret Process. The Clarity™ Advanced Aesthetics Bracket contains a vertical slot extending in an occlusal-gingival direction through the center of the body and a (b)(4)Trade Secret in the base. The vertical slot and (b)(4)Trade Secret facilitate debonding of the bracket from the tooth. In addition, the bracket incorporates a water-soluble color placement indicator system on the tie-wings to facilitate positioning of the bracket on the tooth. The color indicators are composed of color additives (b)(4)Trade Secret and a water soluble (b)(4)Trade Secret Process (b)(4)Trade Secret Process. The (b)(4)Trade Secret Process (b)(4)Trade Secret Process in a (b)(4)Trade Secret Process and then the (b)(4)Trade Secret Process so that only the (b)(4)Trade Secret Process remain on the bracket. The sponsor states that the estimated amount of color indicators used in the orthodontic treatment is approximately (b)(4)Trade Secret; however it is not clear from the original submission what is the (b)(4)Trade Secret Process for the colorants used in the device (Deficiency #3).

The components of the Clarity™ Advanced Aesthetics Brackets and their functions are listed in the Table below.

Component	Function
Bracket Body	Bonded to the teeth to guide the (b)(4)Trade Secret of the teeth via an archwire
Bonding Base	(b)(4)Trade Secret and alumina grit to create a (b)(4)Trade Secret surface for (b)(4)Trade Secret
Water-soluble indicator	Facilitate positioning of brackets on teeth

The Table below shows the chemical composition of the Clarity™ Advanced Aesthetics Brackets. In the original submission, the sponsor did not provide the percentage of components below that makes up device (Deficiency #2).

Component	Composition	CAS #
Bracket Body	Aluminum oxide (b)(4)Trade Secret Process	(b)(4)Trade Secret
Bonding Base	Alumina oxide grit (b)(4)Trade Secret	(b)(4)Trade Secret
Water-soluble indicator	Color indicators	See Table 3 in original submission

Bracket Body:

The bracket body is (b)(4)Trade Secret (from translucent (b)(4)Trade Secret polycrystalline alumina (aluminum oxide)). The aluminum oxide meets the chemical composition requirements of American Society for Testing and Materials (ASTM) standard F603-00,

High Purity Dense Aluminum Oxide for Medical Application.

Bonding Base:

Glass matrix and polycrystalline alumina grit form the (b) bonding base of the bracket. The main component of the glass matrix is (b)(4)Trade Secret combined (b)(4)Trade Secret (b)(4)Trade Secret Process

Water-soluble indicator:

This system facilitates placement of brackets on teeth via the location of one or two colored dots on the bracket tie wings. The (b)(4)Trade Secret of the colored dots (b)(4)Trade Secret during the (b)(4)Trade Secret process, so that only the (b)(4)Trade Secret Process and (b)(4)Trade Secret Process the bracket. Table 3 on page 33 in the original submission lists the colorants used, the (b)(4)Trade Secret of the colorants (b)(4)Trade Secret their CFR references, and their CAS numbers. In addition, the (b)(4)Trade Secret Process is found in Table 3.

IV. Indications for Use

"Clarity™ Advanced Aesthetic Brackets are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth."

V. Predicate Device Comparison

The sponsor claims substantial equivalence to *Clarity™ Modified Ceramic Brackets* (K062305), *Metal-Lined Transcent™ Ceramic Brackets* (K944286), *Ceramaflex™ Ceramic Brackets* (K950992), and *Mystique® MB Clear Braces* (K082974).

The Clarity™ Advanced Aesthetic Brackets are similar in composition to the predicate devices. All devices have ceramic bracket bodies made from translucent alumina (aluminum oxide). Alumina materials are comprised of (b)(4)Trade Secret called (b)(4)Trade Secret Clarity™ Advanced Aesthetic Brackets, Clarity™ Modified Ceramic Brackets Brackets, and Ceramaflex™ Ceramic Brackets are (b) from (b)(4)Trade Secret (b)(4)Trade Secret. The bonding surface on the Clarity™ Advanced Aesthetic Brackets, Clarity™ Modified Ceramic Brackets, and Metal-Lined Transcent™ Ceramic Brackets is formed by glass and alumina grit.

All the predicates have an archwire slot which enables the bracket to slide along on the archwire. The archwire slots of Clarity™ Advanced Aesthetic Brackets (b)(4)Trade Secret Clarity™ Modified Ceramic Brackets (b)(4)Trade Secret Metal-Lined Transcent™ Ceramic Brackets, and Mystique® MB Clear Braces contain a liner or coating. Clarity™ Advanced Aesthetic Brackets (b)(4)Trade Secret Clarity™ Modified Ceramic Brackets (b) (and Ceramaflex™ Ceramic Brackets do not contain a liner or coating. (4)

The design of the Clarity™ Advanced Aesthetic Brackets and its predicates are identical in design. Each bracket includes a tie wing undercut, true twin tie-wings, base flange,

(b) smooth edges, (b)(4)Trade Secret Process, vertical slot, stress concentrator, and adhesive pre-coated. In addition, all Clarity™ Modified Ceramic Brackets and the predicate devices contain color slots and/or color dots on the bracket tie wings to facilitate bracket positioning of the tooth. However, the (b) used in the water-soluble indicator system (In the predicate, Clarity™ Modified Ceramic Brackets, the (b)(4)Trade Secret Process. For the Clarity™ Advanced Aesthetic Brackets it is (b)(4)Trade Secret Process. The reviewer is not aware of this type of (b)(4)Trade Secret Process. There is a (b)(4)Trade Secret Process (see biocompatibility section).

VI. Labeling

Labeling as been provided which includes device package label, instructions for use, and proposed claims. The package label for the device includes the device name, usage status, company's name, ref number, and lot number. The label does not include the required "Rx only" logo or prescription statement as required by 21 CFR 801.109 (Deficiency #5).

The draft of the instructions for use provided in the original submission include warnings, cautions, bracket bonding and debonding procedures, warranty info, and limitation of liability info. The indications for use statement for the device were not found in the instructions (Deficiency #4).

The sponsor made the following proposed claims for their device. The data provided in the submission adequately supports each claim.

- a. "Clarity™ Advanced Aesthetic Brackets feature a better aesthetics when compared to ceramic brackets with metal liners."
- b. "Clarity™ Advanced Aesthetic Brackets use a finer grain ceramic material that improves strength when compared to the leading polycrystalline ceramic brackets."
- c. "Clarity™ Advanced Aesthetic Brackets (b) feature a (b) slot coating that reduces friction."
- d. "Clarity™ Advanced Aesthetic Brackets feature a (b) bonding base for bond strength similar to Clarity™ Metal-Reinforced Ceramic Brackets and Clarity™ SL Self-Ligating Ceramic Brackets."

VII. Sterilization/Shelf Life/Reuse

Typically these types of devices are not labeled or otherwise represented as sterile, nor are they intended to be sterilized by the end user. The Clarity™ Advanced Aesthetic Brackets are indicated for single use.

