

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
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Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

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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)

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(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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