



March 16, 2018

3M Health Care  
c/o Mark Job  
Responsible Third Party Official  
Regulatory Technology Services, LLC  
1394 25<sup>th</sup> Street, NW  
Buffalo, Minnesota 55313

Re: K180404

Trade/Device Name: 3M<sup>TM</sup> Clarity<sup>TM</sup> Ultra Self-Ligating Brackets and Adhesive Coated Appliance System  
Regulation Number: 21 CFR 872.5470  
Regulation Name: Orthodontic Plastic Bracket  
Regulatory Class: Class II  
Product Code: NJM, DYH  
Dated: February 12, 2018  
Received: February 14, 2018

Dear Mark Job:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Andrew I. Steen -S**

for Tina Kiang, Ph.D.  
Acting Director  
Division of Anesthesiology,  
General Hospital, Respiratory,  
Infection Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K180404

Device Name

3M™ Clarity™ Ultra Self-Ligating Brackets and Adhesive Coated Appliance System

Indications for Use (Describe)

3M™ Clarity™ Ultra Brackets and Adhesive Coated Appliance System are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 CFR 807.92.

**510(k) Submitter:** 3M Health Care  
2510 Conway Avenue  
St. Paul, MN 55144-1000 USA

**Contact person:** Lam Duong  
Regulatory Affairs Associate  
Phone: (651) 733-5945  
Fax: (651) 736-1599  
[lduong@mmm.com](mailto:lduong@mmm.com)

**Date Summary was Prepared:** 15 March 2018

**Trade Names:** 3M™ Clarity™ Ultra Self-Ligating  
Brackets and Adhesive Coated Appliance  
System

**Classification Name:** Orthodontic Plastic Bracket

**Regulation Number:** 21 CFR 872.5470

**Product Code:** NJM, DYH

**Classification Panel:** Dental

**Device Classification:** Class II

**Primary Predicate Device:**  
Clarity™ Advanced Ceramic Brackets (K102803)

**Reference Predicate Device:**  
Damon 4Clear (K081415)  
APC™ Flash-Free Adhesive (K113197)

**Description of Device:**

3M™ Clarity™ Ultra Brackets and Adhesive Coated Appliance System are intended for use in orthodontic treatment. Clarity Ultra Bracket is an esthetic bracket with a sliding door. The brackets are composed of aluminum oxide, which gives them a clear appearance. A nickel titanium wire serves as part of the door mechanism and is attached to the bracket using a cured adhesive. The brackets incorporate a water-soluble color placement indicator system. The archwire slot, vertical slot, and door are marked to facilitate bracket positioning. Tie wing(s) and/or door are color coded with dots to facilitate bracket identification. The brackets are available with or without APC™ Flash-Free pre-coated adhesive. The pre-coated adhesive ensures a consistent amount of adhesive on the bracket.

**Indications for Use:**

3M™ Clarity™ Ultra Brackets and Adhesive Coated Appliance System are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth.

**Performance Testing:**

Bench testing consistent with the clinical application and intended use was used to evaluate the performance of Clarity™ Ultra Self-Ligating Brackets and Adhesive Coated Appliance System compared to the predicate devices, Clarity™ Advanced and Damon 4Clear. Properties evaluated include: rotation play angle, wire rotation strength, shear-peel bond strength, torque strength, and squeeze debond strength. 3M Health Care has tested Clarity™ Ultra Self-Ligating Brackets and Adhesive Coated Appliance System and has concluded that the performance test results demonstrate substantial equivalence to the predicate devices.

**Technological Characteristics:**

Clarity Ultra Brackets are substantially equivalent in design feature to the predicate devices. Clarity Ultra, Clarity Advanced, and Damon 4Clear brackets all have a bracket body made of ceramic. Clarity Ultra and Damon 4 Clear both have a self-ligating ceramic door with a nickel-titanium spring mechanism. Clarity Ultra and Clarity Advanced both have a water-soluble placement indicator system and a glass-grit bonding base that can be pre-coated with APC Flash-Free adhesive.

**Mechanism of Action:**

Clarity Ultra Brackets are substantially equivalent in mechanism of action to the predicate devices, Clarity Advanced and Damon 4Clear brackets. Orthodontic brackets are affixed to teeth using an orthodontic adhesive. Pressure is exerted on a tooth when the brackets are used in combination with archwires and/or other intraoral modules. The pressure causes tooth movement.

Clarity Ultra and Damon 4Clear brackets both have a self-ligating mechanism that ligates the archwire and secures it inside the bracket's wire slot instead of using a manually-placed elastomeric or steel ligature.

Clarity Ultra and Clarity Advanced brackets can be pre-coated with APC Flash-Free adhesive. The methacrylate functionalities of the APC Flash-Free adhesive resins and surface-treated

fillers undergo a light-induced polymerization to form a hard composite that bonds the orthodontic appliance to a tooth and can be removed at the completion of the orthodontic treatment.

#### **Biocompatibility Testing:**

The biocompatibility evaluation for the device was conducted in accordance with the FDA Guidance Docket Number FDA-2013-D-0350 and International Standard ISO 10993-1:2009 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. 3M™ Clarity™ Ultra Self-Ligating Brackets and Adhesive Coated Appliance System are considered mucosal membrane contacting for a duration of greater than 30 days. The following are some of the evaluated endpoints:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Pyrogenicity
- Genotoxicity

The results of the evaluation met the requirements of internationally recognized guidelines as mentioned above and further support a determination of substantial equivalence.