VIII. Biocompatibility

Clarity™ Advanced Aesthetic Brackets consists of the bracket Body, Bonding base, and

Water-soluble Indicator System. The Bracket Body is made from (b)(4)Trade Secret polycrystalline alumina (aluminum oxide) that meets the chemical composition requirements of American Society for Testing and Materials (ASTM) standard F603-00, High Purity Dense Aluminum Oxide for Medical Application. The bonding base is made mainly from (b)(4)Trade combined with (b)(4)Trade Secret Process. The water-soluble indicator (b)(4)Trade Secret Process colorants.

The sponsor provided a biocompatibility statement in the submission that states that biocompatibility testing has been performed on their "Aesthetic Ligated Brackets" according to ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11, and ISO 7405. The tests performed were Cytotoxicity, Sensitization, Irritation/Intracutaneous Reactivity, Acute Systemic Toxicity, Repeated-Dose Systemic Toxicity, and Genotoxicity. The biocompatibility statement states that the product demonstrated (b)(4)Trade Secret for cytotoxicity, sensitization, irritation, intracutaneous reactivity, acute systemic toxicity, repeated-exposure systemic toxicity, and genotoxicity. It is not clear what the term (b)(4)Trade Secret Process. The actual biocompatibility reports were not submitted as part of the original submission and must be submitted for complete evaluation (Deficiency #1). There is a concern in the use of the water-soluble indicator system of this device. The (b)(4)Trade Secret Process along with the colorants will be released in the patient's mouth. The sponsor states that the estimated amount of color indicators used in the orthodontic treatment is approximately (b)(4)Trade Secret. It is unknown whether the above chemicals (b)(4)Trade Secret and colorants) exposed to the patient are biocompatible. Additional biocompatibility testing is required to address the above safety concern (Deficiency #1). In addition, it is not clear from the biocompatibility statement provided if the Clarity™ Advanced Aesthetic Brackets were used in the testing (Deficiency #1).

IX. Software

The operating principle of this device does not rely upon software; therefore this section does not apply to this 510(k).

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

This device does not include electronic components; therefore this section is not required for this 510(k).

XI. Performance Testing - Bench

The sponsor conducted the following tests to demonstrate that Clarity™ Advanced Aesthetic Brackets are substantially equivalent to the predicate devices: (b)(4)Trade Secret Process

XII. Performance Testing - Animal

No animal testing has not been provided to evaluate the performance of this device.

XIII. Performance Testing - Clinical

No clinical testing has not been provided to evaluate the performance of this device.

XIV. Substantial Equivalence Discussion

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

XV. Deficiencies:

1. You provided a biocompatibility statement in your original submission that states

that biocompatibility evaluation was performed on your Aesthetic Ligated Brackets. Was biocompatibility testing conducted on the Clarity™ Advanced Aesthetic Brackets? Is the Aesthetic Ligated Brackets the same as the Clarity™ Advanced Aesthetic Brackets? In addition, please provide the actual test reports for the biocompatibility testing performed on your device.

2. Please provide the percentage of each component that make up your device, e.g. colorants.
3. One feature of your device is the "color indicator" that includes the (b)(4)Trade Secret Process. Please provide a predicate that utilizes the above (b) with similar intended uses. In addition, please provide information on (b)(4)Trade Secret Process for the colorants used in your device? How long does it take the colorants to be all released?
4. It is required that the instructions for use manual include the indications for use statement. The instructions for use manual you provided do not include your device indications. Please revise your instructions for use to include your indications for use statement. Please note that the indications found on the IFU form, 510(k) summary, and instructions for use must be identical.
5. The draft label provided for your device does not include the required "Rx only" logo or prescription statement required by 21 CFR 801.109. Please revise your device label accordingly.
6. It is required that Standard data report forms 3654 are provided for all standards your device **claims conformity or referenced** in your submission for any sterilization, **materials, or testing**. Please submit these missing standard data report forms for standards referenced such as ASTM F603-00, ISO 10993-5 etc. These forms can be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>
7. FDA conducts a comprehensive review of the 510(k) Summary in accordance with 21 CFR 807.92 and the Required Elements for 510(k) Statements in accordance with 21 CFR 807.93. Based on our assessment of your 510(k) Summary found on pages 14 of your original submission, FDA believes that your Summary does not meet the regulation. Please revise your 510(k) summary to include the following information:

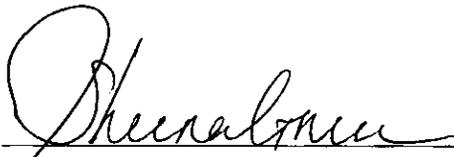
- Revised predicate device section that also includes the 510(k) numbers of the predicate devices listed
- Summary of technological characteristics and if different from those of predicate, how characteristics compare to those of predicate
- Description of nonclinical data used to support Substantial equivalence (SE) claim.
- Description of clinical data used to support Substantial equivalence (SE) claim, if any.
- Conclusions drawn from clinical and nonclinical data indicating that the new device is safe and effective for its intended use and performs as well or better than predicate device.

XVI. Contact History:

- December 2, 2010: The above deficiencies were provided to the sponsor via e-mail and they were also notified that the file was placed on telephone hold as of this date.

XVII. Recommendation:

After review of K102803, I recommend that this submission be placed on telephone hold until the deficiencies in section XV of this document are adequately addressed.



12-2-2010

Reviewer
Sheena A. Green
Biomedical Engineer

Date

Branch Reviewer
M. Susan Runner, D.D.S., M.A.
Branch Chief Dental Devices

Date

Green, Sheena

From: Green, Sheena
Sent: Thursday, December 02, 2010 6:06 PM
To: 'mscheff@mmm.com'
Subject: K102803: CLARITY ADVANCED AESTHETIC BRACKETS (12-2-2010)

Dear Ms. Scheff,

I reviewed your submission *Clarity Advanced Aesthetic Brackets (K102803)* and found that the following issues must be addressed before review can continue. **Please note that your file will be placed on hold as of this date until the following issues below are adequately addressed. Please confirm receipt of this e-mail with a reply.**

Additional Information requested:

1. You provided a biocompatibility statement in your original submission that states that biocompatibility evaluation was performed on your Aesthetic Ligated Brackets. Was biocompatibility testing conducted on the Clarity™ Advanced Aesthetic Brackets? Is the Aesthetic Ligated Brackets the same as the Clarity™ Advanced Aesthetic Brackets? In addition, please provide the actual test reports for the biocompatibility testing performed on your device.
2. Please provide the percentage of each component that make up your device, e.g. colorants.
3. One feature of your device is the "color indicator" that includes the (b)(4)Trade Secret Process. Please provide a predicate that utilizes the above (b) with similar intended uses. In addition, please provide information on (b)(4)Trade Secret for the colorants used in your device? How long does it take the colorants to be all released?
4. It is required that the instructions for use manual include the indications for use statement. The instructions for use manual you provided do not include your device indications. Please revise your instructions for use to include your indications for use statement. Please note that the indications found on the IFU form, 510(k) summary, and instructions for use must be identical.
5. The draft label provided for your device does not include the required "Rx only" logo or prescription statement required by 21 CFR 801.109. Please revise your device label accordingly.
6. It is required that Standard data report forms 3654 are provided for all standards your device **claims conformity or referenced** in your submission for any sterilization, materials, or testing. Please submit these missing standard data report forms for standards referenced such as ASTM F603-00, ISO 10993-5 etc. These forms can be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>
7. FDA conducts a comprehensive review of the 510(k) Summary in accordance with 21 CFR 807.92 and the Required Elements for 510(k) Statements in accordance with 21 CFR 807.93. Based on our assessment of your 510(k) Summary found on pages 14 of your original submission, FDA believes that your Summary does not meet the regulation. Please revise your 510(k) summary to include the following information:
 - Revised predicate device section that also includes the 510(k) numbers of the predicate devices listed
 - Summary of technological characteristics and if different from those of predicate, how

