March 3, 2022

3M Company, Unitek Orthodontic Products
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K211190
Trade/Device Name: 3M Clarity Aligners (3M Clarity Aligners-Force, 3M Clarity Aligners-Flex)
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC

Dear Prithul Bom:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 23, 2021. Specifically, FDA is updating this SE Letter for a typo in the trade name as an administrative correction

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Michael Adjodha, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices, 301-796-6276, Michael.adjodha@fda.hhs.gov.

Sincerely,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

April 23, 2021

3M Company, Unitek Orthodontic Products
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K211190
Trade/Device Name: 3M Clarity Aligners (3M Clarity Aligners-Force, 3M Clarity Aligners-Fix)
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: April 20, 2021
Received: April 21, 2021

Dear Prithul Bom:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

Submission Number *(if known)*

K211190

Device Name

3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex)

Indications for Use *(Describe)*

3M™ Clarity™ Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"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 number."*

# 510(k) Summary

# 3M™ Clarity™ Aligners

# (Force and Flex)

## 510(k) Summary

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

**510(k) Submitter**…… 3M Company
Unitek Orthodontic Products
2510 Conway Avenue
St. Paul, MN 55144
Establishment Registration No.: 2110898

**Primary Contact**……Yanine Garcia-Quezada
Regulatory Affairs
Phone: (651) 736-8238
Fax: (651) 736-1599
ygarcia-quezada@mmm.com

**Secondary Contact**……...Brendan Casey, Ph.D.
Regulatory Affairs Manager
Phone: (651) 737-4488
Fax: (651) 736-1599
bcasey@mmm.com

**Submission Date**……7 April 2021

**Proprietary Trade Name**…….3M™ Clarity™ Aligners

**Device Name**……..……...….Aligner

**Common Name**…….Sequential Aligner

**Classification Name**……..…Orthodontic Plastic Bracket

**Regulation Number**……..21 CFR 872.5470

**Product Code**…….....…….NXC

**Classification Panel**……..….Dental Products Panel 76

**Classification**…….....….Medical Device, Class II

## Indications for Use:

Clarity Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion.

## Predicate Devices:

3M Clarity Aligners (K192119)

## Description of Device:

The 3M Clarity Aligners, 3M Clarity Aligners-Flex and 3M Clarity Aligners-Force are a series of clear plastic aligners that offer a solution for patients who want an aesthetic orthodontic treatment by utilizing a set of removable aligners to correct tooth malocclusions without the use of conventional wire and bracket orthodontic technology. The present Premarket Submission is for the addition of a new form of the aligner called 3M Clarity Aligners-Flex to the 3M Clarity Aligner system. 3M will continue to offer aligners composed of the same material as previously cleared (K192119) as 3M Clarity Aligners-Force. 3M will offer the option of combination treatment plans where both 3M Clarity Aligners-Flex and 3M Clarity Aligners-Force can be used.

A dental health professional (e.g. orthodontist or dentist), prescribes 3M Clarity Aligners, 3M Clarity-Flex, 3M Clarity Aligners-Force based on an assessment of the patient's teeth and determines a course of treatment with the system. Patient data is collected via intra-oral scanning or taking physical impressions. The prescribing physician reviews and approves the model scheme before the molds are produced. Once approved, 3M produces trays, which are formed of clear, thin, thermoformed plastic. The trays are sent back to the dental health care professional who then provides them to the patient, confirming fit and design. The dental care professional monitors treatment from the moment the first aligner is delivered to when the final aligner is delivered. The trays are held in place by pressure and can be removed by the patient at any time.

## Technological Characteristics:

3M Clarity Aligners-Flex and the previously cleared 3M Clarity Aligners (K192119) have the same design, device features, software as well as their manufacturing processes.

## Performance Testing:

Results of optical properties, mechanical stability, durability, staining, transportation, use life, force, conditioning among others are included in this Premarket submission which showed acceptable results for all tested samples.

## Software

There are no changes in the software compared to the existing 3M Clarity Aligners (K192119).

## Biocompatibility Testing

The biocompatibility evaluation for the device was conducted in accordance with US FDA Docket Number FDA-2013-D-0350 edition dated: September 4, 2020. The aligner is considered mucosal membrane contacting device that is intended to be in contact with the body for greater than 30 days. The evaluation found this product to be safe for its intended use.

**Substantial Equivalence Comparison**

| Feature | Predicate Device:<br>3M™ Clarity™ Aligner | Proposed Device:<br>3M™ Clarity™ Aligner-Flex |
|---|---|---|
| **Manufacturer** | 3M Company<br>2510 Conway Avenue<br>St. Paul, MN 55144 | 3M Company<br>Unitek Orthodontic Products<br>2510 Conway Avenue<br>St. Paul, MN 55144 |
| **510(k) Number** | K192119 | To be determined |
| **Regulation Number** | 21 CFR 872.5470 | No change |
| **Product Code** | NXC | No change |
| **Device Class** | Class II | No change |
| **Indications for Use:** | 3M Clarity Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion. | Clarity Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion. |
| **Manufacturing Process** | Aligners are manufactured using an automated state of the art process. | No change |
| **Material** | 3M Force Thermoplastic Material | 3M Flex Thermoplastic Material |
| **Technical Features and Properties** | Orthodontic tooth movements occur through forces applied to the dentition as each tooth follows the programmed displacement based on a doctor's prescription. | No change |
| **Software** | Proprietary software is used in the manufacturing process of the currently commercialized aligners. | No change |

## Substantial Equivalence Conclusion:

The 3M Clarity Aligners-Flex and the previously cleared 3M Clarity Aligners (K192119) have the same indications for use, same manufacturing processes, same design, and same device features and are considered substantially equivalent (21 CFR 807.100).