#### **Substantial Equivalence Comparison:**

The following table compares the Clarity Ultra Brackets to the predicate devices, Clarity Advanced and Damon 4Clear brackets with respect to intended use, technological characteristics, and principles of operation.

|                                    | <b>3M™ Clarity™ Ultra Brackets and Adhesive Coated Appliance System</b>   | <b>Clarity™ Advanced Ceramic Brackets</b> | <b>Damon 4Clear</b>             |
|------------------------------------|---------------------------------------------------------------------------|-------------------------------------------|---------------------------------|
| <b>Premarket Notification</b>      | New Device                                                                | K102803                                   | K081415                         |
| <b>Manufacturer</b>                | 3M Health Care                                                            | 3M Unitek Corporation                     | Sybron Dental Specialties, Inc. |
| <b>Regulation Numbers</b>          | 21 CFR 872.5470                                                           | 21 CFR 872.5470                           | 21 CFR 872.5470                 |
| <b>Device Classification Names</b> | Orthodontic Plastic Bracket, Bracket Adhesive Resin and Tooth Conditioner | Orthodontic Plastic Bracket               | Orthodontic Plastic Bracket     |
| <b>Product Codes</b>               | NJM, DYH                                                                  | NJM                                       | NJM                             |
| <b>Device Class</b>                | Class II                                                                  | Class II                                  | Class II                        |
| <b>Intended Use</b>                | Orthodontic brackets                                                      | Orthodontic brackets                      | Orthodontic brackets            |

|                                                                                                                                                                                                  | <b>3M™ Clarity™ Ultra Brackets and Adhesive Coated Appliance System</b>                                                                                                                         | <b>Clarity™ Advanced Ceramic Brackets</b>                                                                                                                         | <b>Damon 4Clear</b>                                                                                                         |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| <b>Indications for Use<sup>1</sup></b>                                                                                                                                                           | 3M™ Clarity™ Ultra Brackets and Adhesive Coated Appliance System are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth. | 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. | The Damon 4Clear is a ceramic bracket system intended to aid in the movement of patient teeth during orthodontic treatment. |
| <b>Composition</b><br>• Bracket body<br><br>• Door<br><br>• Bonding base<br>• Water-soluble indicators                                                                                           | Micro-fine alumina ceramic<br><br>Micro-fine alumina ceramic<br><br>Glass-grit<br>Color slots & dots                                                                                            | Micro-fine alumina ceramic<br><br>None<br><br>Glass-grit<br>Color slots & dots                                                                                    | Alumina ceramic<br><br>Micro-fine alumina ceramic<br><br>Laser-etched alumina<br>None                                       |
| <b>Device Design</b><br>• Tie wing undercut<br>• Base flange<br>• Parallel sides<br>• Molded ceramic<br>• Optional Hook<br>• Vertical slot<br>• Stress concentrator<br>• Self-ligating mechanism | √<br>√<br>√<br>√<br>√<br>√<br>√<br>√                                                                                                                                                            | √<br>√<br>√<br>√<br>√<br>√<br>√<br>-                                                                                                                              | √<br>-<br>-<br>√<br>√<br>-<br>-<br>√                                                                                        |
| <b>Available with pre-coated adhesive</b>                                                                                                                                                        | Yes                                                                                                                                                                                             | Yes                                                                                                                                                               | No                                                                                                                          |

|                                          | <b>3M™ Clarity™ Ultra Brackets and Adhesive Coated Appliance System</b>                                                                                                                                                                                                     | <b>Clarity™ Advanced Ceramic Brackets</b>                                                                                                                                                    | <b>Damon 4Clear</b> |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <b>FDA-recognized standards followed</b> | Risk Management:<br>ISO 14971<br><br>Biocomp stds:<br>ISO 10993-1<br>ISO 10993-3<br>ISO 10993-4<br>ISO 10993-5<br>ISO 10993-6<br>ISO 10993-10<br>ISO 10993-11<br>ISO 10993-12<br>ISO 7405<br><br>Labeling:<br>ISO 15223-1<br><br>ASTM F603-12<br>ASTM F2063-12<br>ISO 27020 | Risk Management:<br>ISO 14971<br><br>Biocomp stds:<br>ISO 10993-1<br>ISO 10993-3<br>ISO 10993-5<br>IISO 10993-10<br>ISO 10993-11<br>ISO 7405<br>ISO 6872<br><br>ASTM F603-00<br>ASTM G133-05 | NA <sup>2</sup>     |

<sup>1</sup> Indications from FDA 510(k) clearance letter enclosure

<sup>2</sup> Not Available, details not disclosed by manufacturer

Clarity Ultra Brackets have substantially equivalent Indications for Use as the identified predicate devices. The verbiage of the Indications for Use of the subject device is slightly different than the predicate devices; however these slight differences do not alter the intended therapeutic use of the device as compared to the predicates.

The technological characteristics, how the device functions, and the mechanical properties of Clarity Ultra Brackets compared to the predicates have not fundamentally changed. Orthodontic brackets are designed to be affixed to teeth and to hold an archwire so that pressure can be exerted to move the teeth to new positions. Bench testing shows that Clarity Ultra Brackets are substantially equivalent in performance to the predicate devices.

### **Conclusion**

3M™ Clarity™ Ultra Brackets and Adhesive Coated Appliance System are substantially equivalent to the predicate devices in terms of intended use, indications for use, design, performance, technological characteristics, mechanism of action, composition, and biocompatibility.