- characteristics compare to those of predicate
- Description of nonclinical data used to support Substantial equivalence (SE) claim.
- Description of clinical data used to support Substantial equivalence (SE) claim, if any.
- Conclusions drawn from clinical and nonclinical data indicating that the new device is safe and effective for its intended use and performs as well or better than predicate device.

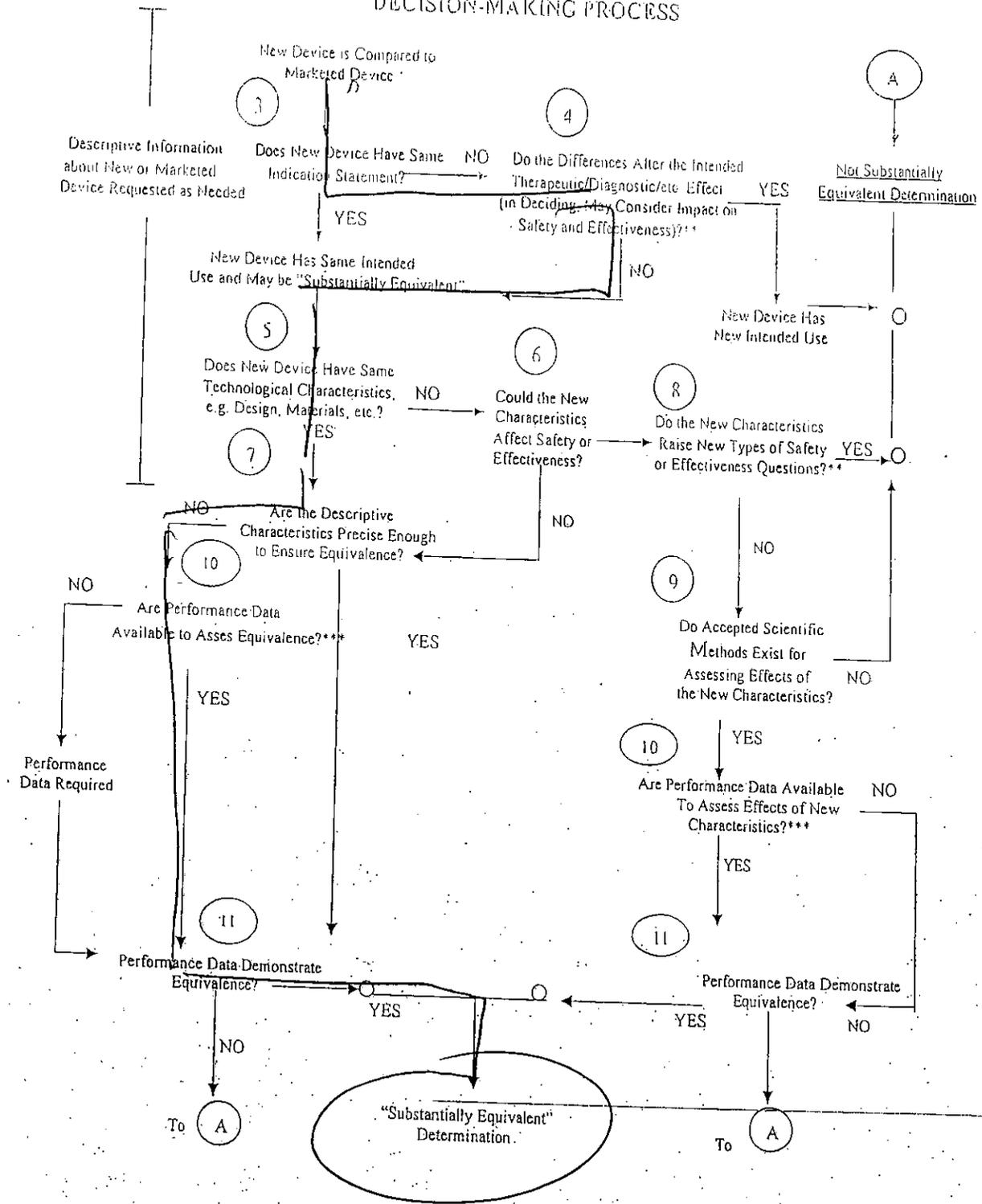
Best Regards,
Sheena

Sheena A. Green, M.S.

Biomedical Engineer
U.S. Food & Drug Administration
Office of Device Evaluation
Dental Devices Branch
10903 New Hampshire Avenue
WO66, RM 2545
Silver Spring, MD 20993
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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.



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 01, 2011

3M UNITEK CORPORATION
2724 SOUTH PECK RD.
MONROVIA, CALIFORNIA 91016
UNITED STATES
ATTN: MARLYN L. SCHEFF

510k Number: K102803

Product: CLARITY ADVANCED AESTHETIC

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

- 0032



K102803/S1

January 26, 2011

Confidential

FDA CDRH DMC

FEB 1 2011

Revised

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

Attn: Sheena A. Green, M.S., Biomedical Engineer
Re: K102803, Clarity™ Advanced Aesthetic Brackets (now Clarity™ Advanced Ceramic Brackets)

Dear Ms Green:

Below is the additional information you requested for our 510(k) submission for Clarity™ Advanced Aesthetic Brackets, which has been renamed as Clarity™ Advanced Ceramic Brackets.

1. *You provided a biocompatibility statement in your original submission that states that biocompatibility evaluation was performed on your Aesthetic Ligated Brackets. Was biocompatibility testing conducted on the Clarity™ Advanced Aesthetic Brackets? Is the Aesthetic Ligated Brackets the same as the Clarity™ Advanced Aesthetic Brackets? In addition, please provide the actual test reports for the biocompatibility testing performed on your device.*

Clarity™ Advanced Aesthetic Brackets are the same as Aesthetic Ligated Brackets. Please see note at the bottom of page 52 in the submission for K102803.

A biocompatibility evaluation was performed on Clarity™ Advanced Ceramic Brackets, but no biocompatibility testing was performed. The justification for no biocompatibility testing is contained in the Standards Data Reports for ISO 10993-1:2003 Biological evaluation of medical devices-Part 1: Evaluation and Testing, and ISO 7405:2008 (E) Dentistry-Evaluation of Biocompatibility of Medical Devices used in Dentistry (see §9 of the 510(k) submission).

Attachment #1 contains the revised Standards Data Report for ISO 10993-1:2003 Biological evaluation of medical devices-Part 1: Evaluation and Testing. We added the justification for the color indicator ingredients and corrected "no" to "yes" (a typographical error) for the

- 0033

K-33

Confidential

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

Attachment #2 contains the revised Biocompatibility statement for Aesthetic Ligated Brackets. We added "...the established use of color indicator ingredients in foods and drug products..." to the following sections: sensitization, acute systemic toxicity, repeated-dose systemic toxicity, and genotoxicity.

2. Please provide the percentage of each component that make up your device, e.g. colorants.

The table below shows the percentage of each component of Clarity™ Advanced Ceramic Brackets. Please refer to Table 3 on page 33 in the 510(k) submission for K102803 for CAS numbers for the water-soluble indicators.

#	Component	Chemical Name	CAS#	Weight %
2a	Bracket Body	Aluminum oxide	1344-28-1	(b) (4) Trade Secret
	(b) (4) Trade Secret Surface Coating	(b)(4)Trade Secret Process		
2b	Bonding Base	Aluminum oxide (b) (4) Trade Secret matrix	(b)(4)Trade Secret Process	(b) (4) Trade Secret
2c	Water-soluble Indicator	Color Indicators	Table 3 K102803	(b)(4)Trade Secret

3. One feature of your device is the "color indicator" that includes the (b)(4)Trade Secret. Please provide a predicate that utilizes the above (b) (4) Trade Secret with similar intended uses. In addition, please provide information on (b)(4)Trade Secret for the colorants used in your device? How long does it take the colorants to be all released?

Predicates

3M Sustel Dental System, K970500, is a predicate device that (b)(4)Trade Secret in dental applications. 3M Sustel Dental System has been (b)(4)Trade Secret Process (b)(4)Trade Secret System and is indicated for restoring cavities in adult and primary teeth. Secret

(b) (4) Trade Secret, an additive in (b)(4)Trade Secret Process (b)(4)Trade Secret concentrations in tablet form, (b)(4)Trade Secret Process and (b) (4) Trade Secret

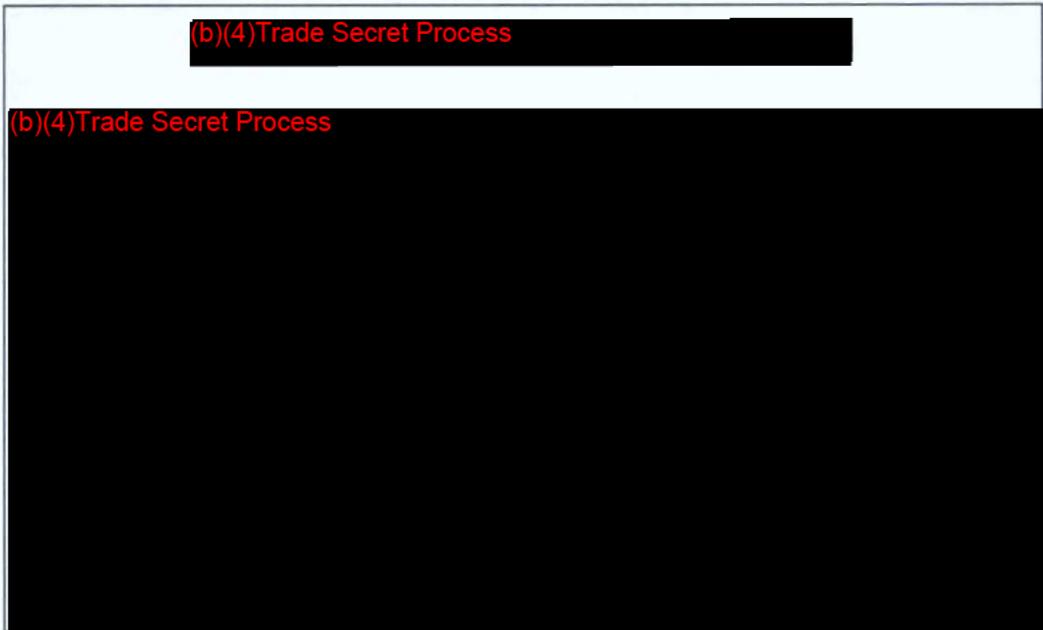
(b)(4)Trade Secret Process and (b) (b)(4)Trade Secret Process

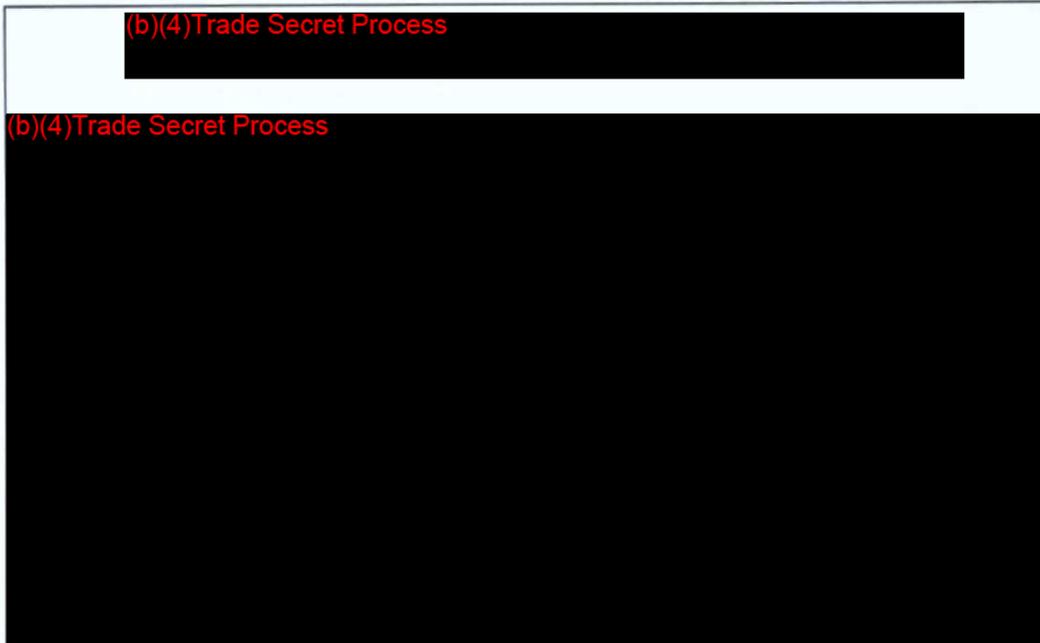
International Journal of Toxicology, 1998. 17(5 supp 4): (b)(4)Trade Secret appropriate purity is used as a vehicle for pharmaceuticals and as a (b)(4)Trade Secret Process working group, (b) (4)Ti

(b)(4)Trade Secret Process (United States Pharmacopeia, (b)(4)Trade Secret is used in pharmaceutical preparations at levels as high as (b) unit dose [USFDA. *Inactive Ingredients Database for Approved Drug Products*. 2008 May 29, 2009; Available from: <http://www.accessdata.fda.gov/scripts/cder/iig/index.cfm>]. (b) is approved for use as an (b)(4)Trade Secret Process and paper/paperboard (b) (4)Trade Secret

(b)(4)Trade Secret Process

The (b)(4)Trade Secret of each of the (b) colorants was determined (b)(4)Trade Secret. The weight loss of the colorant on (b) brackets was obtained at multiple (b)(4)Trade Secret brackets in (b)(4)Trade Secret in a beaker which was maintained in a (b)(4)Trade Secret and swirled at (b). The percentage of the colorant released was (b) as the colorant weight loss at various time points as a percentage of the initial colorant weight. The (b) are in the two graphs shown below. (4)Trade Secret The graphs include all (b) colorants in separate curves (each curve is an average of (b) (4)Trade Secret).





Colorant (b)(4)Trade Secret

Per the (b)(4)Trade Secret for either colorant (b)(4)Trade Secret Process, colorants are all (b)(4)Trade Secret. In addition, the instruction for use (attachment 3) contains the following recommendations:

Bracket Identification and Bracket Positioning section: "Vertical and horizontal identification and positioning colored indicators are water soluble. It is recommended that the patient brush after bonding, but before the placement of the archwire to remove the identification and positioning colored indicators."

Bracket Bonding section: "Before Placing the archwire, patient should brush to remove the identification and positioning colored indicators."

4. *It is required that the instructions for use manual include the indications for use statement. The instructions for use manual you provided do not include your device indications. Please revise your instructions for use to include your indications for use statement. Please note that the indications found on the IFU form, 510(k) summary, and instructions for use must be identical.*

We have added the following indications for use statement to the instructions for use:

"Clarity™ Advanced Ceramic Brackets are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth." Please see attachment #3 for the instructions for use.

Confidential

In addition, we have revised the indications for use statement for K102803 to include the name change to Clarity™ Advanced Ceramic Brackets. Please see attachment #4 for the revised indications for use statement.

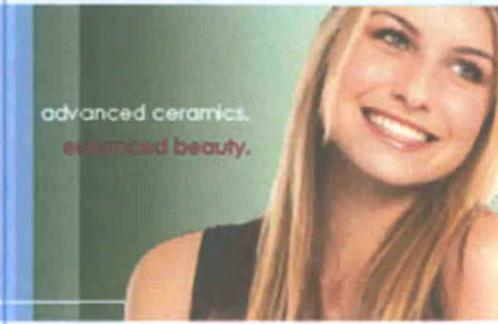
5. *The draft label provided for your device does not include the required "Rx only" logo or prescription statement required by 21 CFR 801.109. Please revise your device label accordingly.*

We have revised the device labeling to include the prescription statement as shown below.

3M Unitek 2724 South Peck Road Menrovia, CA 91016 USA Caution: U.S. Federal Law restricts this device to sale by or on the order of an orthodontic professional. © 2010 3M. All rights reserved. 36624 Rev. 1012	European Representative 3M Unitek Ohmstrasse 3 86899 Landsberg, Germany	CE 0086 
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CLARITY™ ADVANCED MBT™
System Rx
1 Case Kit U/L 5X5
.018 (0,46 mm) w/Cuspid Hk
LOT SAMPLE
REF 006-100 **GS1-128**
Made in U.S.A. for
3M Unitek

(01)(30)1(10)SAMPLE



CLARITY™ | ADVANCED
advanced ceramic brackets
3M Unitek



6. It is required that Standard data report forms 3654 are provided for all standards your device **claims conformity or referenced** in your submission for any sterilization, **materials, or testing**. Please submit these missing standard data report forms for standards referenced such as ASTM F603-00, ISO 10993-5 etc. These forms can be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>

Attachments 5 and 6 are the standard data reports for:

- ASTM F603-00, High Purity Dense Aluminum Oxide for Medical Application
- ASTM G133-05, Standard Test Method for Linearly Reciprocating Ball-on-Flat Sliding Wear

ISO 10993-1 provides the option not to conduct any biocompatibility testing based on the availability of other relevant information. The standard data report for ISO 10993-1 documents the information supporting our option not to test (Attachment 1). (b) (4)



7. FDA conducts a comprehensive review of the 510(k) Summary in accordance with 21 CFR 807.92 and the Required Elements for 510(k) Statements in accordance with 21 CFR 807.93. Based on our assessment of your 510(k) Summary found on pages 14 of your original submission, FDA believes that your Summary does not meet the regulation. Please revise your 510(k) summary to include the following information:

- Revised predicate device section that also includes the 510(k) numbers of the predicate devices listed
- Summary of technological characteristics and if different from those of predicate, how characteristics compare to those of predicate

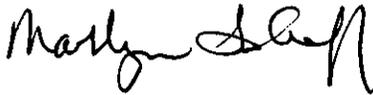
Confidential

- *Description of nonclinical data used to support Substantial equivalence (SE) claim.*
- *Description of clinical data used to support Substantial equivalence (SE) claim, if any.*
- *Conclusions drawn from clinical and nonclinical data indicating that the new device is safe and effective for its intended use and performs as well or better than predicate device.*

We have revised the 510(k) Summary to include the information listed above. Please see attachment 7.

Please let me know if you require any additional information to complete the review of K102803 for Clarity™ Advanced Ceramic Brackets.

Sincerely,



Marlyn Scheff
3M Unitek
mscheff@mmm.com
☎ 626-574-4496

Attachments

1. Revised Standards Data Report for ISO 10993-1:2003 Biological evaluation of medical devices-Part 1: Evaluation and Testing (3 pages)
2. Revised biocompatibility statement for Clarity™ Advanced Ceramic Brackets (2 pages)
3. Revised instructions for use with indications for use statement (1 page)
4. Revised indications for use statement (1 page)
5. ASTM F603-00, High Purity Dense Aluminum Oxide for Medical Application (3 pages)
6. ASTM G133-05, Standard Test Method for Linearly Reciprocating Ball-on-Flat Sliding Wear (3 pages)
7. Revised 510(k) Summary (3 pages)

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-1:2003 Biological evaluation of medical devices-Part 1: Evaluation and testing

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 2-98

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

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

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

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

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

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

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

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

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: G95-1, Use of international standard ISO 10993

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

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

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

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

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

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

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-1:2003 Biological evaluation of medical devices-Part 1: Evaluation and testing

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3.8	General principles applying to biological evaluation of medical devices	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Assessed based on relevant experience for the same and equivalent materials in commercially available products

DESCRIPTION
Clinical complaint history for the same alumina material and colorant ingredients in commercially available products

JUSTIFICATION
States to consider "other information", other non-clinical tests, and post-market experience

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Selection of biological evaluation tests	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
No biological evaluation tests conducted

DESCRIPTION
Based on complaint history for same alumina material in commercial products , and published test results for alumina and zirconia

JUSTIFICATION
Section 6 states that such evaluation may result in conclusion that no testing is needed

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Selection of biological evaluation tests	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
No biological evaluation tests conducted

DESCRIPTION
Based on use of color indicator ingredients in commercial devices, foods and drug products

JUSTIFICATION
Section 6 states that such evaluation may result in conclusion that no testing is needed

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

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-1:2003 Biological evaluation of medical devices-Part 1: Evaluation and testing

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
A.2, subclause 3.6	Rationale for specific clauses, Annex A	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

No biological evaluation tests conducted

DESCRIPTION

Assessed established use of alumina & zirconia in devices, published test results, and complaint history

JUSTIFICATION

States that testing may not be needed if the material has history of use in same role as the device under design

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
A.2, subclause 3.6	Rationale for specific clauses, Annex A	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

No biological evaluation tests conducted

DESCRIPTION

Assessed established use of color indicator ingredients in devices, foods and drug products

JUSTIFICATION

States that testing may not be needed if the material has history of use in same role as the device under design

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex B	Flow chart to aid in ensuing a systemic approach to biological evaluation...	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Final assessment was completed without biological evaluation tests

DESCRIPTION

Materials are same as in existing commercially available devices, with same properties as to manufacturing and body contact

JUSTIFICATION

Per flow chart, material characterization can be sufficient for assessment without need for biological evaluation tests

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

Paperwork Reduction Act Statement

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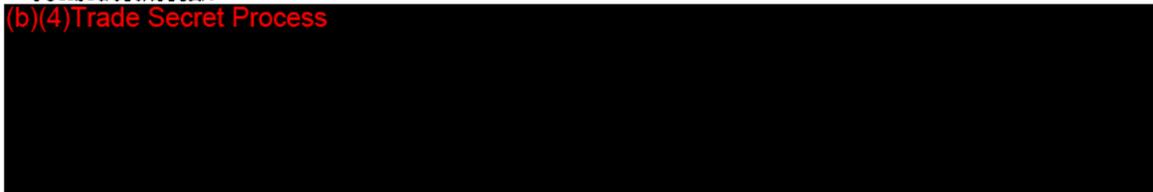


Biocompatibility Statement 3M™ Unitek™ Aesthetic Ligated Brackets

A Diplomate of the American Board of Toxicology has assessed the safety of this product. Standard risk assessment techniques and consideration of internationally recognized guidelines were used in this evaluation.

Aesthetic Ligated Brackets are safe for their intended use based on the following considerations:

(b)(4)Trade Secret Process



joints, dentistry and orthodontia.

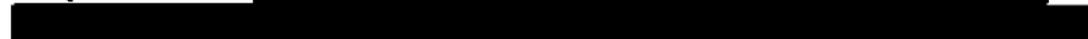
The biocompatibility assessment for this product was conducted in accordance with the following standards:

- 1) Testing guidelines outlined in the FDA General Program Memorandum G95.
- 2) ISO 10993-1:2009(E) Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process; in addition, relevant detailed guidance in ISO Standards 10993-3:2003 (Tests for genotoxicity, carcinogenicity and reproductive toxicity), 10993--5:2009 (Tests for in vitro cytotoxicity), 10993-10:2002/Amd1:2006 (Tests for irritation and delayed-type hypersensitivity); and 10993-11:2006 (Tests for systemic toxicity) was considered;
- 3) ISO 7405: 2008 (E) Dentistry - Evaluation of Biocompatibility of Medical Devices used in Dentistry;
- 4) Japan: PFSB Medical Device No 0831002; August 31, 2007 (as translated (b) [redacted] February 1, 2008); and (4)Trade Secret
- 5) (b)(4)Trade Secret Operating Procedure AAA-0033. de

In accordance with the combined guidance found in ISO 10993 and ISO 7405, the endpoints below must be considered in the biocompatibility evaluation of this product. The following summary describes the information that was used in the evaluation of each endpoint and in support of the overall conclusion that the product is safe for its intended use.

Cytotoxicity

The product shows (b)(4)Trade Secret Process

Biocompatibility Statement 3M™ Unitek™ Aesthetic Ligated Brackets

[Redacted] (b) (4) Trade Secret

Sensitization

The product shows low potential for sensitization, based on: the extremely low (ppb)

(b)(4) Trade Secret Process in ISO 10993- and ISO 6872-compliant (b)(4) Trade Secret product.

Irritation/Intracutaneous Reactivity

The product shows (b)(4) Trade Secret Process [Redacted] product.

Acute Systemic Toxicity

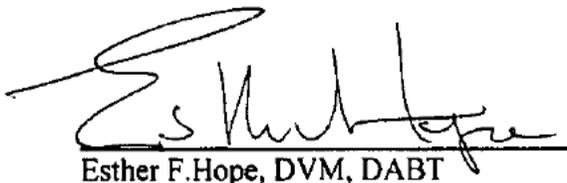
The product shows (b)(4) Trade Secret Process [Redacted] ceramic materials in medical devices.

Repeated-Dose Systemic Toxicity

The product shows (b)(4) Trade Secret Process [Redacted] ceramic materials in medical devices.

Genotoxicity

The product shows (b)(4) Trade Secret Process [Redacted] ceramic materials in medical devices

 21 January 2011
Date

Esther F. Hope, DVM, DABT
Advanced Toxicology Specialist
Toxicology Assessment and Compliance Assurance Section
3M Medical Department

Clarity™ ADVANCED Ceramic Brackets

REF 006-XXX
3006-XXX
5006-XXX

Instructions For Use



Indications for use

Clarity™ ADVANCED Ceramic Brackets are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth.

Warnings

- Do Not Reuse Brackets: Reuse of brackets may result in compromising product integrity or may create risk of patient infection or cross contamination which may lead to injury, illness or death of the patient.
- Due to the hardness of ceramic brackets, bonding brackets in occlusion should be avoided to prevent wearing of enamel surfaces during all phases of treatment.
- Deep bite cases should be opened prior to bonding with Clarity™ ADVANCED Ceramic Brackets to prevent wearing of enamel surfaces. Unitek™ Elastomeric Ligatures with Guard are designed to help protect opposing tooth surfaces from occlusal interference and from potential enamel wear. Bite plates and other intrusion mechanics may also be necessary to prevent bracket to tooth contact. Indications for using Unitek™ Elastomeric Ligature with Guard modules include deep bite cases, protection of cusp tips during retraction and situations in which tooth to bracket contact is possible during finishing.
- Instruct patients not to chew or bite on hard substances such as hard candy, ice, carrots, etc. Careful and thorough patient instruction is a key to avoiding appliance or enamel damage.
- Bonding of ceramic brackets to compromised teeth (i.e., with large restorations, peg laterals or preexisting conditions) can increase the risk of tooth damage.
- Bonding to porcelain crowns or facings may cause chipping or breakage of the crown or facing during treatment or debonding.
- It is recommended to debond Clarity ADVANCED Ceramic Brackets using a Unitek™ Self-Ligating Bracket Debonding Instrument, REF 804-170. No other debonding instrument is recommended to debond Clarity ADVANCED brackets. Doing so may result in fractured tie-wings, losing fractured portions of bracket in patient's mouth, or tooth damage.
- It is recommended to debond Clarity ADVANCED brackets with the archwire in place and ligated. However, if debonding is done without a ligated archwire, extra precautions need to be taken to assure that bracket parts are held securely.
- If a bracket fractures during treatment or debonding, use a diamond burr to carefully remove the ceramic parts. Failure to follow the correct debonding procedure may lead to tooth damage.

Bracket Identification and Bracket Positioning

- Clarity ADVANCED brackets are identifiable by a color coded recessed distal gingival dot.
- Colored reference markers provide vertical and horizontal visual guidance for bracket positioning. These reference markers are water soluble.
- It is recommended that the patient brush after bonding, but before the placement of the archwire to remove the identification dot and reference markers.

Bracket Bonding

Remove adhesive flash at bonding to minimize staining of the adhesive and reduce the risk of bracket breakage during the debonding procedure. Clarity ADVANCED brackets feature mechanical retention on the bonding base. No special primers or pretreatments are necessary.

Clarity ADVANCED brackets can be used with traditional direct or indirect bonding methods. No change in bonding technique is necessary. For bonding procedures please follow the adhesive manufacturer's recommendations. When placing Clarity ADVANCED brackets, it is suggested that the bracket be placed in a sliding motion, occlusal to gingival, forcing excess adhesive to the incisal edge of the bracket for easier clean-up. Care must be taken when cleaning up adhesive flash so as not to disturb the final positioning before adhesive curing. Before placing the archwire, patient should brush to remove the identification dot and reference markers.

Debonding Instruments

Use the recommended Unitek Self-Ligating Bracket Debonding Instrument, REF 804-170, to debond the Clarity ADVANCED bracket.

Important: Clean the jaws of the Unitek Self-Ligating Bracket Debonding Instrument after debonding each bracket to ensure even contact and force distribution.

Debonding Procedure

Note: It is recommended to debond Clarity ADVANCED brackets with the archwire in place and ligated (Figure 1). However, if necessary, single brackets may be debonded with the archwire removed (Figure 2).

- 1) Remove adhesive flash around base of bracket to be debonded. **Note:** Failure to remove flash around bracket base, especially on the mesial-distal sides, may result in incomplete debonding.

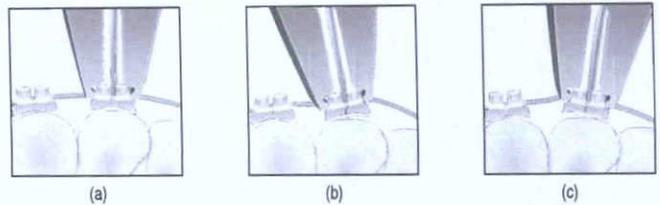


Figure 1: Squeeze debond procedure on archwire (a) position of tool and (b, c) rocking motion.

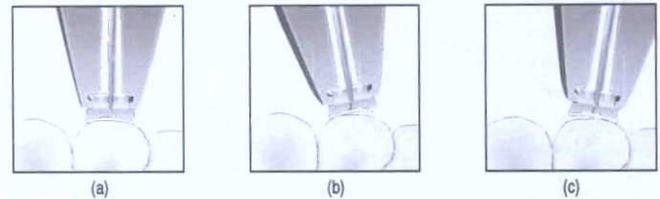


Figure 2: Squeeze debond procedure without archwire (a) position of tool and (b, c) rocking motion.

- 2) Place the centering guide of the Unitek™ Self-Ligating Bracket Debonding Instrument vertically into the center of the bracket, perpendicular to the archwire slot. Be sure that the inner ledges of the instrument are symmetrically positioned against the tie-wings of the bracket.
- 3) Gently squeeze instrument handles until the Clarity ADVANCED bracket collapses. Gently rock the bracket in the mesial or distal direction to completely separate the bracket from the enamel, if necessary.

Note: Maintain the hold on the bracket to keep the debonded bracket parts in the instrument tips. Extra caution should be taken when debonding without the archwire in place.

Bracket Rebonding Procedure

In the case of a spontaneous bond failure, it may be necessary to rebond a bracket. The following steps are recommended:

1. Carefully inspect the bracket for any damage. Brackets that have fractured through the vertical debonding slot cannot be rebonded and must be replaced. If a tie-wing is cracked, replace the bracket.
2. Remove any excess adhesive. Extra care must be taken to prevent chipping or breaking of the bracket. Use a hand scaler to remove any excess flash from around the edges of the bracket. **Do not use a burr. Do not attempt to scrape adhesive from the base of the bracket or attempt to micro-etch the adhesive as this may damage the bracket's bonding surface.**
3. If the bracket has been contaminated (e.g., moisture), rinse the bracket in isopropyl alcohol and allow to dry.
4. Prepare the tooth surface and bond the bracket using the procedure as described by the adhesive manufacturer.

Torquing Precautions

Clarity ADVANCED brackets are capable of withstanding all normal torque requirements. However, care should be taken when making large torquing activations since large corrections with full size stainless steel wires may result in bracket failure and should be avoided.

Warranty and Limited Remedy

3M Unitek warrants that all products are free from defects in materials and manufacture. 3M Unitek's sole obligation and buyer's sole remedy in the event of any claimed defect shall be, at 3M Unitek's option, repair of the product, replacement of the product, or refund of the purchase price. Written notice of claimed defect must be received by 3M Unitek at the address below within reasonable time after discovery not to exceed one year from the date of delivery.

Waiver of Implied Warranties

ALL IMPLIED WARRANTIES, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OR USE ARE DISCLAIMED.

Limitation of Liability

Except where prohibited by law, 3M Unitek will not be liable for any loss or damages arising from any product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.



3M Unitek
Orthodontic Products

2724 South Peck Road
Monrovia, CA 91016 USA

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REF 011-648 1101

European Representative:

3M Unitek



Ohmstrasse 3
86899 Landsberg, Germany
+49/(0)8191/ 9474-0

0045

Indications for Use

510(k) Number (if known): K102803

Device Name: Clarity™ Advanced Ceramic Brackets

Indications for Use:

Clarity™ Advanced Ceramic Brackets are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth.

Prescription Use X
(Per 21 CFR 801 Subpart D)

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

- 0046

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ASTM F603-00, Standard Specification for High-Purity Dense Aluminum Oxide for Medical Application (Jan 2000)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 017

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

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

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

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

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

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

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

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

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

Title of guidance: _____

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

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

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

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

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

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

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ASTM F603-00, Standard Specification for High-Purity Dense Aluminum Oxide for Medical Application (Jan 2000)

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED *
[redacted] (was selected for (b)(4)Trade [redacted] option.

DESCRIPTION
The chemical composition of the aluminum oxide is [redacted] (b) [redacted] aluminum oxide by weight.

JUSTIFICATION
[redacted] (b) [redacted] is one of the [redacted] (b) [redacted] options in the standard.

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

TYPE OF DEVIATION OR OPTION SELECTED *
none

DESCRIPTION
The bulk density is [redacted] (b) [redacted], and the median grain size is [redacted] (b) [redacted].

JUSTIFICATION
none

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

TYPE OF DEVIATION OR OPTION SELECTED *
see attached file

DESCRIPTION
see attached file

JUSTIFICATION
Mechanical testing is performed on the finished part to meet service requirements.

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

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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

Form FDA 3654

ASTM F603-00, Standard Specification for High-Purity Dense Aluminum Oxide for Medical Application (Jan 2000)

(page 3 of 3)

Attached File for Section 5, Mechanical Requirements

Because of the unique (b)(4)Trade Secret situations on orthodontic brackets in service, we have chosen to perform (b)(4)Trade testing on (b)(4)Trade part as detailed in Section 12.2.4 Performance Comparison with SE Devices.

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

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

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ASTM G133-05 Standard Test Method for Linearly Reciprocating Ball-on-Flat Sliding Wear (April 2010)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? Yes No

FDA Recognition number ³ # _____

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? Yes No

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

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? Yes No

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

Does this standard include more than one option or selection of tests? Yes No
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? Yes No
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? Yes No

Were deviations or adaptations made beyond what is specified in the FDA SIS? Yes No
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? Yes No
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard? Yes No
If yes, was the guidance document followed in preparation of this 510(k)? Yes No

Title of guidance: _____

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

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

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

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

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

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

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ASTM G133-05 Standard Test Method for Linearly Reciprocating Ball-on-Flat Sliding Wear (April 2010)

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED *

see attached file

DESCRIPTION

see attached file

JUSTIFICATION

The cleaning method described in the standard could affect the (b) coating.

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

TYPE OF DEVIATION OR OPTION SELECTED *

see attached file

DESCRIPTION

see attached file

JUSTIFICATION

see attached file

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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510(k) Summary

510(k) Submitter..... 3M Unitek Corp, 2724 S Peck Rd, Monrovia, CA 91016
Contact person..... L. Marlyn Scheff, Regulatory Affairs
Phone: (626) 574-4496
Date Summary was Prepared..... January 12, 2011
Device Name..... Clarity™ Advanced Ceramic Brackets
Common Name..... Orthodontic ceramic bracket
Recommended Classification..... Orthodontic ceramic bracket
(21 CFR 872.5470, Product Code: NJM)

Predicate Devices

K062345, Clarity™ SL Self-Ligating Ceramic Brackets
K944286, Clarity™ Metal-Reinforced Ceramic Brackets
K950992, InVu® Aesthetic Braces
K082974, Mystique® MB Clear Braces

Description of Device

Clarity Advanced Ceramic Brackets are intended to be bonded to teeth, upon which an orthodontic wire is used to move the teeth to new positions. Clarity Advanced Ceramic Brackets consist of a translucent alumina body and a glass-grit bonding base. The bracket is either uncoated or coated with a thin film of stabilized zirconia. The brackets incorporate a water-soluble color placement indicator system that marks archwire and vertical slots to aid in bracket positioning and color codes tie wing(s) to facilitate bracket identification.

Indications for Use

Clarity™ Advanced Ceramic Brackets are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth.

Substantial Equivalence

Both the non-clinical data and the biocompatibility evaluation indicate that Clarity™ Advanced Ceramic Brackets are safe and effective for their intended use in orthodontic treatment and perform as well or better than predicate devices. The table on the next page compares the new device with the predicate devices. Information provided in this 510(k) submission shows that Clarity™ Advanced Ceramic Brackets are substantially equivalent to the predicate devices in terms of intended use, indications for use, composition, device design, and performance. This 510(k) also includes data from bench testing to evaluate the performance of Clarity™ Advanced Ceramic Brackets compared to the predicate devices. The properties evaluated include bond strength, bracket strength, material friction, and debond strength.

Technological Characteristics

Clarity Advanced Ceramic Brackets are substantially equivalent in design features to the predicate devices.

Device Material

Clarity Advanced, Clarity SL, Clarity, InVu and Mystique MB brackets all have a bracket body made of ceramic, with Clarity Advanced, Clarity SL, and InVu brackets made of micro-fine ceramic. Clarity Advanced, Clarity SL, and Clarity have a glass-grit bonding base whereas InVu has a molded polymer bonding base and Mystique MB have a molded alumina bonding base. Clarity Advanced has a zirconia, or no coating, on the bracket and in the archwire slot, Clarity SL has a metal liner, or no liner, in the archwire slot, Clarity has a metal liner in the archwire slot, InVu has no liner or coating in the archwire slot, and Mystique MB has a silica coating in the archwire slot. Clarity Advanced has color slot & dot indicators whereas Clarity SL, Clarity, InVu have color dot indicators and Mystique MB has no color indicators.

Device Design

Clarity Advanced, Clarity SL, Clarity, InVu and Mystique MB brackets all have tiewing undercut spaces for orthodontic ligatures. Clarity Advanced, Clarity SL, Clarity and InVu brackets have true-twin tiewings, i.e. four tiewings, for versatile use with auxiliaries. Clarity Advanced, Clarity, and InVu brackets contain base flanges for bracket placement and adhesive flash cleanup. Clarity Advanced, Clarity SL and InVu brackets contain a molded ceramic bracket body with rounded corners and edges, which replaces the angular profile of machined ceramic brackets, and round hook on the distal-gingival tiewings. Clarity Advanced, Clarity SL and Clarity brackets contain vertical slot and stress concentrator to facilitate debonding of the bracket from the tooth.

Nonclinical Performance Testing

The nonclinical performance testing analysis shows that Clarity Advanced Ceramic Brackets perform comparably to the predicate devices as follows:

1. The shear-peel bond strength test measures the force required to debond a bracket when a force is applied in the occlusal direction. The test results showed that the bond strengths of Clarity Advanced, Clarity SL and Clarity brackets are comparable and exceed the minimum bond strength to hold the bracket to the tooth.
2. The bracket strength test measures the torsional force to break a bracket when a rectangular archwire is twisted in the wire slot. The test results showed that the bracket strengths of Clarity Advanced Ceramic Brackets are comparable to Clarity Metal-Reinforced Ceramic Brackets and InVu Aesthetic Braces and exceed the minimum requirements.
3. The bracket material friction test measures the surface frictional forces of a stainless steel wire against a bracket surface. The test results showed that the zirconia-coated aluminum oxide surface exhibited lower coefficients of friction as compared to the uncoated aluminum oxide surface.

4. The squeeze debond test measures the forces applied to the sections left and right of the vertical slot in the Clarity Advanced, Clarity and Clarity SL brackets which cause the bracket to debond from the adhesive. The test results showed that squeeze debond moments for Clarity Advanced Ceramic Brackets are comparable to those for Clarity™ SL brackets and slightly lower for Clarity brackets.

In addition, a biocompatibility assessment was developed for Clarity Advanced Ceramic Brackets using standard risk assessment techniques and consideration of FDA and internationally recognized guidelines.

Clinical Performance Testing

No clinical performance testing was conducted on Clarity™ Advanced Ceramic Brackets.

Conclusion

The results from the nonclinical performance testing and the biocompatibility assessment demonstrate that Clarity Advanced Ceramic Brackets are safe and effective for their intended use and perform as well as predicate devices.